JMIR Serious Games

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Using Virtual Reality in a Rehabilitation Program for Patients With Breast Cancer: Phenomenological Study

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Abstract

Background: Surgery is an essential treatment for early-stage breast cancer. However, various side effects of breast cancer surgery, such as arm dysfunction and lymphedema, remain causes for concern. Rehabilitation exercises to prevent such side effects should be initiated within 24 hours after surgery. Virtual reality (VR) can assist the process of rehabilitation; however, the feasibility of applying VR for rehabilitation must be explored, in addition to experiences of this application.

Objective: This study explored patients' attitudes toward and experiences of using VR for their rehabilitation to determine the feasibility of such VR use and to identify potential barriers.

Methods: A phenomenological qualitative study was conducted from September to December 2021. A total of 18 patients with breast cancer who had undergone surgical treatment were interviewed using open-ended questions. The Colaizzi 7-step procedure for phenomenological analysis was used for data analysis. To ensure high study reliability, this study followed previously reported quality criteria for trustworthiness.

Results: Three themes were identified: (1) VR was powerful in facilitating rehabilitation, (2) early and repetitive upper limb movements were an advantage of VR rehabilitation, and (3) extensive VR use had challenges to be overcome. Most of the interviewed patients reported positive experiences of using VR for rehabilitation. Specifically, VR helped these patients identify appropriate motion and angle limits while exercising; in other words, knowledge gained through VR can play a key role in the rehabilitation process. In addition, the patients reported that the use of VR provided them company, similar to when a physiotherapist is present. Finally, the gamified nature of the VR system seemed to make VR-based rehabilitation more engaging than traditional rehabilitation, particularly with respect to early rehabilitation; however, the high cost of VR equipment made VR-based rehabilitation difficult to implement at home.

Conclusions: The interviewed patients with breast cancer had positive experiences in using VR for rehabilitation. The high cost of both VR equipment and software development presents a challenge for applying VR-based rehabilitation.

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KEYWORDS

breast cancer; rehabilitation; virtual reality; VR; virtual reality design process; VR design process; feasibility; accessibility

Introduction

Breast cancer is a major global health problem. In Taiwan, more than 10,000 women are diagnosed with breast cancer every year; approximately 80% of these diagnoses are early-stage breast cancer and most require surgical treatment [1]. More than 1 in 5 women who are breast cancer survivors might eventually develop upper limb lymphedema [2]. In addition, the life expectancy of patients with stage 0 to stage 3 breast cancer is 20 to 32 years [3]. Breast cancer treatments include surgery, radiation therapy, chemotherapy, endocrine therapy, and targeted therapy. Because of advancements in diagnosis and treatment in recent years, the 5-year relative survival rate of breast cancer is now higher than 80% [4]. However, both ancillary dissection and axillary radiation are known to increase the incidence of lymphedema and axillary web syndrome [5]; associated symptoms include pain, upper extremity weakness, paresthesia, and limited range of motion (ROM), each of which can not only delay the commencement of radiation therapy but also lead to patients being unable to perform basic self-care tasks. This is a problem because less-mobile patients are more likely to experience side effects after surgery; for example, a frozen

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shoulder is a side effect that commonly occurs in the short term as a result of immobility after surgery [6]. These associated symptoms may persist for up to 1.5 years after surgery and therefore predispose patients to depression and other mental health conditions that can become long-term health problems [7,8].

Studies have suggested that the early commencement of postoperative rehabilitation exercises, including upper extremity abduction and flexion exercises, can reduce the risk of upper extremity pain and dysfunction [9,10]. Although the optimal time to start ROM exercises remains unclear, one study suggested that activity recovery tends to be more successful following earlier rehabilitation [11]. Typically, rehabilitation is recommended to be commenced within the first 7 days after surgery, with shoulder ROM initially being limited to 90° [12]. Hence, a patient's willingness to undergo rehabilitation after surgery to prevent their arms from becoming motionless is essential. However, after surgery, a patient's motivation to undergo physical rehabilitation tends to be low because of wound pain and fear of movement [13,14].

Virtual reality (VR) can reduce fear of movement and improve motivation to engage in rehabilitation. In addition, VR can promote compliance and rehabilitation success among patients [15-17]. Furthermore, VR appears to be effective in increasing shoulder ROM compared with standard physiotherapy for postoperative rehabilitation in patients with breast cancer [18]. The use of VR for rehabilitation is not new; however, feasibility studies that use VR to provide individualized, progressive practice for arm movements after surgery for breast cancer remain scarce. Feasibility research is often conducted prior to a randomized controlled trial [19]. In recent years, most studies investigating VR for rehabilitation in patients with breast cancer have used a randomized controlled design and have been prospective, adequately powered, and methodologically rigorous. Nevertheless, according to According to the recommendations of the VR-CORE (Clinical Outcomes Research Experts) [20], the development of new VR content should include 3 phases: VR1 to VR3. VR1 provides guidance for the development of new VR content; VR2 constitutes early testing related to the feasibility, acceptability, tolerability, and initial clinical efficacy of VR; and VR3 evaluates the efficacy of VR in comparison with controls. Bypassing feasibility and accessibility tests to jump immediately to clinical trials may lead to a gap between program development and bedside application and cause barriers to implementing VR in practice. Even though there is sound evidence that VR is effective in improving rehabilitation effects in patients with breast cancer, VR is not currently used in many clinical settings. According to Brennan et al [21], barriers to the implementation of VR include usability problems, cognitive limitations, cost, a lack of patient safety, low patient motivation, and negative patient responses. In addition, VR's unfamiliarity to many patients may dampen their willingness to use VR [22]; thus, patients' attitudes, experiences, and opinions related to VR must be understood. Further explorations of feasibility and accessibility are recommended for the use of VR in health care [23,24].

To the best of our knowledge, most studies regarding postoperative rehabilitation in patients with breast cancer have been clinical trials (ie, VR3) that evaluated only treatment effects, such as pain, grip power, muscle power, or ROM; VR2 studies are skipped. This study used a phenomenological approach to investigate the feasibility and experiences of a VR rehabilitation program (ie, this was a VR2 study) in patients with breast cancer. Therefore, this study was conducted to answer the following questions: (1) What are the lived experiences of patients using VR for arm rehabilitation? (2) How do they perceive the process? In answering these questions, this study determined the clinical effectiveness of and barriers to VR rehabilitation as a prelude to a definitive randomized controlled trial.

Methods

Design and Development of the VR System

The VR system in this study was designed and developed in accordance with the VR–CORE–VR1 guidelines [20]. Our VR design team was a multidisciplinary team comprising users and technicians. The rehabilitation program was developed in 3 stages. The first stage was based on inspiration gained through empathy. Specifically, interviews were held with 2 patients who were invited to share their rehabilitation experiences and express their perspectives and opinions to facilitate the design of an effective VR-based treatment program. The interview questions in this stage considered (1) smart device use behavior and (2) willingness and acceptability to use VR rehabilitation systems. The second stage involved ideation through team collaboration. Specifically, our team comprised experts in surgery, rehabilitative physicians, and software engineering, as well as a case manager. Innovative ideas were generated through methods such as brainstorming and collective ideation, and the ideas that were most suitable for prototyping were then compiled. The third stage involved prototyping based on user feedback. Specifically, further discussions were held with the aforementioned 2 patients to obtain further information. Our team then built prototypes to test 3 VR rehabilitation exercises prior to implementation (Table 1). Ultimately, we extracted 3 key sets of limb motions that are described as follows. The first motion was a Whac-A-Mole–like game that involved the abduction of the shoulder (no more than 90°). The second motion was wiping a table and involved external forearm rotation. The third motion was combing one's hair and involved flexion of the shoulder (no more than 90°) (Figures 1-3). This study used the PC-based Oculus Quest 2 head-mounted display (HMD) to provide the most immersive VR experience possible.

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Table . Summary of our design principles and strategies based on recommendations for best practices in VR1 (virtual reality phase 1) studies [20].

Design principles and strategies	Our practices
Inspiration through empathy, recruitment, observation, patient interviews, and expert interviews	Two patients with breast cancer who had experienced axillary web syndrome were invited for individual interviews regarding their relevant needs, experiences, fears, and expectations; a group discussion was then conducted to determine the patients' needs.
Ideation through team collaboration, sharing stories and notes, and generating ideas	We analyzed, aggregated, and discussed the stories and data obtained in the previous phase. Our team then formulated 10 ideas for rehabilitation actions. After considering the restrictions on drainage tube indwelling the day after surgery (shoulder joint movement must not exceed 90°), we extracted 3 motions: (1) Whac-A-Mole, which involved abduction of the shoulder; (2) wiping a table, which involved external forearm rotation; and (3) combing one's hair, which involved flexion of the shoulder.
Prototyping through continuous feedback, building a prototype, and repeatedly testing the prototype	We drew the height of a mallet on a wall and placed a picture of a gopher on a table to simulate the Whac-A-Mole game. For the wiping the table and combing hair scenarios, we used a table and a comb, respectively, and we then collected feedback from the patients after their first use. Our team found that the Whac-A-Mole game was difficult to perform owing to the different heights of the patients and seats (eg, a patient may need to raise their shoulder angle excessively to pick up the mallet, leading to pain and an inability to perform the exercise, forcing it to be abandoned). Thus, the software engineer adjusted the height of the controllable mallet and the adjustable gopher table to meet the need of each individual patient.

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Figure 1. Whac-A-Mole–like scenario.

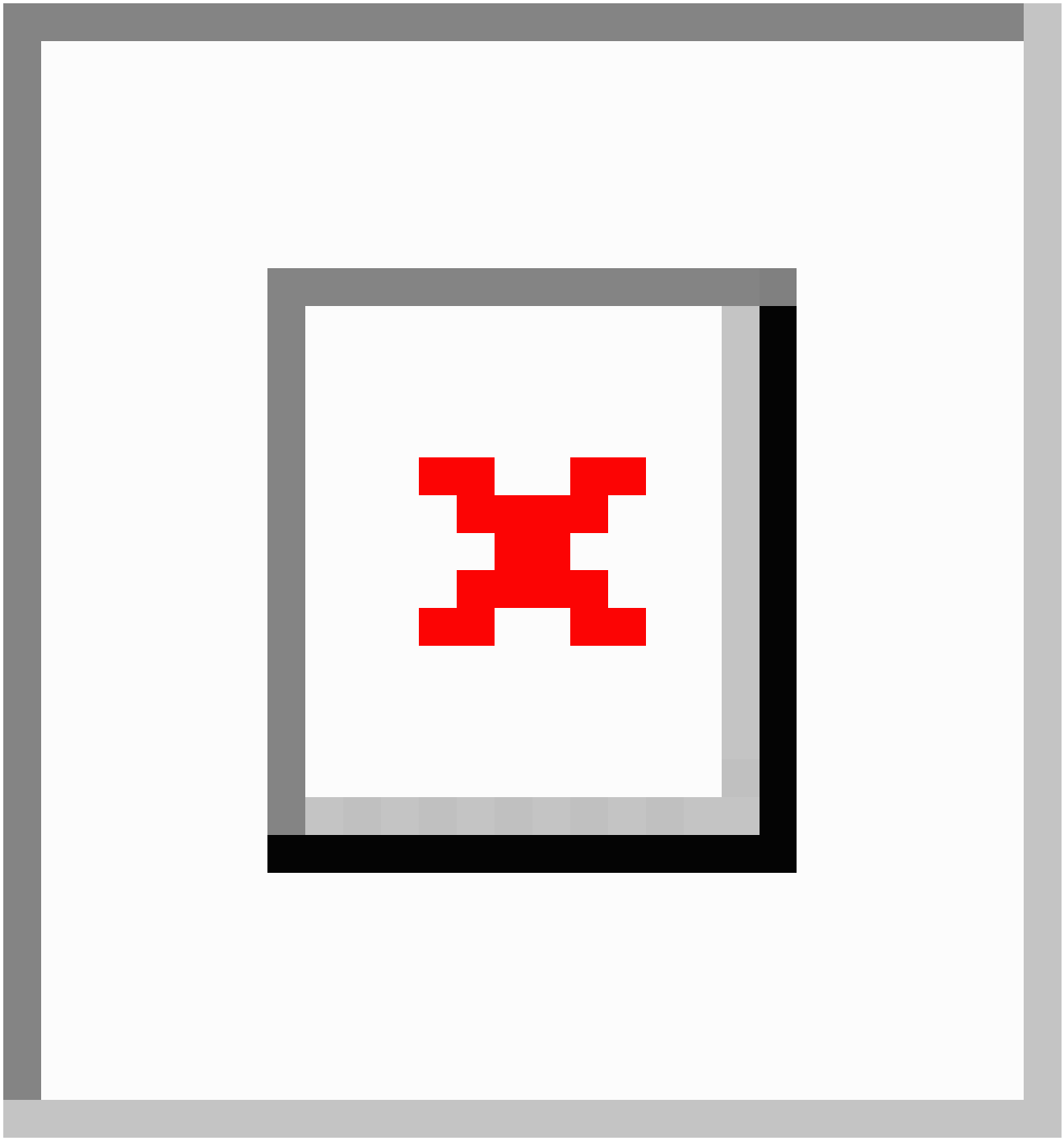

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Figure 2. Wiping a table scenario.

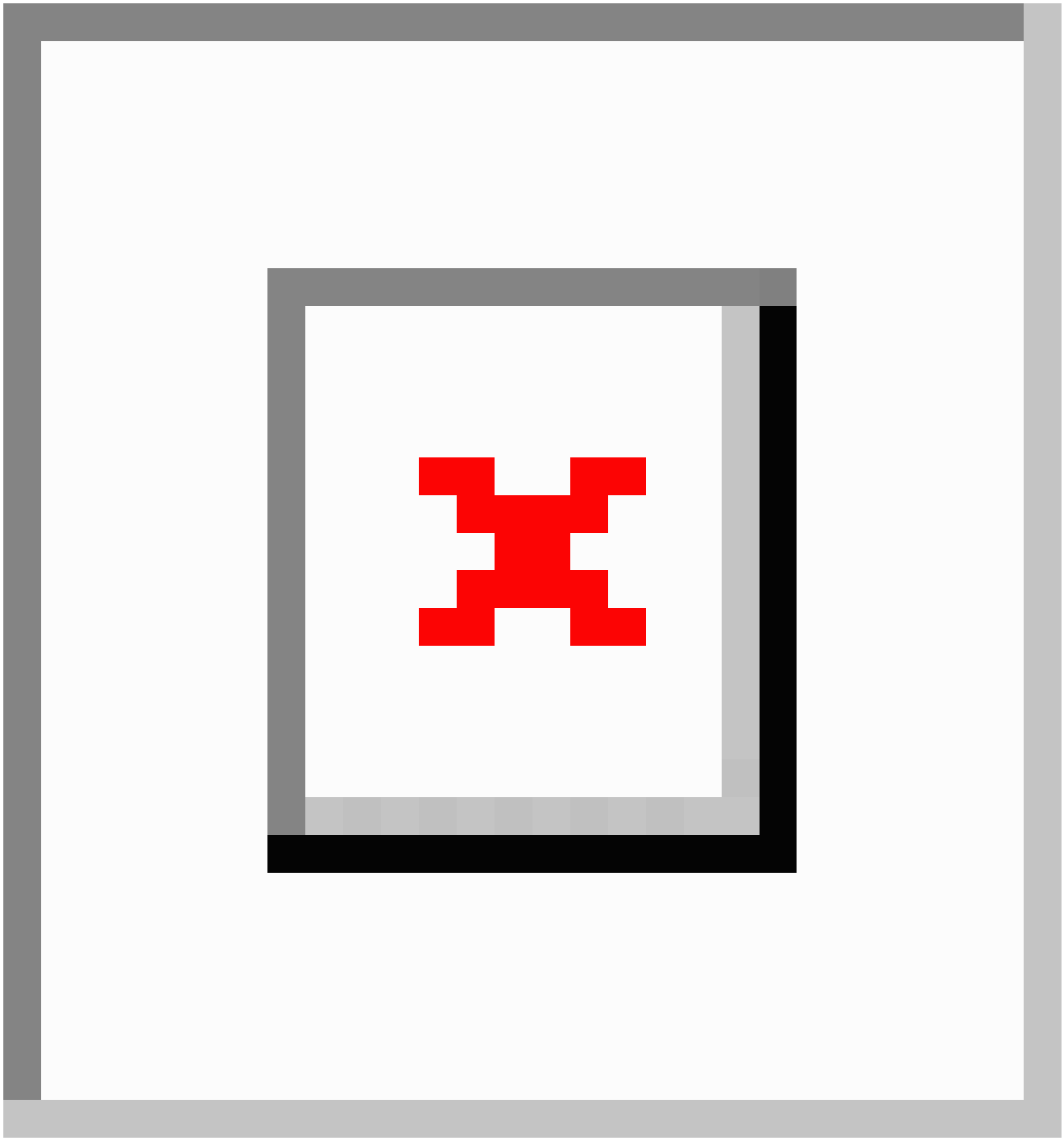

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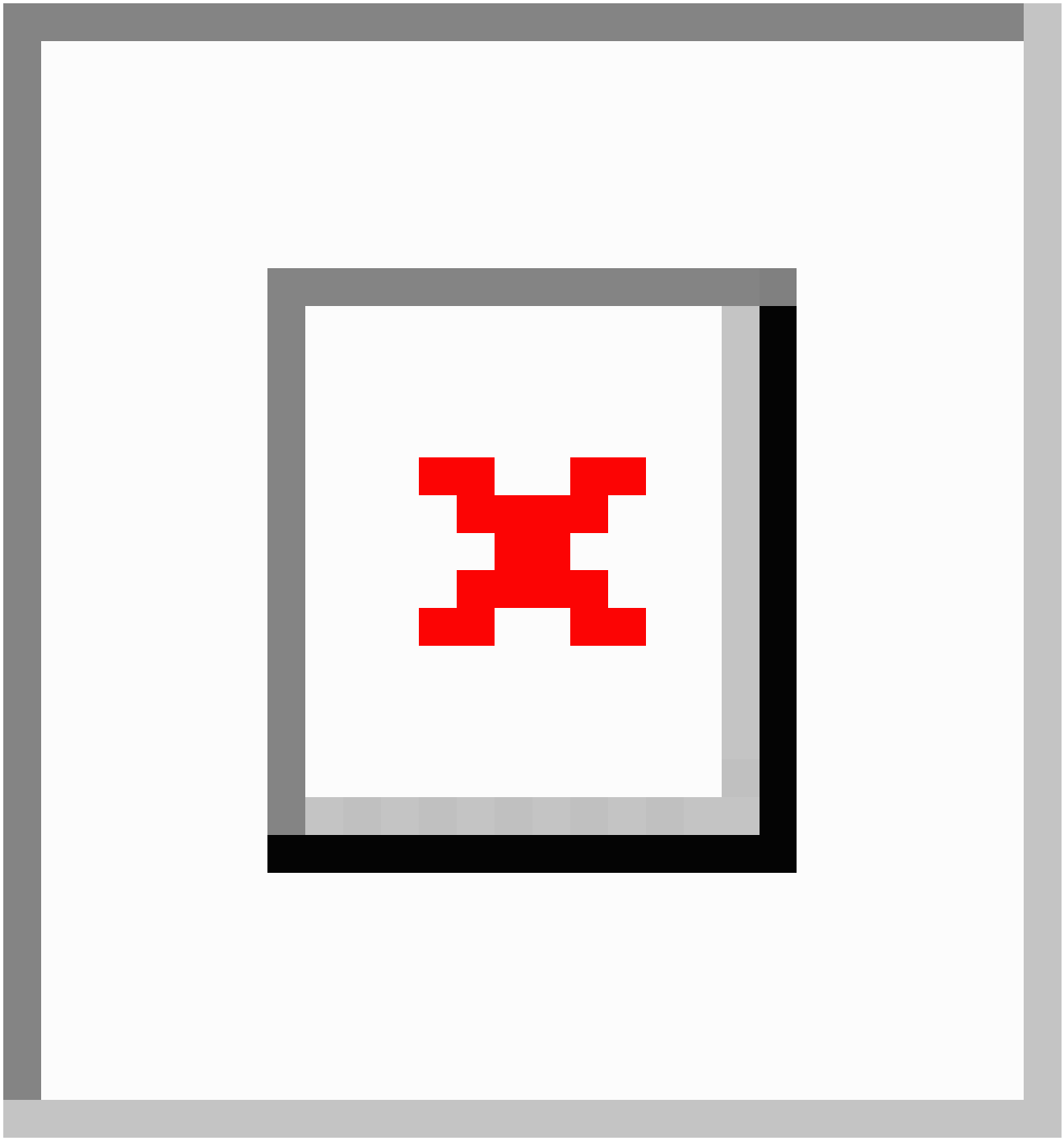
Figure 3. Combing one's hair scenario.



Study Design

This qualitative study was guided by the phenomenological methodology; it focused on investigating the perceived experience of using VR rehabilitation and then used an inductive approach and the Colaizzi [25] interview data analysis method to identify themes from the VR rehabilitation experiences.

Ethics Approval

Ethical approval for this study was granted by the Human Trials Ethics Committee of Chang Gung Memorial Hospital, Taiwan (202001617A3C501). All the participants provided written informed consent to participate in this study.

Setting

This study was conducted at a medical center in Taiwan that receives up to 20 new patients with breast cancer per month.

Participants and Recruitment

The criteria for participation in this study were as follows: (1) a new diagnosis of breast cancer and being hospitalized for surgical treatment; (2) being aged 20 to 65 years; (3) being able to read and speak Mandarin Chinese or Taiwanese; (4) being willing to use a wearable VR HMD and having sufficient cognitive ability to understand and follow instructions, as well as to interact with the VR environment; (5) having sufficient physical ability (self-reported) to use the VR equipment in the VR rehabilitation program; and (6) being willing to be

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interviewed. After surgical treatment for breast cancer, patients were invited to a rehabilitation consultation to ask about their willingness to try VR rehabilitation and were recruited to participate in this study. The recruitment period ran from September to December 2021, with 18 patients interviewed.

Data Collection

First, the participants filled out a questionnaires on demographic data (including age, gender, and type of breast surgery), the Distress Thermometer (DT) questionnaire, and the Chinese Health Questionnaire–12 (CHQ-12). The DT is a visual analog scale for routine screening for distress in all patients with cancer; scores range from 0 (indicating no distress) to 10 (indicating extreme distress). A cutoff score of ≥7 is optimal for distress in patients with a new diagnosis [26]. The CHQ-12 was modified from the General Health Questionnaire–12, a widely used psychometric test for screening mental problems, with a score of ≥4 indicating psychological distress [27].

After completing the questionnaires, a face-to-face interview was conducted with each participant for approximately 30 minutes. Interview guides were developed by the research team, which included an expert in qualitative studies and a clinical nurse specialist in breast cancer. After the content of the first interview was analyzed, the interview questions were discussed and modified with the research team.

During the interview process, the researchers actively listened and continuously clarified any perspectives and meanings that the participants wanted to express. Participants were allowed to freely express their views. All interviews were audiorecorded. After the data analysis, the researchers reviewed the data with the patients to ensure data accuracy and completeness.

Inductive Content Analysis

According to Kyngäs [28], an inductive approach, which is common in qualitative research, should be used when no prior research has addressed a specific phenomenon or if existing knowledge is fragmented. Because prior studies had not investigated the experiences of patients with breast cancer to evaluate the effectiveness of VR-based rehabilitation, our study used an inductive approach to content analysis, which involved data reduction, data grouping, and, finally, concept formation. The content was analyzed with the Colaizzi [25] phenomenological analysis method, which involves a 7-step procedure for content analysis. Specifically, 3 researchers analyzed the data and grouped them into themes to enhance comprehension. First, the interview transcript was read to obtain an idea of its overall meaning. Second, a researcher extracted significant statements relevant to the purpose of the study. Third, each statement considered meaningful was recorded for accurate representation of the research data. Fourth, the researcher classified significant statements into categories based on their meaning. Fifth, the researcher grouped similar categories together and organized them into themes. Sixth, all themes presented were combined to produce an exhaustive description. Seventh, the results were presented to each participant for feedback and to verify their accuracy.

Trustworthiness

To enhance the trustworthiness of our study, we referred to the Guba and Lincoln [29] quality criteria of credibility, transferability, dependability, and confirmability.

To establish confidence in the credibility of the findings, triangulation was used to examine the consistency of the data. Researchers presented their summaries of the categories and themes from data analysis and discussed any uncertainty about any category or theme by replaying and reanalyzing the interview recording.

High transferability was ensured through the interview process, including the stability of observations and the interrater reliability. As an interviewer, the researcher was attentive to the interviewees' experiences and avoided bias arising from their values and beliefs. The interviewer was conscious about avoiding misperceptions about what the interviewees were saying to ensure the stability of observations. There was only 1 interviewer, hence interrater reliability was not measured.

The study had high dependability, as the data collecting procedures were approved by an expert in qualitative methodology, and the themes and subthemes that emerged were consistent among all researchers after the coding and recoding procedure during the data analysis.

Finally, during the data analysis stage, 3 researchers who were not part of the study team confirmed the collected data by distinguishing between the units of the main themes and subthemes to verify the main themes' theoretical saturation and thus achieved confirmability.

Results

Characteristics of Participants

Table 2 shows the participants' characteristics. The mean age of the participants was 46.66 (SD 8.05) years; 17 participants were female (95%) and 1 was male (5%); 11 were married (61%); 11 (61%) were full-time workers; and 7 (39%) were housekeepers or had no formal employment. Regarding the types of surgery received, 9 participants (50%) underwent mastectomy and sentinel lymph node biopsy, 4 (23%) underwent mastectomy and axillary lymph node dissection, 2 (11%) underwent mastectomy and reconstruction, and 3 (16%) underwent modified radical mastectomy. All participants had DT scores less than 7, indicating no distress. In the CHQ-12 items, some participants reported having shaking or numbness of limbs (n=3, 17%), losing a great deal of sleep because of worry (n=4, 22%), and losing confidence in themselves (n=4, 22%) (items 4, 5, and 8). However, all participants had CHQ-12 scores less than 4, indicating no mental problems. Finally, 7 (39%) and 11 (61%) of the participants reported moderate (4-6) and mild (1-3) wound pain on the Numeric Rating Scale for Pain, respectively.

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Table . Distribution of sociodemographic variables of participants (N=18).

Variables		Participants, n (%)
Sex		
	Female	17 (95)
	Male	1 (5)
Age group (years)		
	35-44	6 (33)
	45-54	8 (44)
	55-64	4 (3)
Educational level		
	Senior high school	9 (50)
	College	9 (50)
Distress		
	Yes (DT[a] score ≥7)	0 (0)
	No (DT score <7)	10 (100)
Mental problems		
	Yes (CHQ-12[b] score ≥4)	0 (0)
	No (CHQ-12 score <4)	18 (100)
Numerical Rating Scale for Pain score		
	1-3	11 (61)
	4-6	7 (39)
Marital status		
	Married or in a domestic partnership	11 (61)
	Single	5 (28)
	Separated or divorced	2 (11)
Employment status		
	Employed	11 (61)
	Unable to work	7 (39)
Type of breast surgery		
	Mastectomy with sentinel lymph node biopsy	9 (50)
	Mastectomy with axillary lymph node dissection	4 (23)
	Mastectomy with reconstruction	2 (11)
	Modified radical mastectomy	3 (16)

[a]DT: Distress Thermometer.

[b]CHQ-12: Chinese Health Questionnaire–12.

Themes

The following 3 themes were inductively extracted from the interview data: (1) VR was powerful in facilitating rehabilitation, (2) early and repetitive upper limb movements were an advantage of VR rehabilitation, and (3) extensive VR use had challenges to be overcome. Tables 3-5 present these themes in greater detail alongside their subthemes and interviewee statements.

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Table . Subthemes and interviewee quotes related to theme 1: virtual reality (VR) was powerful in facilitating rehabilitation.

Subthemes	Quotes
Obtaining knowledge	• "It turns out that some actions are unsuitable [because of the drainage tube]; after use, I have a better idea of the angle of movement" (participant 2). • "After practicing with this system [VR] and being discharged from the hospital, I know that some actions are not suitable for me to do, so I will not do them randomly" (participant 3). • "I was anxious, thinking that not moving my arms was suitable for wound healing" (participant 13). • "I can adjust my range of motion according to my tolerance, and I will not feel frustrated" (participant 17).
Companionship	• "This way of rehabilitation [VR] is like a kind of support for me when exercising because thephysiotherapist does not always accompany me" (participant 9). • "The usage process is very simple. I think it is well executed in the hospital and I can concentrate on practicing" (participant 5). • "The physiotherapist was very busy and left after teaching me the rehabilitation movement, so I had to do it independently" (participant 11). • "I didn't understand what this was at first, and I was a little scared, but it turned out that I was doing rehabilitation while playing games" (participant 1).

Table . Subthemes and interviewee quotes related to theme 2: early and repetitive upper limb movements are an advantage of virtual reality (VR) rehabilitation.

Subthemes	Quotes
Reduced fear of movement	• "The VR rehab game method is more fun than the traditional rehab method because it lets me know I need to do rehab exercises; I think I can do it a few more times" (participant 1). • "My time in the hospital was short, and it was a pity that I didn't do VR many times" (participant 6). • "I experienced no pain or discomfort during the VR rehab; I want to do it a few more times" (participant 7). • "After playing Whac-A-Mole, I attempted to move my arm" (participant 11). • "While using it, I temporarily forgot that I had surgery" (participant 14). • "Initially, I was terrified of moving my arms, but now, I'm having so much fun that I don't realize I'm doing rehab" (participant 18).
Enhanced motivation to engage in rehabilitation	• "The VR program can be performed as soon as possible; I have been performing VR for seven days since surgery. In the execution of the Whac-A-Mole and wiping the table exercises, I did not have too much discomfort or pain, and I am doing better and better" (participant 15). • "Although there is no VR at home, I can continue to do the VR movements, and I will not worry about my arm's limited range of motion in the future" (participant 16). • "After using VR for rehabilitation, I found that my condition was not as bad as I thought" (participant 7).

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Table . Subthemes and interviewee quotes related to theme 3: extensive virtual reality (VR) use has challenges to be overcome.

Subthemes	Quotes
Safety of the real-world environment	• "I was initially scared because I had never used VR" (participant 4). • "Wearing a VR HMD, I can't see the outside world, so I'm worried about hitting something" (participant 5).
Cost of virtual reality rehabilitation equipment is too high to extend to home use	• "VR rehabilitation equipment is too expensive to buy and can only be used in hospitals" (participant 5). • "Without equipment, there is no way to use VR for rehabilitation" (participant 8). • "VR rehabilitation can only be used in hospitals; at home, we use traditional rehabilitation methods" (participant 17). • "I hope to rent VR equipment for my home so I can use it anytime" (participant 18). • "Although there is the Switch, finding a suitable sports game for rehabilitation is difficult" (participant 9).
Motion sickness	• "After wiping the table, I felt a little dizzy" (participant 10). • "My eyes constantly roll when wiping the table, which is a little uncomfortable" (participant 9).

VR Was Powerful in Facilitating Rehabilitation

Overview

A key concept of this inductive theme was the "power" obtained from knowledge and companionship. Related subthemes and interviewee statements are presented in Table 3.

Obtaining Knowledge

A total of 12 (70%) of the participants described how the VR content helped them learn the most helpful rehabilitation movements and the angular limitations of their exercises and thus enabled them to perform these exercises safely and relatively early in the rehabilitation process.

Companionship

Most of the participants stated that playing games enabled them to feel as though they were interacting with health care professionals and experiencing companionship and support.

Early and Repetitive Upper Limb Movements: An Advantage of VR Rehabilitation

Overview

After surgical treatment for breast cancer, rehabilitative exercises must be performed early. In this study, wound pain and discomfort during such exercises were the main concerns of the participants, leading to fear of movement. Related subthemes and interviewee statements are presented in Table 4.

Reduced Fear of Movement

A total of 14 (80%) of the participants stated that the gamified design of VR rehabilitation made it more interesting than traditional rehabilitation, while 7 of the patients experienced moderate pain after surgery. However, during the use of VR for rehabilitation, these patients reported no wound pain or discomfort. In addition, their willingness to engage in rehabilitation was enhanced by the second day after surgery.

Enhanced Motivation to Engage in Rehabilitation

Most of the participants described an immersive virtual environment that facilitated the performance of early rehabilitative exercises. In addition, the participants were subsequently able to continue performing the aforementioned 3 rehabilitation movements at home without VR.

Extensive VR Use Has Challenges to Be Overcome

Overview

Most of the patients had safety concerns, mainly because while wearing the VR HMD, they were unable to pay attention to the environment around them. Consequently, some of the patients initially felt apprehensive, fearing collisions with nearby objects. In addition, high equipment costs limited the accessibility of the equipment for home use, and many of the patients expressed disappointment that they were able to use the system only in hospital. Related subthemes and interviewee statements are presented in Table 5.

Safety of the Real-World Environment

While the patients were wearing the VR HMD and engaging in VR-based exercise, they were unable to pay attention to the environment around them. Thus, patients had the not-unfounded fear that they might collide with nearby objects and were initially apprehensive. Therefore, patients should be in a clutter-free environment when engaging in VR rehabilitation.

Cost of VR Rehabilitation Equipment Is Too High to Extend to Home Use

The cost of VR equipment for rehabilitation is high, making it relatively inaccessible for home use. Each new technology faces the problem of high equipment cost in its initial stage, and similarly, the main problem for most of the participants in this study was that they wanted to continue using the rehabilitation equipment at home. They indicated that they thought it was a pity that the system could be used only in hospital.

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Motion Sickness

We found that 3 of the participants reported the side effect of motion sickness after performing the wiping table exercise.

Discussion

Principal Findings

To the best of our knowledge, this study is the first phenomenological study to investigate the feasibility of an immersive VR experience for facilitating postoperative rehabilitation in patients with breast cancer. Through inductive thematic analysis, our study found VR to be an effective and suitable intervention for our patient population. Tables 3 and 4 address feasibility in relation to 2 of the 3 inductive themes of this study: "VR was powerful in facilitating rehabilitation" and "early and repetitive upper limb movements are an advantage of VR rehabilitation." Table 5 reveals the key finding that the high costs of VR hardware and software limit its at-home use. These results further support the recommendations of the VR CORE group [20]. However, the high cost of VR equipment remains a concern.

VR Was Powerful in Facilitating Rehabilitation

This study found that "power" was an essential concept and that power was cultivated through knowledge and companionship. One key finding related to this inductive theme was the knowledge obtained by the individual. In our study, most of the participants were skeptical about their early postoperative rehabilitation, and some had no idea how to proceed with it; however, through VR, these patients gained information about rehabilitation, which then led to behavioral changes. A previous study noted the importance of people's need to know which approach they should adopt to improve their health [30]. In addition, most patients with breast cancer desire information concerning recovery details; in particular, they want real-time, transparent information regarding appropriate rehabilitative measures [21]. Our findings were consistent with those of the 2 aforementioned studies. Another present finding was related to companionship; specifically, the participants reported that they felt as if a medical care team was with them in their rehabilitation in the VR world. This finding is notable because not every patient with breast cancer receives a rehabilitation exercise consultation after surgery. Our interactive VR system provides clear information regarding the commencement and completion of rehabilitation exercises, and its prompts align with how the clinical rehabilitation program operates (eg, 20 prompts for each motion). The literature notes that an ideal user experience must include interaction with VR applications in order to encourage and support users to complete clinical activities; this assertion is consistent with our findings [31].

Early and Repetitive Upper Limb Movements: Advantage of VR Rehabilitation

VR elicited engagement in early postoperative rehabilitation in most of this study's patients, seemingly stemming from their reduced fear of movement and their enhanced motivation. Early postoperative rehabilitation in patients who have undergone breast cancer surgery aims to improve shoulder mobility, arm mobility, or both. VR is believed to be as effective as conventional physiotherapy in improving upper limb function to facilitate the maintenance of activities of daily living [32]. Some of the participants in this study were initially apprehensive to undertake postoperative rehabilitation primarily because of fear related to insufficient knowledge of the appropriate degree of movement. Nevertheless, our VR rehabilitation system was based on the concept of gamification; the participants who used the system were attracted to the game screen, and consequently, their negative feelings—including fear, pain, and discomfort—were temporarily alleviated. In this manner, the VR system considerably enhanced the participants' motivation to engage in rehabilitation; this finding was consistent with those of previous studies [18,33]. In addition, the game design can be adjusted according to the needs of the patient to prevent patients from giving up on movements that are either difficult or so simple that the desired training outcomes cannot be achieved by performing them.

Challenges of Extensive VR Use to Be Overcome

The participants in this study were required to wear HMDs; thus, they could not see their surroundings during rehabilitation. Related studies that have recommended VR have stated that when using such technology, a space of at least 70 cm × 70 cm is required; however, in our study, the participants took a seated position to minimize the risk of tripping and thus needed only to pay attention to whether the seat back was affecting exercise safety. Although research has shown that the cost of HMDs has fallen in recent years [15], VR devices remain unaffordable for many people in Taiwan. Therefore, even if patients with breast cancer are interested in using this emerging technology for rehabilitation, doing so without an HMD is difficult. In addition, the development and maintenance costs of VR software and hardware are high, and thus, the cost of VR equipment remains a challenge for large-scale implementation in postoperative rehabilitation.

Motion sickness (MS) is a common physiological response to VR immersion [34]. Previous studies have shown that behavioral and dietary strategies and physical therapy, such as listening to music or chewing gum [35], are effective in alleviating MS symptoms. Although each movement in our VR rehabilitation system was accompanied by music with a brisk tempo, 3 of the patients in this study still experienced MS due to unsuitable seat height. A previous study demonstrated that positive emotions can relieve MS [36]; we found that most patients have positive emotions while using VR for rehabilitation. Accordingly, this paper suggests that the use of VR should be combined with emotional assessments to effectively prevent MS. With regard to feasibility, we found that the present VR system met the patients' needs, conformed to their values, and satisfied their expectations. The system also provided an engaging and interactive rehabilitation environment that stimulated the patients' motivation to engage in early and continuous rehabilitation and, in turn, reduced their risk of developing defensive functional impairments. Nevertheless, the accessibility of VR proved to be a challenge because of the difficulty of using VR technology at home. Thus, such interventions may tend to be limited to in-hospital use because not every patient can afford to purchase VR equipment and software.

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Study Limitations

This study has some limitations. First, we did not conduct a pilot study of the interview guide. However, after the content of the first interview was analyzed, the interview questions were discussed and modified with the research team to identify and address any potential issues in the data collection methods. It may be recommended to incorporate a pilot study in future research to ensure validity and robustness. Second, the development of VR technology to facilitate postoperative rehabilitation in patients with breast cancer is still in its infancy. In this study, only 3 rehabilitation exercises were developed and clinically tested. The facilitators of and barriers to rehabilitation were investigated. To determine the clinical efficacy of the proposed VR system, a large-scale randomized controlled trial is needed.

Conclusion

Feasibility research related to health care is crucial for generating novel ideas and improvements to provide more effective care for patients. From the perspective of this study, rehabilitation is an iterative, active, and educational process of problem-solving that must focus on a patient's behavior. VR technology was effective in facilitating rehabilitation by providing knowledge and companionship to participants. It helped reduce fear of movement and enabled early and repetitive upper limb movements. However, safety concerns, high equipment costs, and potential side effects like MS were reported as challenges to extensive VR use.

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Authors' Contributions

SCW and CWC were responsible for the study design and coordination. CWC, HHS, and CFL extracted the data. SCW and WCL drafted the manuscript. All authors have contributed to, read, and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CHQ-12: Chinese Health Questionnaire–12
CORE: Clinical Outcomes Research Experts
DT: Distress Thermometer
HMD: head-mounted display
MS: motion sickness
ROM: range of motion
VR: virtual reality

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Original Paper

Digital Interventions for Stress Among Frontline Health Care Workers: Results From a Pilot Feasibility Cohort Trial

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Abstract

Background: The COVID-19 pandemic has challenged the mental health of health care workers, increasing the rates of stress, moral distress (MD), and moral injury (MI). Virtual reality (VR) is a useful tool for studying MD and MI because it can effectively elicit psychophysiological responses, is customizable, and permits the controlled study of participants in real time.

Objective: This study aims to investigate the feasibility of using an intervention comprising a VR scenario and an educational video to examine MD among health care workers during the COVID-19 pandemic and to use our mobile app for longitudinal monitoring of stress, MD, and MI after the intervention.

Methods: We recruited 15 participants for a compound intervention consisting of a VR scenario followed by an educational video and a repetition of the VR scenario. The scenario portrayed a morally challenging situation related to a shortage of life-saving equipment. Physiological signals and scores of the Moral Injury Outcome Scale (MIOS) and Perceived Stress Scale (PSS) were collected. Participants underwent a debriefing session to provide their impressions of the intervention, and content analysis was performed on the sessions. Participants were also instructed to use a mobile app for 8 weeks after the intervention to monitor stress, MD, and mental health symptoms. We conducted Wilcoxon signed rank tests on the PSS and MIOS scores to investigate whether the VR scenario could induce stress and MD. We also evaluated user experience and the sense of presence after the intervention through semi–open-ended feedback and the Igroup Presence Questionnaire, respectively. Qualitative feedback was summarized and categorized to offer an experiential perspective.

Results: All participants completed the intervention. Mean pre- and postintervention scores were respectively 10.4 (SD 9.9) and 13.5 (SD 9.1) for the MIOS and 17.3 (SD 7.5) and 19.1 (SD 8.1) for the PSS. Statistical analyses revealed no significant pre-

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to postintervention difference in the MIOS and PSS scores (*P*=.11 and *P*=.22, respectively), suggesting that the experiment did not acutely induce significant levels of stress or MD. However, content analysis revealed feelings of guilt, shame, and betrayal, which relate to the experience of MD. On the basis of the Igroup Presence Questionnaire results, the VR scenario achieved an above-average degree of overall presence, spatial presence, and involvement, and slightly below-average realism. Of the 15 participants, 8 (53%) did not answer symptom surveys on the mobile app.

Conclusions: Our study demonstrated VR to be a feasible method to simulate morally challenging situations and elicit genuine responses associated with MD with high acceptability and tolerability. Future research could better define the efficacy of VR in examining stress, MD, and MI both acutely and in the longer term. An improved participant strategy for mobile data capture is needed for future studies.

Trial Registration: ClinicalTrails.gov NCT05001542; https://clinicaltrials.gov/study/NCT05001542

International Registered Report Identifier (IRRID): RR2-10.2196/32240

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KEYWORDS

virtual reality; simulation; mobile app; stress; moral distress; moral injury; COVID-19; mobile phone

Introduction

Background

The COVID-19 pandemic has exerted unprecedented strain on health care workers (HCWs) globally [1]. Frontline HCWs have been forced to make difficult medical decisions that are contrary to their moral and professional principles and to work in conditions where they cannot meet standards of quality care [2,3], which has put them at a greater risk of experiencing moral distress (MD) than possibly ever before [4,5]. Distressing situations such as being forced to deal with a shortage of personal protective equipment and having to prioritize who will receive life-sustaining treatment have become common during the pandemic. For HCWs, experiencing such situations may cause significant emotional burden and induce the phenomenon of MD [6-8]. MD is defined as distress stemming from the inability to enact actions believed to be morally right owing to external constraints [8,9]. Moral injury (MI), an extreme form of MD, can occur when individuals witness or perpetrate actions that violate deeply held moral beliefs, resulting in severe emotional reactions with long-lasting consequences [7]. However, further investigation is needed to enable a more precise distinction between MD and MI [7].

The first description of MI was made in the military context by Shay [10] and was defined as a betrayal of moral character, usually as a result of the actions of a person in a position of authority [10], leading to feelings of powerlessness, helplessness, and loss of faith in humanity [7,10]. Shay [11] argues that MI occurs when the following conditions are met: (1) there has been a betrayal of what is considered right (2) by someone holding legitimate authority and (3) in high-stakes situations. Litz et al [12] expanded the concept of MI to include "the lasting psychological, biological, spiritual, behavioral, and social impact of perpetrating, failing to prevent, or bearing witness to acts that transgress deeply held moral beliefs and expectations." As part of the definition, the authors also defined potentially morally injurious events (PMIEs) as the acts of perpetrating, failing to prevent harm, or bearing witness to acts that transgress deeply held moral beliefs [12]. Experiencing a PMIE is frequently associated with feelings of betrayal, guilt, shame, and self-blame [13]. Furthermore, PMIEs may not only cause acute MD but can also have long-term consequences because MD and MI may develop weeks or months after a PMIE [14].

MI was originally associated with, and frequently co-occurs with, posttraumatic stress disorder (PTSD) [13], which has been conceptualized as a fear-related disorder [15,16]. However, MI has not yet been defined in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition [16], and a PMIE does not necessarily fulfill the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition criterion A for PTSD. The concept of MI was conceived to encompass the following criteria, among others: (1) reexperiencing self-referential moral emotions (eg, anger, guilt, and shame); (2) strong negative beliefs about the self, the world, and others; and (3) self-destructive behaviors that inflict severe distress or functional impairment [17,18]. In addition, emerging literature has defined MI as being mechanistically different from PTSD [13,15]. A positron emission tomography study in veterans with PTSD showed that regional blood glucose metabolism differed according to the nature of traumatic exposure as follows: the group with PTSD owing to danger-based traumas (ie, life-threatening events) showed higher metabolism in the amygdalae; by contrast, the group with PTSD secondary to non–danger-based traumas (eg, MI by self or others) had increased metabolism in the precuneus [19], a region that has been associated with the processing of self-referential feelings (eg, shame and guilt) [15]. Therefore, further research is needed to determine the ecological validity of MI as an independent diagnostic category [13]. In addition, there is a need to investigate specific interventions for MI because it has been found to not generally respond to evidence-based treatments for PTSD [12,17]; for example, moral resilience training, the development of emotional intelligence skills, and strategies for promoting moral repair have already been proposed as specific treatments for MI and are currently under investigation [5,17,20].

Although MI has been largely studied in military contexts [17], it is also applicable to HCWs, particularly in light of the COVID-19 pandemic. However, MI and PMIEs are poorly

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understood in this context. Čartolovni et al [7] argue that MI occurs in HCWs when they experience PMIEs involving high-stakes situations that are beyond their control. To investigate MI in the COVID-19 context, Rushton et al [5] conducted a survey with frontline HCWs and reported an overall prevalence rate of 32% for MI, with nurses being the most affected (38%). Fewer years of experience were positively associated with MI, whereas religious affiliation or spirituality and higher levels of moral resilience were associated with lower MI scores. In addition, the study showed a moderate correlation between MI and various ethically challenging situations, such as experiencing negative consequences at work after expressing safety concerns, working with limited resources, and carrying out decisions of others which threaten one's own values [5].

Litam and Balkin [4] examined the relationship between MI and the professional quality of life in a convenience sample of HCWs during the COVID-19 pandemic. The authors reported that secondary traumatic stress was a strong predictor of MI in frontline HCWs, but the contribution of compassion, satisfaction, and burnout to MI scores was nonsignificant. Of note, nurses had significantly higher burnout scores than physicians. Zerach and Levi-Belz [21] conducted a survey to investigate the patterns of exposure to PMIEs in a sample of HCWs and social care workers during the COVID-19 pandemic. The prevalence rate of symptoms of MI was 40%, with betrayal events being the most frequent PMIEs with a prevalence rate of 62%. In general, exposure to PMIEs was positively related to perceived stress, depression, anxiety, and self-criticism, whereas it was negatively associated with self-compassion. Interestingly, the duration of care for patients with COVID-19 was not associated with MI [21].

To increase the ecological validity of MI as a diagnostic entity, the experiences of the MD-MI continuum should be examined using accurate methods [13]. To date, several measurement instruments have been developed to identify MI outside of military contexts, including the Moral Injury Symptom Scale–Healthcare Professionals version [22] and the Moral Injury Outcome Scale (MIOS) [18]. The MIOS is a self-rated scale, developed as an assessment tool to evaluate MI as a multidimensional outcome [18]. This scale comprises 10 binary (*yes* or *no*) questions and 15 five-point Likert scale questions about experiencing a PMIE and feelings associated with this event; higher scores indicate greater severity of MI symptoms. At the end, the MIOS has an additional 7-point Likert scale question that assesses the extent to which the experience of PMIEs has interfered in one's self-care or caused functional impairment (from *not at all* to *extremely*). The MIOS is in the final stage of development by the MIOS Consortium [18].

Conducting interventional studies to investigate the impact of PMIEs on mental health in real-world settings is challenging owing to operational constraints. This is especially true in health care, where limitations imposed by patient privacy regulations may make traditional clinical trials in MI impractical. Another important aspect to consider is the ethical implications of submitting an already strained workforce to moral stressors in an uncontrolled real-world environment such as an intensive care unit (ICU). A promising strategy to address these limitations is the use of virtual reality (VR) scenarios. VR is a powerful technology for examining mental health and the MD-MI continuum because it offers several advantages over traditional observational research in naturalistic environments. First, VR allows researchers to observe, monitor, and potentially support participants in fully controlled environments in real time [23]; therefore, it is safer and provides more accurate measures of one's reactions to ethically challenging situations compared with observational studies in naturalistic environments. Second, VR allows for the design of fully customizable scenarios [23], making it especially suitable to simulate real-world scenarios in health care that otherwise would be impractical to replicate. As traumatic events in both PTSD and MI are highly idiosyncratic, and treatment for PTSD requires exposure to individual cues, we assume that virtual environment customization should be a critical feature to provide personalized and effective interventions to treat MD and MI [24]. In addition, extensive evidence has demonstrated the effectiveness of VR-based interventions for PTSD [25-27]. Third, VR environments can effectively elicit real psychophysiological responses because individuals are immersed in virtual scenarios as if these were real events, with the advantage of enabling real-time data capture [23,24]. All these advantages make VR-based trials ideal to study the MD-MI phenomena in HCWs. However, no prior research has investigated the feasibility of VR interventions to examine MD and MI in the context of the COVID-19 pandemic.

Objectives

The overarching goal of this study was to determine the feasibility of using a compound VR intervention to examine MD and MI among HCWs during the COVID-19 pandemic. To achieve this, we designed a VR scenario in which HCWs faced a morally challenging situation in a midpandemic hospital environment while being monitored for acute psychological and physiological measures of stress. As outlined in our protocol paper [28], our aims were to (1) evaluate the feasibility of using a VR scenario to simulate the experience of a COVID-19–related morally challenging event by using measures of tolerability, dropouts, and suitability of the virtual scenario; (2) assess the potential of our VR scenario to elicit mild stress and MD, as measured by quantitative self-report questionnaires as well as qualitative analyses of semistructured interviews; and (3) investigate the feasibility of our novel mobile app (*DiiG App*) for longitudinal monitoring of stress and MD in naturalistic settings in the 8 weeks after the intervention.

On the basis of the findings with PTSD [25-27], we hypothesized that VR scenarios would be a feasible method for assessing MD and MI. Given the ability of VR to generate genuine responses, we additionally hypothesized that our virtual scenario would significantly increase stress levels and elicit feelings and symptoms associated with MD and MI. Finally, we hypothesized that our mobile app would successfully capture symptoms associated with stress and MD in the 8-week follow-up.

To the best of our knowledge, this pilot study is the first to assess the feasibility of using a VR scenario to simulate the experience of a morally challenging event related to the

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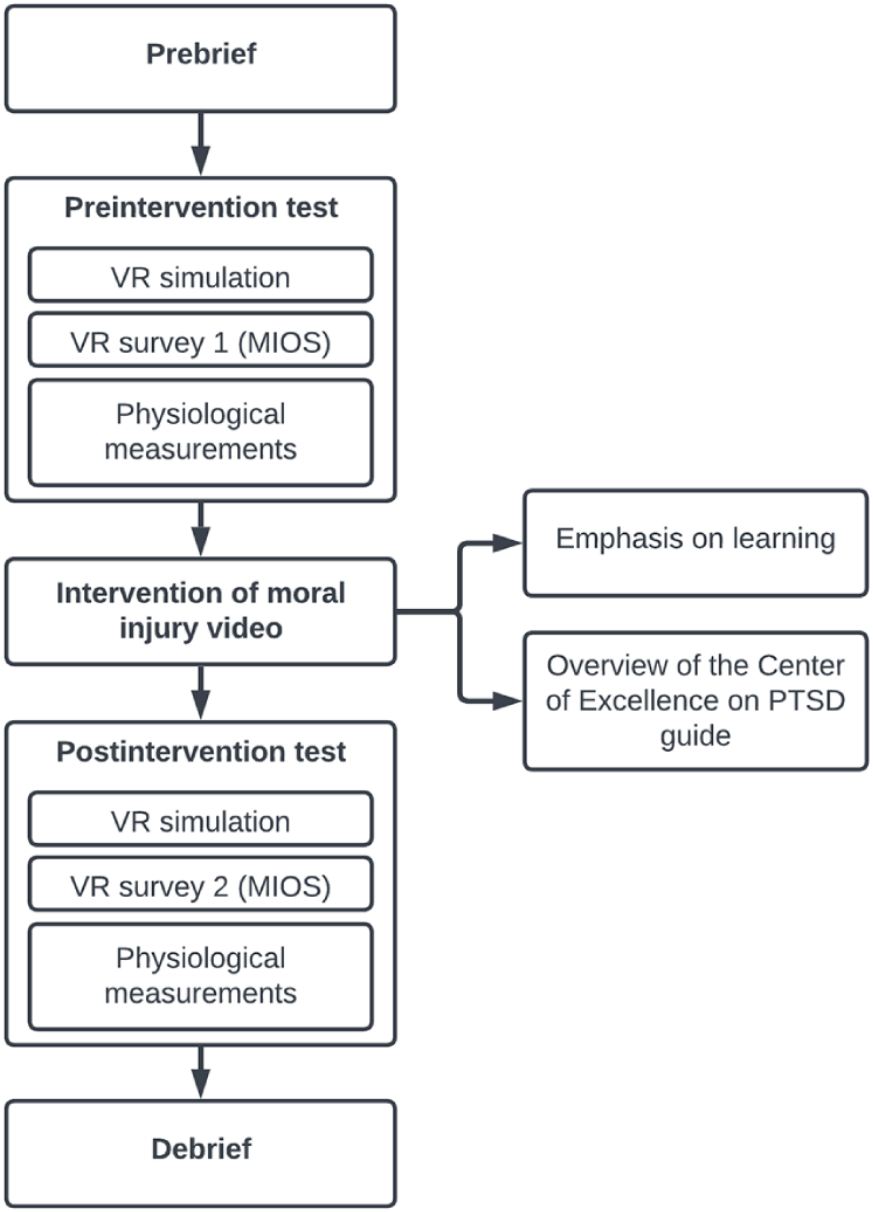
COVID-19 pandemic by HCWs while assessing its acute perceptual, psychological, and physiological effects in real time.

Methods

Study Design

In this single-cohort pilot study (ClinicalTrials.gov: NCT05001542), we adopted a multimethod approach in a pretest-posttest design to develop a compound intervention consisting of three successive parts: (1) a VR scenario to simulate a morally complex situation, (2) an educational video on MI and appropriate mitigation strategies, and (3) a repetition of the VR scenario. The intervention was followed by longitudinal data collection of mental health and MI surveys using our mobile app. The MI educational video was based on the Center of Excellence on PTSD guide [29] that summarized the causes and identifiers of MI and potential interventions to mitigate MD. The effectiveness of the VR-based educational intervention was assessed using the MIOS [18], the Perceived Stress Scale (PSS) [30], and the Igroup Presence Questionnaire (IPQ) [31]. The PSS is a self-reported measure of stress, whereas the IPQ evaluates the experience of presence during the VR scenario. As previously mentioned, the MIOS is a self-rated scale that was developed as an assessment tool to evaluate MI. For the purposes of this pilot study, we adopted a brief version of the MIOS (hereinafter referred to as *the MIOS*), which comprises 10 five-point Likert scale questions and 4 binary (*yes* or *no*) questions [32]. During the VR scenario, respiratory impedance, electrocardiography (ECG), galvanic skin response, and photoplethysmography were continuously collected. In addition to the original signals, we extracted the derivation of these signals, including ECG pulse rate, ECG RR interval, respiratory rate, and elevated respiratory rate. A visualization of the VR experimental flow can be seen in Figure 1. Further details on the intervention and data collection have been explained and outlined in the paper by Nguyen et al [28].

Figure 1. Flowchart of the virtual reality (VR) experiment. MIOS: Moral Injury Outcome Scale; PTSD: posttraumatic stress disorder.



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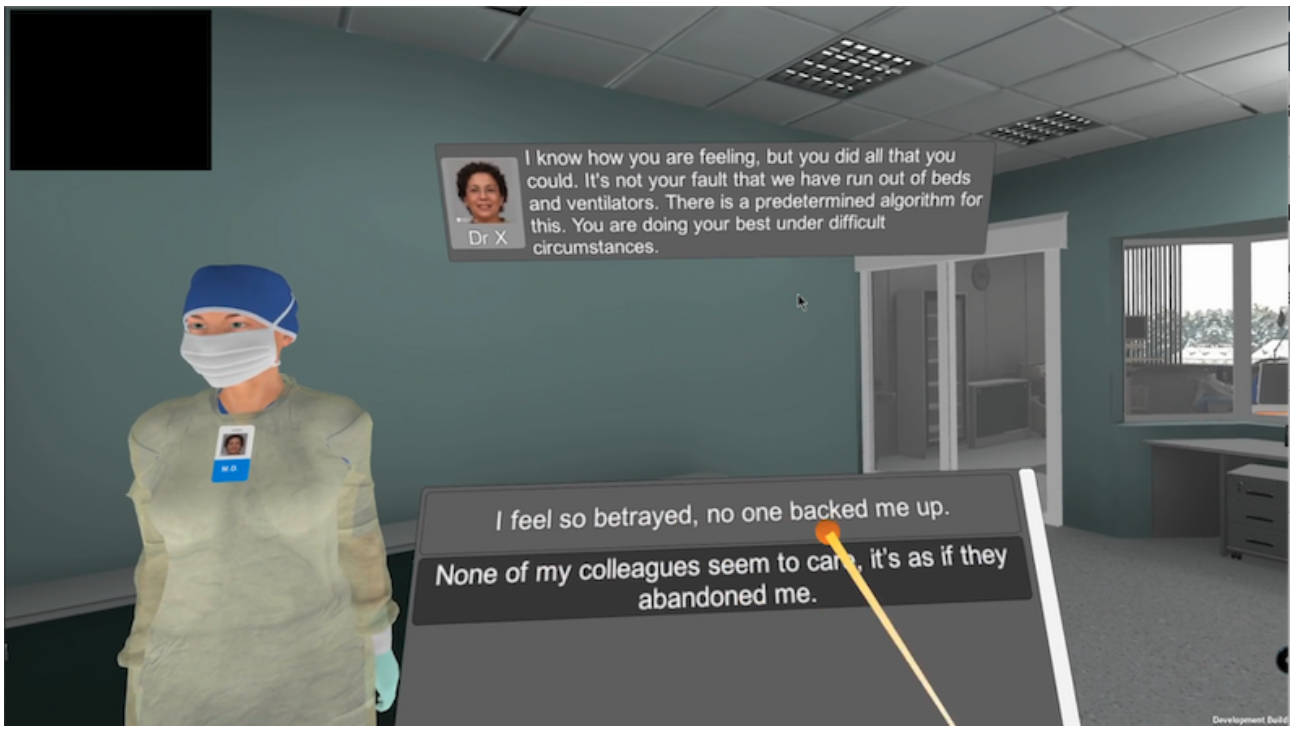
The experimental session was divided into prebrief, preintervention test, intervention video, postintervention test, and debrief components (Figure 1). The preintervention test and postintervention test were conducted in VR, whereas the prebrief and debrief occurred outside the virtual environment. The MIOS was performed at 4 time points as follows: as a paper-based version for the prebrief and debrief and in the virtual scenario for the preintervention test and postintervention test. The PSS was performed twice, at prebrief and debrief. The MIOS and the PSS focus on symptoms of MD and stress, respectively, over the last month. However, when answering these scales, participants were told to rate symptoms at that exact moment. The goal of the prebrief was to explain how the physiological data would be collected and prepare the participant for the VR scenario; it consisted of an orientation to the virtual space and equipment, safety precautions, and the expected outcome of the study. During the preintervention test, participants were immersed in the VR scenario where they took on the role of a physician in an ICU during the COVID-19 pandemic. To experience the VR scenario, participants used a VR headset and 2 wireless controllers that tracked their head and hand movements, mapping it to an avatar. Semitranslucent panels were displayed as spatial elements in the VR scenario (Figure 2), providing information to the participant in the form of the dialogue panel (which displayed the current nonplayable character's photograph, name, and the text version of the dialogue being spoken) and the interaction panel (which displayed a list of available choices and responses for the participant to choose from).

Figure 2. User interface displaying the dialogue and interaction panels.



In the scenario, a shortage of life-saving equipment resulted in the decision to move a ventilator from 1 patient to another patient who had a greater chance of survival. After being informed of this, the participant's avatar appeared in the next scene, where they had to communicate this decision to the first patient's family and respond to the family's reactions of frustration and anger. After completing the preintervention test and while still immersed in the VR scenario, participants watched a brief 2D educational video comprising key concepts of MD and MI and adaptive behaviors to cope with morally complex situations at the individual, team, and organizational levels. Participants then completed the postintervention test, which consisted in a repetition of the VR scenario played in the preintervention test. Finally, in the debrief, participants were asked open-ended questions to encourage them to describe their experiences in the virtual setting, followed by an exit survey [28].

After the experiment, participants were instructed to use our mobile app [33] to collect passive and active data for distress monitoring during the following 8 weeks. As MI may have a delayed onset, such data collection allows for longer-term monitoring of emotions associated with MD, offering insights into the distress experienced in real time.

Participants

Participants were recruited and enrolled between May 2021 and August 2021 from the 3 affiliated hospitals at Unity Health Toronto. Participants were enrolled if they were an HCW currently providing health care at their respective hospital of employment, aged ≥18 years, and owned a mobile phone (an Android mobile phone with operating system version 6.0 or above or an iPhone with operating system version 11.0 or above).

Statistical Analysis

As this was a pilot feasibility trial, we summarized dropout rates, easiness of use, tolerability, acceptability, and utility using counts and percentages. Continuous data were summarized using range, mean and SD, and median and IQR. To assess the

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effect of the VR scenario on symptoms of MI, we compared MIOS scores across the 4 time points using a Friedman test. In addition, follow-up MIOS scores were compared with the score at prebrief using Wilcoxon signed rank tests with Bonferroni correction (.05/3=.0167) to adjust for multiple comparisons. As PSS scores were collected only at 2 time points (ie, at prebrief and debrief), a Wilcoxon signed rank test was used to compare the difference in the PSS scores between these 2 time points. A *P* value of <.05 was considered significant unless otherwise specified. We performed statistical analysis using SAS 9.4 (SAS Institute Inc).

Quantitative Analysis

Stress and MD Analysis

In this feasibility study, we piloted the application of the MIOS to assess MD both acutely and longitudinally. As mentioned in the *Study Design* section, MIOS was administered during the prebrief, preintervention test, postintervention test, and debrief. Participants were also prompted to complete MIOS on the mobile app in the 8 weeks after the intervention for a longitudinal assessment of MD and MI. All questionnaires used in the mobile app (eg, the MIOS and the PSS) are available in the appendices of the study by Nguyen et al [28].

IPQ Assessment

To objectively assess user experience within the VR scenario, we adopted the IPQ, which is a questionnaire for measuring the sense of presence experienced in a virtual environment [31]. Composed of 14 questions (answered on a 6-point Likert scale), the IPQ has a high reliability (Cronbach α=.87) and outputs four items (1 general item, not belonging to a subscale, and 3 subscales): (1) general presence (sense of being there), (2) spatial presence (the sense of being physically present in the virtual environment), (3) involvement (measuring the attention devoted to the virtual environment), and (4) experienced realism (measuring the subjective experience of realism in the virtual environment).

Hereinafter, the 4 outputs will be referred to as *IPQ components*. More information about the construction and structure of the scale and the IPQ's reliability analysis is available on the Igroup project consortium website [34,35].

Mobile Data Analysis

After participating in the intervention, participants were instructed by our research staff to download and regularly use our mobile app to answer surveys in the 8-week follow-up. Participants received push notifications on the mobile app 3 times weekly to answer short versions of the scales related to depression (2-item Patient Health Questionnaire), anxiety (2-item Generalized Anxiety Disorder), stress (4-item PSS) MI (4-item MIOS), and loneliness (3-item University of California Los Angeles Loneliness Scale). With the exception of the 3-item University of California Los Angeles Loneliness Scale, participants were also asked to answer the full version of these scales once weekly. Short versions of the scales were used on weekdays to minimize participant burden. The mobile app also had the option of collecting passive data from built-in smartphone sensors (GPS and accelerometer) from participants who provided in-app consent to gather information on distance traveled and activity patterns. Details on the mobile data collection were previously overviewed in the study by Nguyen et al [28]. We used in-app automated survey reminders to promote app use.

Qualitative Analysis

Content Analysis

We performed a content analysis on the data collected from the scenario debriefing conducted immediately after the compound intervention. Qualitative content analysis is a method to interpret meaning from text data and draw conclusions from words, themes, or concepts that occur in the text, in reference to their context, so that research questions can be answered [36]. We used inductive category development by becoming immersed in the data and allowing insights on categories to emerge from the data [37]. The scenario debriefing consisted of a semistructured interview that allowed participants to answer open-ended questions about their overall experience, followed by a semistructured debriefing methodology (the interview guide is included in Multimedia Appendix 1). The researchers (BN and AT) who collected the VR data were trained using the Promoting Excellence and Reflective Learning in Simulation (PEARLS) health care debriefing tool [38], a simulation debriefing framework to help learners assess their experience within a safe environment. A flow diagram of the debriefing can be seen in Figure 3. After completion of the intervention, we conducted a postexperiment procedure, which consisted of removing the VR headset from the participant but keeping the physiological sensors attached. In addition, we confirmed with the participant that they were able to continue with the debriefing.

Figure 3. Flow diagram of the debriefing. PEARLS: Promoting Excellence and Reflective Learning in Simulation; VR: virtual reality.

During the open-ended feedback part of the debrief, we asked participants to speak freely about their experience with the experiment. We specifically asked the following questions:

1. "What suggestions or feedback would you give to improve the scenarios? Please comment on what can be improved, what can be more realistic, and any deviation from real-life applications."
2. "Could you share something that you have learned about moral injury today? How might this apply to your clinical practice?"

The research questions we sought to answer with our content analysis from this feedback were as follows:

1. "How can the VR scenario be improved?"

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2. "How accessible and relevant was our intervention?"

We subsequently conducted scenario-based debriefing using the PEARLS [38] methodology, which involved an exploration of the following predetermined topics: participant experience with the technology used, decision-making during the scenario, and emotions elicited during the scenario. The research questions we sought to answer with the content analysis from the scenario-based debriefing were as follows:

1. "What is the overall user experience of participants with the VR technology?"
2. "What were the determining factors for the decisions that participants made in the scenario?"
3. "How did the scenario make the participant feel?"

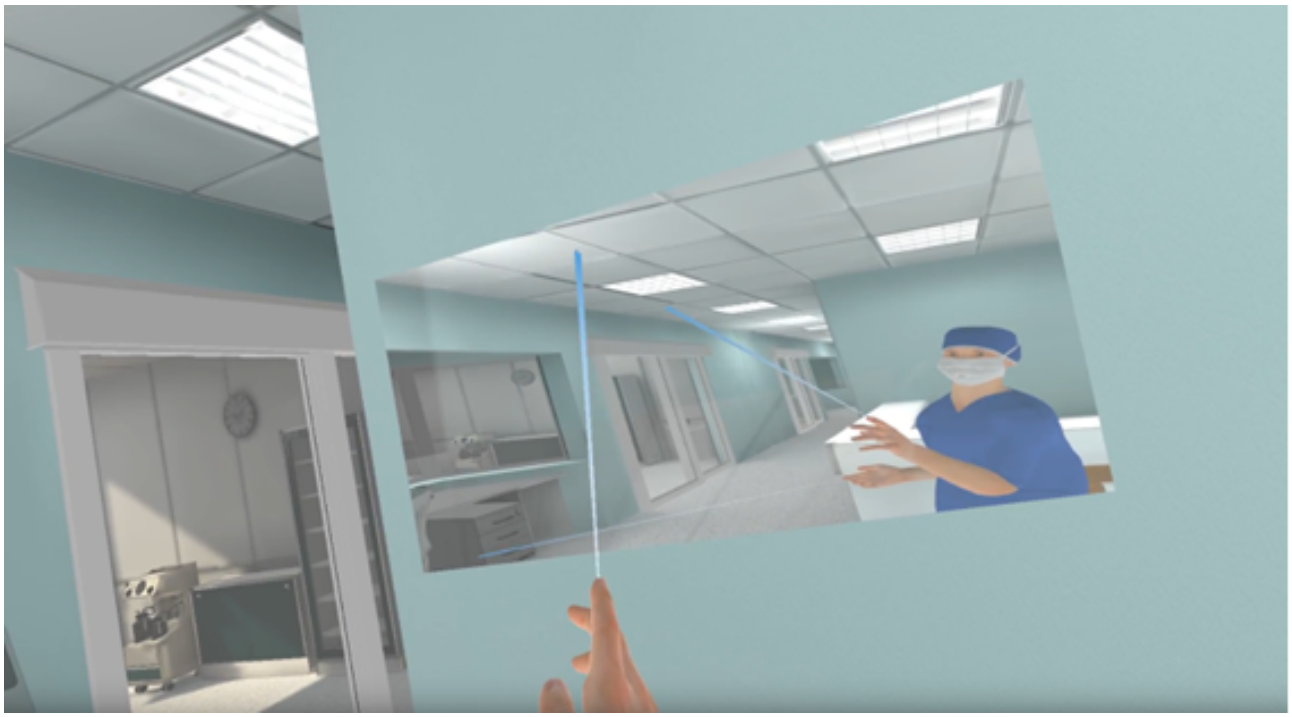
The PEARLS structure is a well-validated debriefing tool that is typically used to provide introspection on performance for a simulation participant [38]. It has been used extensively in the simulation literature, including a recent user qualitative study with patient-led simulations [39]. A PEARLS debrief integrates 4 main segments: setting the scene, eliciting reactions, description and analysis of the experience, and summary or reflections.

After the debrief, participants were asked to answer a debrief feasibility questionnaire with 3 five-point Likert questions answered on a scale ranging from 1 (*strongly disagree*) to 5 (*strongly agree*) about the relevance and utility of the psychoeducational content on MD for real-life situations as well as the ability of the VR scenario to elicit emotions (Multimedia Appendix 1).

User Experience

To assess the user experience within the VR scenario, we evaluated the dropout rate, the feasibility questionnaire, and the qualitative responses provided during the debrief. During the VR scenario, participants had their head and hand movements tracked by the VR headset and controllers, and all movements were mapped into a virtual avatar (Figure 4). To help improve the sense of body ownership (ie, making the users recognize the virtual body as their own) [40], the preintervention test started with a tutorial that had the participants looking at a mirror and moving their head and hands to visualize that their virtual avatar actions reflected their own.

Figure 4. Snapshot of the virtual reality scenario showing the participant's avatar reflected in a mirror. The blue beam indicates the cursor used to interact with the virtual environment.



Ethics Approval

Ethics approval was obtained from the research ethics board at St. Michael's Hospital before starting any study activities (21-066).

Results

Participants

Participant Flow

A total of 16 participants were assessed for eligibility; 1 (6%) declined to participate, and therefore 15 (94%) participants were allocated to the intervention. All 15 participants received the intervention. No participants were lost to follow-up, and data from all 15 participants were analyzed. Information on participant flow is presented in Figure 5.

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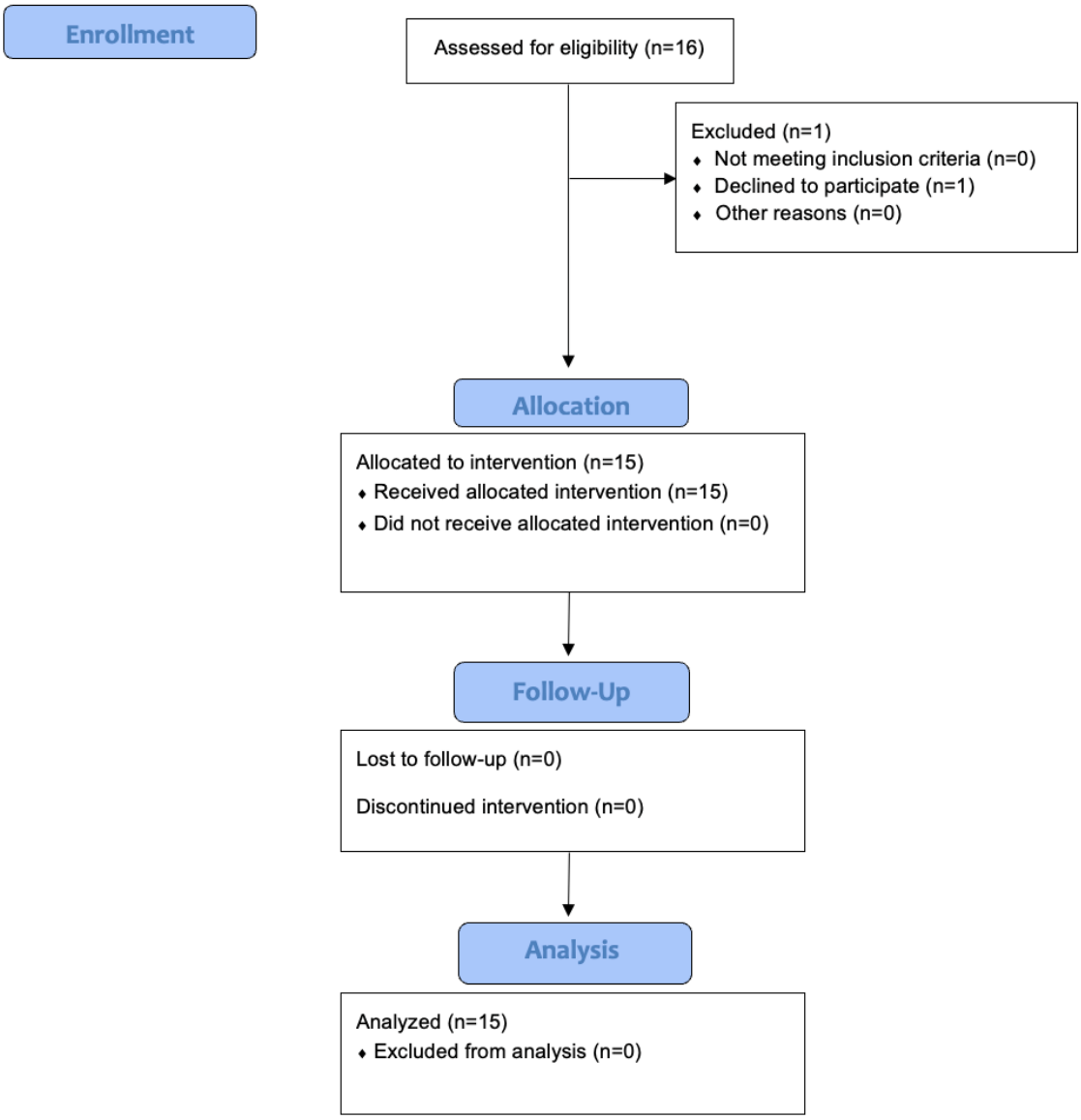
Figure 5. Flowchart of participant enrollment and attrition.



Baseline Data

Our sample consisted of 15 HCWs (female participants: n=11, 73%; male participants: n=4, 27%). The participants had a mean age of 32.7 (SD 9.5) years; the male participants had a mean age of 34.3 (SD 4.9) years, whereas the female participants had a mean age of 32.2 (SD 10.9) years. Among the 15 participants, the most common occupations were nursing (n=7, 47%) and medicine (n=3, 20%); other professions included mental health research staff (n=2, 13%), physician assistant (n=1, 7%), educator (n=1, 7%), and graduate student (n=1, 7%). At the time of the experiment, none of the 15 participants had a prior or current COVID-19 infection; however, 4 (27%) had a prior family history of COVID-19 infection. The VR experiments were conducted between May 2021 and August 2021.

Data Analyzed

For 15 participants, MIOS, PSS, IPQ, and mobile data were analyzed. The data of 14 participants were analyzed for the content analysis.

Quantitative Analysis

Stress and MD Analysis

The average MIOS scores for the prebrief, preintervention test, postintervention test, and debrief were 10.4 (SD 9.9), 12.9 (SD 6.9), 12.6 (SD 7.1), and 13.5 (SD 9.1), respectively, with a difference between the debrief and prebrief (between after the intervention and before the intervention) of 3.1 (SD 6.8; Table 1). There was no statistical difference in the MIOS scores at the 5% level when comparing all 4 scores using the Friedman test (Q=4.61; *P*=.20). Using Bonferroni correction (.05/3=.0167), the results showed no significant difference between the prebrief scores and any follow-up score: preintervention test (*P*=.30), postintervention test (*P*=.32), and debrief (*P*=.11). The MIOS is a new scale that is still under development by the MIOS Consortium and has not yet been established for the assessment of MI [18,41].

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Table 1. Wilcoxon signed rank test comparing Moral Injury Outcome Scale follow-up scores at preintervention test, postintervention test, and debrief with the prebrief score (n=15)[a].

	Values, mean (SD)	Values, median (IQR; range)	*P* value
Prebrief score	10.4 (9.9)	12 (0 to 17; 0 to 28)	N/A[b]
Preintervention test score	12.9 (6.9)	13 (6 to 17; 3 to 27)	.30[c]
Postintervention test score	12.6 (7.1)	13 (8 to 17; 1 to 28)	.32[c]
Debrief score	13.5 (9.1)	14 (5 to 18; 0 to 32)	.11[c]
Difference (debrief − prebrief)	3.1 (6.8)	1 (−1 to 7; −8 to 18)	.11[c]

[a]There was no statistical difference in the Moral Injury Outcome Scale scores at the 5% level when comparing all 4 scores using the Friedman test (Q=4.61; *P*=.20).

[b]N/A: not applicable.

[c]Follow-up scores were compared with the preintervention test score using the Wilcoxon signed rank test; Bonferroni correction was used (.05/3=.0167), that is, significance at 1.67% was applied.

PSS scores were only collected at 2 time points: at prebrief and debrief. The average PSS scores during the prebrief and the debrief were 17.3 (SD 7.5) and 19.1 (SD 8.1), respectively, with a postintervention test–preintervention test difference of 1.8 (SD 6.0; Table 2). Similar to the MIOS scores, the prebrief and debrief PSS scores were not statistically different (*P*=.22). Tables 1 and 2 summarize the analysis for the MIOS and PSS scores.

Table 2. Wilcoxon signed rank test of the Perceived Stress Scale prebrief and debrief scores (n=15).

	Values, mean (SD)	Values, median (IQR; range)	*P* value
Prebrief score	17.3 (7.5)	15 (12 to 22; 4 to 33)	N/A[a]
Debrief score	19.1 (8.1)	19 (14 to 26; 4 to 33)	N/A
Difference (debrief − prebrief)	1.8 (6.0)	1 (−1 to 7; −11 to 11)	.22[b]

[a]N/A: not applicable.

[b]Wilcoxon signed rank test to test no difference in the distribution between the preintervention test and postintervention test scores.

IPQ Assessment

On the basis of the data collected from the 15 participants, the VR scenario achieved an above-average degree of overall presence, spatial presence, and involvement, with slightly below-average realism (Table 3 and Figure 6). Considering that the presence component is influenced by the other 3 components, it makes sense that it has a higher variance and SD, which suggests an opportunity to improve the immersion of the VR scenario. The lowest scoring component was realism, with the lowest variance and SD. These findings are corroborated by the qualitative feedback provided during the debrief session, where only 5 (33%) of the 15 participants commented that the environment felt realistic and that they felt immersed in the experience. By contrast, 1 (7%) of the 15 participants stated that they found the environment more immersive than simulation with real people. The participants' feedback also highlighted other areas for future improvement, particularly regarding the realism component, such as having less restrictive dialogues, making the ICU environment more crowded, improving the voice-over acting features, and having the ICU equipment show patients' physiological data (eg, heart rate monitor).

Table 3. Igroup Presence Questionnaire data statistics.

	Values, mean (SD)	Values, median (IQR)	Variance
General presence	3.80 (1.47)	4.0 (2.0)	2.17
Spatial presence	3.53 (1.16)	4.0 (1.6)	1.34
Involvement	3.48 (0.78)	3.5 (1.0)	0.60
Experienced realism	2.20 (0.67)	2.5 (1.3)	0.45

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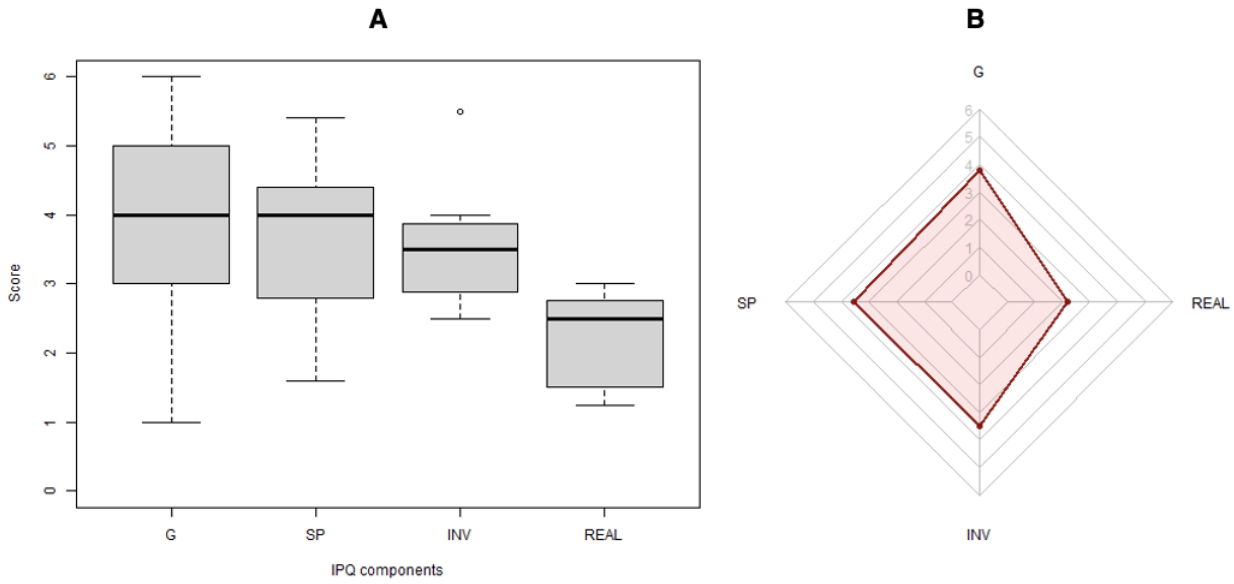
Figure 6. (A) Box plot showing median, quartiles, extreme data points, and outlier. (B) Radar chart of the overall mean of the 4 Igroup Presence Questionnaire (IPQ) components. It uses a radial axis, with the center representing a score of 0 and the outer outline representing a score of 6. G: general presence; INV: involvement; REAL: experienced realism; SP: spatial presence.



Mobile Data Analysis

The dropout rates for the study app were very high. Of the 15 participants, 8 (53%) did not perform any survey, whereas 7 (47%) completed at least 1 questionnaire. Instead of answering surveys periodically, only 4 (27%) of the 15 participants had >1 set of survey results. There were not sufficient mobile data to provide informative analysis. In the future, an improved participant engagement strategy is needed to help optimize mobile data collection.

Post Hoc Sample Size Calculation

As an exploratory analysis, we calculated post hoc sample sizes using 2-tailed paired *t* tests with a significance level of .05 based on the mean differences in the MIOS and PSS scores observed between the respective scores at prebrief and debrief. The common SDs for each score were estimated using the observed larger SD among the 2 scores. The computed correlations between the 2 scores were used in this calculation. The sample sizes required to achieve a power of 80% were 41 and 95 participants based on the observed results for the MIOS and the PSS, respectively (Multimedia Appendix 2).

Qualitative Analysis

Content Analysis

Content analysis was performed for 14 (93%) of the 15 participants because technical issues compromised the speech recording of the 15th participant. Common references to real-life experiences were recognized in the content analysis, with the most frequent themes being the following: the virtual characters' choices during the experiment were too restrictive (10/14, 71%), feelings of some guilt or shame (8/14, 57%), no feelings of failure or being punished (7/14, 50%), no guilt or shame (6/14, 43%), need of organizational support to deal with the morally challenging situation presented in the experiment (7/14, 50%), numbness (5/14, 36%), and the VR scenario was immersive, real, or engaging (5/14, 36%). Of the 14 participants, 1 (7%; participant 13) provided contradictory responses to feelings of guilt and shame, once saying that they did experience these feelings and once saying that they did not. Furthermore, 2 (14%) of the 14 participants considered the learning experience about MD and MI valuable and useful to their daily practice. A complete summary of the content analysis is provided in Multimedia Appendix 3.

Participants also recommended some specific areas of improvement in the VR scenario; for example, the following suggestions were made by 1 (7%) of the 14 participants: the patient's vital signs were at a normal range although he was experiencing respiratory failure, the skin color should be consistent with that of the participant (all virtual characters were White), the scenario was unrealistic because other interventions apart from the ICU ventilator should have been portrayed, and photographs of the patient should have been added to better customize the character's appearance. Finally, 2 (14%) of the 14 participants reported not being able to relate to religious mentions of God in the VR scenario.

User Experience

Although only 3 (20%) of the 15 participants reported prior experience with VR headsets (Multimedia Appendix 4), there were no dropouts during the VR scenario (Figure 5). As we had expected that new VR users could potentially experience nausea or disorientation, participants were reminded multiple times during the prebrief that they could pause or stop the session at any moment. Having said that, of the 15 participants, 14 (93%) did not report any side effects; only 1 (7%) participant reported claustrophobia and slight anxiety at first, but these feelings quickly subsided, and the participant was able to complete the VR scenario without any further side effects or complaints. Finally, all participants agreed that the VR platform and scenario

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were easy to navigate (Multimedia Appendix 4). Regarding the debrief feasibility questionnaire, of the 15 participants, 6 (40%) agreed that they learned about MD and interventions, and 11 (73%) agreed that the knowledge about MD and interventions will help them perform better in real-life events (Multimedia Appendix 5). Although only 8 (53%) of the 15 participants agreed that the VR simulation managed to make them experience the same emotions as they would in a real-life event (Multimedia Appendix 5), during the qualitative debrief, common emotions cited included some guilt, shame, betrayal, and isolation, which are consistent with MD.

Discussion

Principal Findings

In this work, we developed a fully immersive VR scenario to emulate a real experience of a morally distressing situation by HCWs in a simulated ICU setting during the COVID-19 pandemic and assess its acute effects on physiological and psychological parameters as well as longer-term effects on MD. This was followed by an educational video on MD and MI and appropriate mitigation strategies for MD and finally a repetition of the VR scenario in a pretest-posttest design. Because of COVID-19 constraints that resulted in health care settings often being described as a *war zone* [42], HCWs have been particularly exposed to PMIEs in their work environment during this pandemic [4,7]. However, despite the attention it has gained over the last decade, the concept of MI remains poorly understood. VR is a promising strategy to investigate MI owing to its ability to provide highly controlled virtual environments, personalized and tailored experiences, and full control and monitoring of the participants by the research team. The VR scenario created by the research team involved a complex ethical problem that became unfortunately frequent owing to the strain of the pandemic: prioritizing which patients would receive vital support in the face of the shortage of essential equipment such as ventilators [6]. This situation may be considered morally distressing because participants may witness the transgression of some of their core moral values [12], but it is not considered severe enough to induce MI. To achieve our goals, we performed a thorough quantitative and qualitative analysis of the acceptability, easiness of use, tolerability, and utility of the VR technology using a head-mounted display. To the best of our knowledge, this study is the first to examine the feasibility of using an immersive VR scenario to investigate the psychobiological impacts of a moral stressor on HCWs, as well as to use physiological parameters to predict the severity of stress and symptoms of MD and MI.

The feasibility analysis showed high acceptability of the VR scenario among participants, with no dropouts occurring during the study. Although only one-fifth of the participants (3/15, 20%) had previously used VR, all participants reported that the VR technology was easy to use. Moreover, the tolerability was also high because only 1 (7%) of the 15 participants reported mild transient side effects (claustrophobia); no participants reported nausea, whereas other specific side effects (eg, headache and dizziness) were neither reported by participants nor inquired on by the research team. This finding aligns with the literature showing that the incidence rate of VR-induced side effects is low and ranges between 0.5% and 8% [43], with the most common side effects being nausea, eye strain, and dizziness [43]. Specifically, nausea is reported to have an incidence rate of 5.2% [44], whereas vomiting is considered a rare event with an incidence rate of approximately 2% [45]. These symptoms are defined as cybersickness, a form of motion sickness that may be experienced during immersive VR experiences [44]. In this study, we hypothesize that the lack of nausea and other symptoms of cybersickness may have been due to limited head motion during the VR scenario and to the relatively reduced duration (mean 26.3, SD 2.7, min) of the experiment [46].

Regarding the technical quality of our VR scenario, the IPQ results revealed that the scenario achieved a high degree of general presence and spatial presence, above-average involvement, and slightly below-average realism. Therefore, most of the participants felt immersed and involved in the virtual environment but reported that the experiment was not realistic enough (10/15, 67%). This lack of realism was corroborated by the content analysis, where only approximately one-third of the participants (5/14, 36%) felt that the scenario was immersive, real, or engaging. To improve the experience of realism in virtual hospital environments, future studies could address the limitations pointed out by participants in the qualitative debrief session, such as more realistic ICU settings with equipment displaying patients' vital parameters and having ethnically diverse virtual characters to be more representative virtual avatars of participants.

Content analysis of the debriefing revealed that feelings of guilt, shame, betrayal, isolation, and failure were commonly reported; these are impairing moral emotions consistent with MD [7,17,47] and might suggest a violation of moral beliefs. This finding suggests that the VR scenario could acutely induce real experiences of mild MD. Interestingly, numbness was mentioned by approximately a third of the participants (5/14, 36%). This feeling could be considered as a consequence of not having real power in relation to a real-world experience; it may also represent an emotional consequence of being exposed to a PMIE [12,18]. We assume that numbness could be related to potential signs of the erosion of moral agency, not in relation to our intervention but to previous real-world experiences of prolonged and repeated stressors and moral stressors. The content analysis revealed that most of the participants (8/14, 57%) reported guilt and shame, which are feelings consistently related to the experience of MD [7,17]. This finding suggests that the moral stressor experienced during the VR scenario could successfully induce some degree of MD. In addition, half of the participants (7/14, 50%) expressed the need for organizational support, an aspect frequently related to MD. Participants suggested that there could be a greater emphasis on organizational dimensions in future simulations, given the expressed need and the alignment with past research on MD [48]. The findings from the content analysis supported our hypothesis that a VR scenario can be successfully used to elicit and discuss real-life experiences and emotions related to MD.

In contrast to the qualitative results, the quantitative analysis did not show significant changes in the MIOS scores between

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before and after the experiment. The PSS scores showed the same trend and were not significantly different from baseline, which contradicts our hypothesis that the VR scenario would significantly increase stress levels. Both the MIOS and the PSS focus on symptoms developed over the last month. Although participants were instructed to rate their symptoms at that specific moment, these scales might not have enough sensitivity to capture acute changes in stress and MD symptoms. Alternatively, the changes in MD symptoms may have not been severe enough to induce significant changes in the MIOS scores acutely. Combining our findings from the qualitative and quantitative analyses, we assumed that some degree of MD was experienced by most participants, but we believe that these symptoms were not severe enough to induce MI. This is an important ethical aspect because the VR scenario was designed by specialists in MD and MI to minimize the risk of inducing significant MD in participants.

As MI may develop in the long term, we additionally attempted to use a mobile app to monitor participants for stress and MD and offer psychological support during an 8-week follow-up. Unfortunately, a longitudinal analysis of MD during the follow-up was not possible owing to very low app compliance. It is possible that participants might have developed additional symptoms of MD during follow-up that otherwise could not be captured by our analysis. However, we believe that this is unlikely because no participants requested the psychological support offered in the study. Alternatively, the brief version of the MIOS might not have been sensitive enough to detect slight but important changes in MD that would otherwise be detected by its complete version or by another MD scale. Having said that, this study is a feasibility study with a small sample size, and such an implication is beyond the scope of this work. Finally, the MIOS is still under development; hence, future studies are needed to assess the validity of the MIOS and its brief version.

Mobile app retention proved to be challenging because more than half of the participants (8/15, 53%) did not use the study app, and less than one-third (4/15, 27%) completed at least 1 set of surveys. Our app engagement strategy was based solely on in-app automated reminders and was insufficient to promote participant retention. This finding is supported by recent literature that recommends a combination of different engagement strategies to optimize app use [49,50]. In addition, another possible explanation for the low compliance is that a user-centered design process was not adopted during app development; therefore, the study app may not be particularly targeted to HCWs as the end users [51,52]. Nevertheless, our results are in line with previous research that demonstrates that retention is frequently a great challenge in mobile health studies in both clinical and nonclinical samples [50,53].

Post hoc sample size calculations indicate that a 3-fold and 6-fold sample size is required to reach a power of 80% for the MIOS and the PSS, respectively. With a sample of only 15 participants, our results were underpowered, which may at least in theory explain the nonsignificance of our quantitative findings and the discrepancy between the qualitative and quantitative results. This study was developed during a critical period of the COVID-19 pandemic, with recruitment occurring between May 2021 and August 2021, when contact restrictions were very strict. As the VR intervention required in-person data collection, recruitment proved to be very challenging. Nevertheless, our sample size of 15 participants is appropriate for a preliminary analysis, considering previous VR studies published in PTSD and other mental health disorders [54-57]. Our post hoc sample size calculations may be useful to guide the design of future adequately powered studies using VR in the context of MD and MI.

Limitations

This study has several limitations that must be considered. First, it is a pilot feasibility study with a single arm and a small sample size; thus, the results should be interpreted with due caution. Additional studies with a controlled design are necessary to assess the safety and effectiveness of VR interventions in the assessment of MD and MI. Second, stratification analysis by demographic variables was not possible owing to the reduced sample size; therefore, we were unable to compare symptoms of MI among different subpopulations (eg, nurses and physicians). In addition, our experiments were performed on a purposive sample of only HCWs, thus limiting the generalizability of our findings to other populations. Third, the debriefing methodology used may have also provided a different lens than a traditional qualitative interview or focus group. Fourth, the MIOS and the PSS were used outside of their time frame scope; additional studies should include assessments that focus on acute symptoms of stress and MD. Fifth, a standardized cybersickness scale to assess the side effects within the VR scenario, such as the Virtual Reality Sickness Questionnaire [58], was not used and might have caused underreporting of side effects in this study. Sixth and last, the low app engagement found during the 8-week follow-up hindered an analysis of any potential long-term consequences of the experiment related to MD. Considering that the symptoms of MI may have a late onset, this represents an important limitation to our findings.

Conclusions

The COVID-19 pandemic has challenged the mental health of HCWs, with increased rates of distress, anxiety, and depression being reported. During patient care, ethically difficult situations became common and put frontline HCWs at risk of MD and MI. VR-based interventions are a promising method to address these limitations because they allow for the possibility of developing experiments in safe, personalized, and highly controlled environments. This pilot study investigated the feasibility of using a VR scenario to simulate the experience of a mild morally challenging event for HCWs during the COVID-19 pandemic and to examine participants' physiological reactions to making morally difficult decisions in a virtual environment. Our results suggest the feasibility of using a VR scenario to simulate real experiences of morally stressful events and elicit genuine responses associated with MD with high acceptability and tolerability. In addition, our VR-based intervention demonstrated utility as a pedagogical tool for teaching possible ways to prevent and mitigate MD. Future studies should be conducted to further validate our findings in a larger sample.

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Acknowledgments

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Data Availability

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

Authors' Contributions

The study was conceptualized by VB along with SK, EP, and AD. CWE was involved in the interpretation of results, manuscript write-up, and revision. BN and AT were involved in software design of the virtual reality scenario, data collection, data analysis, and the writing of methods and quantitative results. WS was involved in data collection and logistics. AR performed quantitative data analysis. EP was involved in scenario development and qualitative data analysis. LB and DMC provided support with logistics and the debrief component. HJ conducted statistical analysis under the supervision of WL. BK and AD supervised AT for the creation of the virtual reality scenario. SK and VB supervised CWE, BN, and AT on all their tasks.

Conflicts of Interest

VB is supported by an Academic Scholar Award from the Department of Psychiatry, University of Toronto, and has received research support from the Canadian Institutes of Health Research, the Brain & Behavior Research Foundation, Ministry of Health Innovation Funds, the Royal College of Physicians and Surgeons of Canada, the Department of Defence (Canada), and an investigator-initiated trial from Roche Canada. All other authors declare no other conflicts of interest.

Multimedia Appendix 1
Postintervention debrief interview guide.
[DOCX File , 11 KB - games_v12i1e42813_app1.docx]

Multimedia Appendix 2
Post hoc sample size calculations.
[DOCX File , 8 KB - games_v12i1e42813_app2.docx]

Multimedia Appendix 3
Individual summary of the most common themes in the content analysis of data of 14 participants.
[DOCX File , 12 KB - games_v12i1e42813_app3.docx]

Multimedia Appendix 4
Results of the virtual reality scenario feasibility questions.
[DOCX File , 9 KB - games_v12i1e42813_app4.docx]

Multimedia Appendix 5
Scores from the debrief feasibility questionnaire.
[DOCX File , 9 KB - games_v12i1e42813_app5.docx]

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Abbreviations

ECG: electrocardiography
HCW: health care worker
ICU: intensive care unit
IPQ: Igroup Presence Questionnaire
MD: moral distress
MI: moral injury
MIOS: Moral Injury Outcome Scale
PEARLS: Promoting Excellence and Reflective Learning in Simulation
PMIE: potentially morally injurious event
PSS: Perceived Stress Scale
PTSD: posttraumatic stress disorder
VR: virtual reality

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Original Paper

A Serious Game to Train Rhythmic Abilities in Children With Dyslexia: Feasibility and Usability Study

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Abstract

Background: Rhythm perception and production are related to phonological awareness and reading performance, and rhythmic deficits have been reported in dyslexia. In addition, rhythm-based interventions can improve cognitive function, and there is consistent evidence suggesting that they are an efficient tool for training reading skills in dyslexia.

Objective: This paper describes a rhythmic training protocol for children with dyslexia provided through a serious game (SG) called Mila-Learn and the methodology used to test its usability.

Methods: We computed Mila-Learn, an SG that makes training remotely accessible and consistently reproducible and follows an educative agenda using Unity (Unity Technologies). The SG's development was informed by 2 studies conducted during the French COVID-19 lockdowns. Study 1 was a feasibility study evaluating the autonomous use of Mila-Learn with 2500 children with reading deficits. Data were analyzed from a subsample of 525 children who spontaneously played at least 15 (median 42) games. Study 2, following the same real-life setting as study 1, evaluated the usability of an enhanced version of Mila-Learn over 6 months in a sample of 3337 children. The analysis was carried out in 98 children with available diagnoses.

Results: Benefiting from study 1 feedback, we improved Mila-Learn to enhance motivation and learning by adding specific features, including customization, storylines, humor, and increasing difficulty. Linear mixed models showed that performance improved over time. The scores were better for older children ($P<.001$), children with attention-deficit/hyperactivity disorder ($P<.001$), and children with dyslexia ($P<.001$). Performance improved significantly faster in children with attention-deficit/hyperactivity disorder ($\beta=.06$; $t_{3754}=3.91$; $P<.001$) and slower in children with dyslexia ($\beta=-.06$; $t_{3816}=-5.08$; $P<.001$).

Conclusions: Given these encouraging results, future work will focus on the clinical evaluation of Mila-Learn through a large double-blind randomized controlled trial comparing Mila-Learn and a placebo game.

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KEYWORDS

serious game; rhythm; dyslexia; musical abilities; design framework; reading skills; children; digital health intervention; attention-deficit/hyperactivity disorder; ADHD; child development; mobile phone

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Introduction

Background

Music training and music-based interventions are becoming increasingly popular for developing brain and cognitive functions in children [1-5]. Building on brain plasticity induced by learning music and the tight link between musical and cognitive skills [6-8], music interventions have been used as training tools in neurodevelopmental disorders (NDDs) such as dyslexia [9-13]. Musical skills, especially when developed in childhood, are associated with enhanced cognitive abilities in various domains, such as attention, processing speed [3], executive functions [14], or speech and language [15-17]. Improvements in cognitive skills induced by musical training have been attributed to structural and functional brain changes in areas that support both music processing and cognition [6-8,18,19].

Recent studies have focused specifically on the relationship between rhythmic skills, such as the capacity to discriminate musical rhythms or synchronize with a beat [20,21], and cognition during development. Tierney and Kraus [22] showed that correlations exist between synchronization with a metronome and attentional and reading skills in typically developing adolescents. In children, rhythm production accuracy is associated with both phonological awareness and reading [23]. Rhythm perception is also related to reading performance [24,25]. Language and music processing may rely on common timing mechanisms that allow for the extraction of temporal information, which is crucial to accurately perceive sequences of events [7,20,26-28]. This hypothesis is supported by neurofunctional evidence as temporal processing involved in music and language recruits partially overlapping neuronal pathways that include the auditory cortex, dorsal premotor cortex, cerebellum, basal ganglia, and thalamus [29,30].

Further evidence of the link between rhythmic skills and cognitive abilities comes from the observation that rhythmic skills are disrupted in NDDs that also affect cognition. Notably, rhythmic deficits have been extensively reported in individuals with dyslexia. Children and adults with dyslexia exhibit inaccurate rhythm perception [25,31] as well as increased variability in motor tapping tasks [32]. These observed rhythmic deficits have given rise to theories (eg, the temporal sampling framework; Goswami [26]) that postulate that poor predictive temporal sampling and coding of events explain reading difficulties in those with dyslexia [26,33].

Building on the importance of rhythmic skills in development, music-based training protocols for children have been developed in recent decades. Studies have shown that children with dyslexia who participate in music-based interventions display better reading and phonological abilities [10-12]. In addition, the effect of music-based programs was extended to typically developing children, who showed significant improvements in speech processing skills and verbal intelligence [14]. However, these encouraging preliminary data have not reached the recommended quality for evidence-based studies owing to methodological limitations such as limited sample size, lack of blind assessment, and potentially inconsistent delivery of interventions [34]. In addition, access to these interventions is still too limited, with inequalities remaining because of significant disparities according to social background and place of residence [35]. For instance, children in poor and remote urban areas, who are more likely to develop an NDD [36], often have less access to care. Furthermore, these traditional music-based interventions usually require in-person instruction, which can be challenging under certain circumstances such as during the COVID-19 pandemic or in areas with limited access to specialized resources. More research is needed to determine whether written language skills can improve in children with dyslexia after training with more accessible and scalable music-based interventions.

To address these limitations, serious games (SGs) designed for educational and training purposes provide a more standardized, scalable, and accessible format for delivering music-based interventions through information and communications technologies. This approach allows for the delivery of the same training to a large sample regardless of geographic location or in-person resource availability. The number of SGs developed for educational and training purposes has increased over the last decade [37], primarily because of the expansion of information and communications technologies such as mobile technologies and telehealth systems. As most households, including those in low-income brackets and rural areas, are now equipped with at least 1 tablet, smartphone, or computer, these SGs can be broadly accessible [35]. Furthermore, a meta-analysis revealed that, across domains, learning is improved with SGs compared with conventional methods [38]. In addition to motivation, several preliminary findings have supported another exciting alternative hypothesis that playing an SG fosters electrical brain activity related to memory, emotions, and concentration [39], providing a possible neuronal explanation for the beneficial effect of SGs. SGs have been used in typically developing populations [40] and in children with NDDs [41,42]. Notably, SGs have been used to deliver rhythm-based training to healthy young adults [43]. Recently, interest in using computer-based interventions to train rhythm skills has been explored in people with dyslexia [44]. One SG named “Jellys” was developed for this purpose in a usability study and showed that children with dyslexia positively engaged with this type of remediation [45]. However, although some studies seem to support the effectiveness of using SGs as a treatment for people with NDDs, the methodological quality of these studies is limited, and further research is needed [46].

Objectives

In this study, our goal was to evaluate the usability of Mila-Learn, an SG aimed at training rhythmic abilities in children with dyslexia. The methodological design of the game was developed in user participatory pilot studies, allowing the children and their families to provide feedback to shape human-machine interactions. We report on 2 studies conducted during the French COVID-19 lockdowns. The first was a feasibility study to assess the children’s engagement through gameplay frequency and collected their feedback. After modifying the SG according to the feedback by adding specific features such as customization, storyline, humor, or increasing difficulty, we report a usability study that addressed the

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children's performance on the latest version of the SG when played autonomously at home and according to declared diagnoses.

Methods

Overview

Mila-Learn is an SG that delivers rhythm-based exercise designed for children with dyslexia (called "specific learning disorders in the field of reading" in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*). This SG involves a rich musical universe aiming to lead the child to spontaneously come back and engage with the instrument with their parents. It consists of two main elements: (1) a mobile app that offers rhythmic, sensory-motor, and cognitive tasks in the form of musical activities; and (2) secure servers that allow for data analysis. It enables real-time evaluations to understand children's difficulties and improve the effectiveness of Mila-Learn. In this section, we first describe the SG from its initial beta version. We then detail the methodology of the 2 exploratory studies conducted during the COVID-19 lockdown.

Mila-Learn Description

From an Initial Prototype (2018) as a Progressive Web Application to a Version (2019-2020) Developed for Tablets

The first version of Mila-Learn included five tasks:

1. Dance With Your Hands is an auditory-motor coordination exercise. It involves performing a movement following the tempo of a piece of music. These are pieces with a 4/4 signature that easily allow the child to have rhythmic stability and associate a motor action with the rhythm. This action includes gestures such as clapping, silencing, and raising the arms in the air.
2. Play the Drums is a rhythmic memory game. A drum appears on the child's screen, and a sequence is played. The child then presses on the drum elements to reproduce the initially played sequence.
3. Rhythmic Vitamins is an exercise in singing and repetition [47]. An initial recorded vocal sequence consisting of syllables and phonemes is played by the software. The child must reproduce it using the rhythm, pronunciation, and pitch of the initial sequence.
4. Following the Tempo requires recognizing and reproducing different rhythmic structures. In this exercise, the child is asked to mark the strong beats of music using the space key on the keyboard.
5. Musical Pitch is an exercise of association between the pitch and its representation. A sound sequence composed of 3 sounds is played (high, medium, and low), and then a visual representation is displayed composed of lines (low, medium, and high). The child has to judge whether the graphic production of the sound is correct.

This prototype version (Figure 1 [48]) was offered to a small group of children end users with dyslexia. We asked them to provide feedback on the design and players. The data collection method was centered on gathering children's feedback at the end of 15-minute game sessions. A total of 14 children were invited to respond, interact, and provide feedback on the first version of Mila-Learn in the form of a progressive web application [49]. In total, 3 sessions per week over a period of 3 months were conducted.

Figure 1. Landing page of the prototype with 3 different tasks each day [56].

This participatory design phase led to a framework for the development of Mila-Learn enhanced by a literature review on SG playability to increase players' motivation. Although some studies have proposed a framework to develop SGs for people with NDDs, very few have focused specifically on dyslexia [46]. To improve the design of our game, we expanded our research to the use of SGs in the typical population and in children with NDDs, especially children with

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attention-deficit/hyperactivity disorder (ADHD), because of the high co-occurrence between dyslexia and ADHD [50].

Design Framework

We integrated new gaming features to increase players' motivation and engagement. First, we developed a storyline that allowed us to include the different tasks within a larger story. The use of a storyline supported the engagement of a player in the games [51,52]. The storyline was intended to not be complex to prevent the child from losing the main goal of the game [53]. The story in Mila-Learn was designed to correspond to the interests of children aged between 7 and 14 years. The story is inspired by *shonen* manga, which is manga inspired by the cartoon universe. This type of manga is based on a storyline that involves a young hero who starts without knowledge and becomes increasingly powerful during the progression of the story. Some crucial values such as friendship and perseverance are typically present in the story. Most of the time, the first opponent of the hero becomes his friend during the story. In Mila-Learn, the player embodies a little monster who meets another character, a little blue monster named "Blue" who asks for their help—some villagers are held captive by the villain Diabolus, another character. The player has to learn rhythm skills to challenge Diabolus and free the villagers. Over the course of the game, the player discovers that there is a larger villain who holds "Rosa," the Diabolus' scooter. At the end, the player must win a large rhythm tournament to finish the game. The story is divided into 12 chapters containing 6 tasks (see the following section). Each task lasts between 1 minute, 20 seconds and 1 minute, 30 seconds, with rare songs playing for 1 minute, 40 seconds to maintain consistency with the music. In this way, we considered the attention capacity of children [53,54].

As recommended in the literature, we created evolving tasks, gradually increasing the level of difficulty in each task and from one task to another [51,53,54]. The tasks must be challenging but accessible. In total, 6 tasks are used in the second version of Mila-Learn. They are introduced progressively to allow the player to practice a task 2 to 3 times before introducing another one. Once all the tasks are known by the player, they increase in difficulty with progression throughout the game. First, within each task, the rhythm displayed corresponds to each beat of a measure. Then, the rhythm changes to correspond to eighth notes (meaning that the rhythm is clapping 3 times in 2 beats) or slows down to be marked only once every 2 beats. Moreover, the songs are played at an increased speed to challenge the player. At higher levels, the marked rhythms can change during the task.

The SG was built to provide clear instructions to the player [51,53]. The instructions are given orally and with visual support, notably by imitating one or more nonplayer characters. Before each task, a quick tutorial allows the player to repeat the movement they have to perform during the game 3 times (ie, clap their hands, touch the screen, and move the tablet). At the beginning of a task, the character played by the user is clearly identified with an arrow. Moreover, for each task, the player is always placed in the same location.

The visual environment is thought to be easily navigated by children. The graphics are pleasant but minimalistic [53,55]. The visuals are thought to be pleasant for children aged between 7 and 14 years and are inspired by the cartoon universe. During the tasks, the background is mostly static, allowing the child to focus on the goal of the task. The characters only move to the rhythm of the music, with repetitive and predictable movements.

We differentiate between short- and long-term goals [51,53,54]. In each task, there is only 1 clear goal (ie, touch the screen to the rhythm) that is clearly differentiated from the long-term goal of a chapter (ie, complete the chapter to challenge Diabolus; Figure 2). Feedback is provided throughout the different tasks using visual cues [51,53,54]. These cues allow the player to know whether they are performing the exercise properly. The feedback for each task is described in the following section. As rewards have been described as a main feature of SGs [51,54], players obtain a reward of 1 to 3 stars at the end of each task depending on their accuracy during the exercise. Personalization has also been described as an important key to enhancing the motivation of the player [51-54]. As in the first version, players have to pick a name for their character at the beginning of the game and modify its color. Finally, we introduced new songs to work on in this version of the game. We added some famous songs known by most children (ie, songs from Disney movies) to increase the motivation of the players. For some tasks such as Fruity Jump, Karate Fruit, and Sing Lab, the predetermined structures of these songs did not make their use possible. We specifically composed songs to fit with the requirements of these tasks.

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Figure 2. Example of a chapter menu introducing the upcoming adventure.

Description of the Tasks

All the tasks (Figure 3) were designed to work on rhythm, which was the main and explicit goal of each task. However, each task requires the mobilization of other skills such as attention, inhibition, working memory, and motor skills, which are also often impaired in children with dyslexia [50,56].

Follow me aims to introduce rhythm to the player. The child first sees a little monster clapping hands to the rhythm of a song and then has to touch the screen to the rhythm by imitating the monster. Then, the character stops clapping, and the player has to keep going alone without the support of the monster. This task allows the player to work on maintaining regularity in rhythm but also sustained attention.

In Clap Trap, 2 characters and the player appear on the screen. The first 2 characters clap one after another, giving a tempo to the player, who has to complete the sequence by clapping their hands to the rhythm at the right time. The first character claps on the first beat of a 4-time measure of the song played. The second character claps on the second beat, and the player has to clap their hands on the third beat. The microphone records the child's clap. In this task, the child has to anticipate and adapt to the rhythm. It was designed to train inhibition skills as the child has to wait until the right moment to clap their hands.

In River Splash, the player is placed behind 2 other characters who run next to the water and sometimes have to jump across the river to the rhythm. The first character jumps on the first beat of a 4-time measure of a song. The second character jumps on the second beat, and the player jumps on the third beat. The player has to shake the tablet quickly to jump. In addition to rhythm perception, this task was designed to train inhibition skills similarly to the Clap Trap task.

In Sing Lab, the first character produces a sequence of phonemes or syllables at a particular tempo. The player has to reproduce this sequence with particular attention to the pattern and duration of the phonemes. Phonemes or syllables pass across the top of the screen, visually represented by gauges that the player has to fill. If the child sings at the right time, the gauge starts filling. When the duration of the note is complete, the gauge changes color from white to green. In this task, the phonological loop is involved in correctly memorizing the sequence. We used specific music constructed for this task that allowed us to add phonemes or syllables to sing at particular moments and for as long as we wanted.

In Fruity Jump, a character reproduces a rhythmic sequence. The player has to memorize this sequence and then reproduce it correctly by tapping the screen at a good tempo. The tempo is visually indicated by fruits falling from a tree. If the player claps at the right time, the character jumps and hits a fruit with its head to throw it to another tree. If the player misses the fruit, it crashes on the ground. If the player jumps at another time (ie, during the demonstration), their character jumps, and nothing special happens. Working memory and intermodality are particularly engaged in this task.

Finally, in Karate Fruits, the player has to hit fruits that appear based on the rhythm. To hit the fruit, the player has to put the tablet on the floor and extend their arms above it. Each time the camera detects the arm, the player's character punches. If the player punches at the right time, the fruit explodes, and a smiley face appears. If the player misses the fruit, the fruit goes off the screen, and a smiley face with an annoyed head appears. If the player punches at another time, the character punches, and nothing else happens.

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Figure 3. Examples of screens in Mila-Learn: (A) Clap Trap, (B) River Splash, (C) Sing Lab, (D) Fruity Jumps, (E) Karate Fruits, and (F) Follow Me.

Scoring Player Performance

Scoring of player performance is based on rhythmic synchronization through multiple modalities of interaction (sometimes in combination) as rhythmic synchronization is a requirement for all games. Player responses are captured through accelerometers, microphones, webcams, and pressure-sensitive screens, as shown in Table 1.

By assessing the audiomotor synchronization of the child with the rhythmic instruction, we define (1) a time T that corresponds to the exact moment when the player's input is expected (regardless of the interaction mode) and (2) tolerance thresholds ($t_{Perfect}<t_{Good}<t_{Correct}$).

The different intervals allow for judging the quality of the answer with 4 levels of acceptance. An input is considered acceptable when it is in the interval $[T - t_{Correct}; T + t_{Correct}]$ and

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not acceptable otherwise. An input of better quality, either in the interval [T – t_{Good}; T + t_{Good}] or in the interval [T – $t_{Perfect}$; T + $t_{Perfect}$], results in different visual and audio feedback for the child.

In the second improved version, which was a modified version based on the first pilot study, a simplified calculation was performed by considering the ratio of acceptable inputs to total inputs as the main measure. This final score is presented to the child in the form of stars depending on their performance: no stars if the child has an average of <50%, 1 star if ≥50% of inputs are acceptable, 2 stars for ≥75%, and 3 stars for ≥90%. In addition, this architecture allows for the storage of all the child's inputs for retro-analysis purposes.

Table 1. Players' recorded responses and game parameters in the second version of Mila-Learn.

Task	Type	Interaction	Capture technology	Songs	Tolerance threshold
Follow Me[a]	Continuous tapping	Tapping	Contact pressure	Commercial	• $t_{Perfect}$: 0.1 s before or after the beat • t_{Good}: 0.15 s before or after the beat • $t_{Correct}$: 0.25 s before or after the beat
Clap Trap	Last beat	Clapping hands	Microphone	Commercial	• $t_{Perfect}$: 0.1 s before or after the beat • t_{Good}: 0.15 s before or after the beat • $t_{Correct}$: 0.25 s before or after the beat
River Splash	Last beat	Shaking tablet	Accelerometer	Commercial	• $t_{Perfect}$: 0.1 s before or after the beat • t_{Good}: 0.15 s before or after the beat • $t_{Correct}$: 0.25 s before or after the beat
Sing Lab	Call and response	Singing	Microphone	Commercial+built in-house	• $t_{Pattern}$: 0.15 s before or after the beat and up to 30% of the note duration • Song duration: the note must be sung at least 60% of the time
Fruity Jump	Call and response	Tapping	Contact pressure	Built in-house	• $t_{Perfect}$: 0.2 s before or after the beat • t_{Good}: 0.25 s before or after the beat • $t_{Correct}$: 0.3 s before or after the beat
Karate Fruits	Last beat	Punching	Webcam	Built in-house	• $t_{Perfect}$: 0.08 s before or after the beat • t_{Good}: 0.14 s before or after the beat • $t_{Correct}$: 0.3 s before or after the beat

[a]Name of the task.

Feasibility Study

We conducted a feasibility study to evaluate whether children with NDDs involving reading deficits could use Mila-Learn autonomously at home. Our main objective in assessing Mila-Learn's autonomous use was to monitor both the time users spent on the SG and their accuracy in each game played. In the context of the unprecedented health crisis caused by COVID-19, participants were recruited by the French Federation for Learning Disorders (FFDys), a national association that aggregates all regional associations of people with learning disabilities. The FFDys communicated to its members the possibility of testing an app and managed the information and consent of participants. Families were informed that Mila-Learn was an SG for performing rhythmic tasks at home and that we believed this practice might be beneficial for learning to read. In total, 2500 children downloaded Mila-Learn. The analyses were conducted on a subsample of 21% (525/2500) of these children, who spontaneously played at least 15 games. To improve the usability of Mila-Learn, we also asked users (both children and families) to provide feedback on the games and information on the children's impairments. This information was provided freely and was not compulsory to obtain Mila-Learn. In addition, we systematically collected through phone interviews all the problems that the children and their families encountered regarding the computing and web performance of the SG. Finally, we conducted a phone survey of 200 users, which is provided in Multimedia Appendix 1 [56]. The questions asked were designed to gain insights into the families' perceptions of the benefits of the tool, the improvements and difficulties of use they encountered, and their desire to continue using the game in the future; in addition, room was left for unstructured testimony. The data analysis for the feasibility study was limited to descriptive statistics.

Usability Study

This usability study was considered a continuation of study 1 and was conducted under the same ethical rules. In the usability study carried out in a real-life setting over 6 months, our primary focus was 2-fold following modifications to Mila-Learn based on study 1 feedback: first, to ensure that the computational architecture and final version of Mila-Learn were free of computer bugs and, second, to track player progress using Mila-Learn's scoring system over an extended duration. As part of the second lockdown because of the COVID-19 crisis, the final version of Mila-Learn was made available again starting

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on October 10, 2020, on National Learning Disabilities Day. Benefiting from the large amount of feedback received during the first lockdown, very few technical problems occurred, resulting in a game with much better fluidity that provided higher-quality data. A total of 3337 children had access to Mila-Learn for a total of 84,682 games that were played. As in study 1, at the time of registration, the patients' families were given the opportunity to complete the profile of the children, including information such as the children's diagnoses. A total of 304 diagnoses were reported by the parents. Finally, the children and their families had the option of linking the game character to the reported clinical profile. This option was exercised by 2.94% (98/3337) of the children, for whom we had both their reported diagnosis and game performance over time. These 2.94% (98/3337) of the children completed 3922 games.

To assess how children performed with Mila-Learn, we defined and computed the following variables:

1. "Time" is an incremental value representing the number of levels played by a player since the beginning of the experiment. Time is 1 at the beginning of the experiment and represents the total number of levels played by the player at the end of the experiment.
2. "Delta_tap" is the delay between the date of the played input (as defined in Table 1) and the date of the expected input.
3. "Threshold" is a delay defined for each game that was used to construct the performance score.
4. "Performance score" is a variable bounded between 0 and 100 that was created to quantify performance from delta_tap and normalize performance across games. We used the following formulas: performance score = (–100/threshold) × abs(delta_tap) + 100 for abs(delta_tap)≤threshold and performance score=0 for abs(delta_tap)>threshold.

We conducted several linear mixed models. To assess children's progress over time, we tested whether players improved their performance through the progression across the games using a linear mixed model with the following formula: performance score ~ time + (1|PlayerID/GameID/LevelName).

To assess whether a declared diagnosis was associated with the average performance of the children, we also conducted a linear mixed model using the following formula: performance score ~ age + dyscalculia + dysgraphia + dyslexia + dysphasia + ADHD + ExecutiveFunction impairment + (1|GameID/LevelName).

Finally, we also tested whether progress over time was moderated by a declared diagnosis using the following formula: performance score ~ time + diagnosis + time × diagnosis + (1|GameID/LevelName).

Ethical Considerations

Under French legislation, we did not need the approval of a Comité de Protection des Personnes (Committee for the Protection of Persons). However, as the pilot study was conducted in line with the creation of large databases, we obtained the approval of the Commission Nationale de l'Informatique et des Libertés (National Commission for Informatics and Freedoms) under number 2222283.

Results

Feasibility Study

Between April 2020 and June 2020, a total of 2500 children had access to Mila-Learn. Families reported the child's diagnosis in 60% (1500/2500) of cases. As children were recruited through the FFDys, they were diagnosed with an NDD in almost all cases, but only 23% (575/2500) were declared as having dyslexia. The other children had developmental coordination disorders (dyspraxia), dyscalculia, and communication disorders of oral language (dysphasia). In addition, 18% (450/2500) declared a diagnosis of ADHD.

Data regarding the use of Mila-Learn by each user were recorded as time spent on the SG and accuracy in each game played. The average use was 3.5 sessions per week. To ensure the significance of the data, we only kept the data of players who participated over a sufficient period (>15 games). Duration was expressed as the number of games played. We considered the number of games played inside the SG over the number of played sessions as the number of games played in 1 session could vary widely. In total, 21% (525/2500) of players aged 6 to 14 years played at least 15 games, with an overall mean of 54.77 and a median of 42 games played. The average number of games played was similar across ages (no main effect of age). No effect of age was found on the mean score. In addition, no floor or ceiling effects were observed (Multimedia Appendix 2).

It should be noted that several technical issues occurred during the first 2 weeks owing to the wide variety of tablet operating systems. This situation resulted in the deployment of corrective patches, but owing to the correction delay, it may have differentially altered one child's experience relative to another's. To improve the user experience, phone calls were systematically conducted to interview families, determine potential problem areas, and gather feedback for improvement. Parents consistently highlighted the recreational side of the game and its impact on the children's self-confidence. A survey of 200 users, provided in Multimedia Appendix 1, also indicated that 96% (192/200) wished to continue using Mila-Learn after the COVID-19 pandemic. However, they also provided significant feedback (164/200, 82%) to improve the game. Multimedia Appendix 3 [57] presents the most significant feedback with a frequency of ≥10 occurrences. We classified it according to the criteria by Morville [56], which distinguish 7 dimensions: usefulness, usability, findability (the ease of locating a feature or a piece of context), credibility, accessibility design, attractiveness, and value [48]. Usability was questioned in several comments, such as "the detection of movements should be improved," "sound detection needs to be improved," and "the game needs to be better adapted to the child's difficulty profile." Accessibility was also questioned as several parents indicated that "the writing could benefit from being larger and the display of dialogues slower."

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Mila-Learn Description Adjustments Following Study 1

Design Framework

On the basis of the feedback obtained during study 1, we made several modifications to Mila-Learn. To improve accessibility, the first modification was to offer the player the choice between several fonts, including OpenDyslexic. This choice is reversible throughout the game. We also improved sound and movement detection. A second significant choice was to distinguish the children's pathways according to their predominant disorders to facilitate their entry into the game and usability. For example, a player who indicated that they had dyspraxia at the time of registration was offered more moderate motor exercises (ie, Sing Lab), allowing them to enter the adventure before training on River Splash or Karate Fruits that are more challenging in terms of motor abilities. In contrast, a child with dyslexia could be offered River Splash from the beginning, with Sing Lab exercises being offered only afterward as Sing Lab involves the phonological loop.

To increase motivation and interest in the game, we provided new possibilities of personalization for the character: the player could choose the gender of the avatar, their color, and the color of the hat. We then increased the storyline with the help of a screenwriter. This modification improved the consistency of the story and made it more inclusive by adding new characters that could help the player during the game. A new companion named "Mila" appeared, who is a fairy representing the planet "Mila" where the story takes place. These modifications also influenced (1) the dialogues, which were shortened with the language adapted to children; and (2) the appearance of the notion of "rhythmic," which was introduced as a martial art based on rhythm to clarify the main goal of the game during the adventure.

Through this expansion, we created 6 new chapters. We maintained the same concept as the preceding version and gradually increased the level of difficulty during the progression of the game by increasing the speed of the rhythm and varying the type of rhythm clapped (ie, clapping notes, then eighth notes). We also created daily missions. These 4 daily tasks allowed the child to revisit games on which they had practiced in the past and where they encountered difficulties. This allowed us to directly address the tendency to forget what has been learned and allowed for longer practice with Mila-Learn.

Description of the Tasks

Finally, we made structural modifications to the proposed tasks to ensure the game's fluidity and improve motor interactions. First, we changed the way children had to answer during Clap Trap. Instead of clapping both hands, which was recorded using the microphone, we changed the child's interaction with the SG to synchronously tapping both hands on the screen (and, therefore, we used a touch recording). Second, Follow me was extensively modified to be more understandable and involve the child more on a motor level. The interaction was changed from a passive mode (one contact pressure) to a more active hand clapping measured using the microphone. The child did not perform the task all at once but interacted with the character, who gave them instructions that the child reproduced on the principle of call and response. Specific music was created for the game. As a consequence, Follow me was renamed Clap Hero. Finally, we modified the way children had to answer during Fruity Jump—children's interaction with Mila-Learn changed from tapping to shaking the tablet, which was measured using an accelerometer. Table 2 summarizes the changes made in the final version of Mila-Learn.

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Table 2. Players' recorded responses and game parameters in the final version of Mila-Learn.

Task	Type	Interaction	Capture technology	Songs	Tolerance threshold
Clap Hero	*Call and response* [a]	*Clapping hands*	*Microphone*	*Customized*	• Perfect: 0.1 s before or after the beat • Good: 0.15 s before or after the beat • Correct: 0.25 s before or after the beat
Clap Trap	Last beat	*Tapping on the left and right side of the screen*	*Touch*	Commercial	• Perfect: 0.1 s before or after the beat • Good: 0.15 s before or after the beat • Correct: 0.25 s before or after the beat
River Splash	Last beat	Shaking tablet	Accelerometer	Commercial	• Perfect: 0.1 s before or after the beat • Good: 0.15 s before or after the beat • Correct: 0.25 s before or after the beat
Sing Lab	Call and response	Singing	Microphone	*Customized*	• Pattern: 0.15 s before or after the beat and up to 30% of the note duration • Song duration: the note must be sung at least 60% of the time
Fruity Jump	Call and response	*Shaking tablet*	*Accelerometer*	Customized	• Perfect: 0.2 s before or after the beat • Good: 0.25 s before or after the beat • Correct: 0.3 s before or after the beat
Karate Fruits	Last beat	Punching	Webcam	Customized	• Perfect: 0.08 s before or after the beat • Good: 0.14 s before or after the beat • Correct: 0.3 s before or after the beat

[a]Italics indicate game and functional changes that were introduced compared with the Mila-Learn second version summarized in Table 1.

Usability Study

This usability study focused on a sample of 98 children (mean age 9.05; SE 2.4 years), and we had both their reported diagnoses and game performance over time. These 98 children completed 3922 games. The linear mixed models yielded the following significant results. First, we found that the performance of the children significantly improved over time (β=.02; t_{3268}=2.68; *P*=.007). That is, there was an increase in the performance score by an average of 5 points after 250 levels were played.

Second, we explored whether declared diagnosis and age influenced the average performance of the children. Table 3 summarizes the results. We found that older children performed better than younger children. One year of age increased the normalized performance score by 1.08 points (meaning 1.1% of the maximal range). In addition, children with dyslexia and ADHD performed significantly better than those with other diagnoses (performance improved significantly faster in children with ADHD, β=.06; t_{3754}=3.91; *P*<.001, and slower in children with dyslexia, β=−.06; t_{3816}=–5.08; *P*<.001). Having dyslexia increased the normalized performance score by 2.81 points (meaning 2.8% of the maximal range) compared with children without dyslexia, whereas having ADHD increased the normalized performance score by 4.16 points (meaning 4.2% of the maximal range) compared with children without ADHD. In contrast, children with executive function impairment and dysgraphia performed significantly worse than those with other diagnoses. Having dysgraphia decreased the normalized performance score by 2.06 points (meaning 2.1% of the maximal range) compared with children without dysgraphia, whereas having executive function impairment decreased the normalized performance score by 3.26 points (meaning 3.3% of the maximal range) compared with children without executive function impairment.

Finally, we also tested whether progress over time statistically interacted with the declared diagnosis. We found that children with ADHD progressed faster over time than those with other diagnoses (β=.06; t_{3754}=3.91; *P*<.001) and that children with dyslexia (β=−.06; t_{3816}=–5.08; *P*<.001) and executive dysfunction (β=−.03; t_{3805}=–2.09; *P*=.04) improved less over time than those with other diagnoses. We found no significant interaction between time and a diagnosis of dysphasia (β=−.01; t_{3816}=–0.68; *P*=.50), dyscalculia (β=.05; t_{3787}=1.46; *P*=.14), or dysgraphia (β=.00; t_{3816}=–0.1; *P*=.92).

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Table 3. Average scores according to diagnosis during study 3 with the final version of Mila-Learn.

	Estimate (SE)	*t* test (*df*)	*Pr*(>|*t*|)
Intercept	37.83 (4.60)	8.23 (6.04)	<.001
Age	1.08 (0.15)	7.02 (2082.28)	<.001
Dyscalculia (yes)	−0.43 (1.03)	−0.42 (2081.02)	.68
Dysgraphia (yes)	−2.06 (0.79)	−2.60 (2084.61)	.009
Dyslexia (yes)	2.81 (0.70)	4.03 (2087.52)	<.001
Dysphasia (yes)	−0.51 (0.93)	−0.54 (2086.54)	.59
ADHD[a] (yes)	4.16 (0.61)	6.79 (2090.71)	<.001
Executive function impairment (yes)	−3.26 (1.36)	−2.40 (2086.78)	.02

[a]ADHD: attention-deficit/hyperactivity disorder.

Discussion

Principal Findings

The literature on SGs, especially when designed for a specific medical condition, is limited when it focuses on game design methodology or formal clinical validation [42]. In this paper, we described the process and empirical studies to address this issue for Mila-Learn, an SG based on rhythmic training for children with dyslexia. To do so, we placed the patient's experience at the center of the game construction while iterating with clinicians involved in treating children with dyslexia. In this paper, we described the different developmental phases that helped us design the game. We first constructed an initial prototype based on a literature review and with the help of clinicians specializing in learning disorders. Then, based on a first round of feedback from users and comments from professionals, we developed a first version of Mila-Learn for tablets.

In this version, we greatly improved the users' experience with the game by adding new gaming features to increase the motivation and engagement of players. We offered more possibilities for customization, created a storyline, and introduced humorous and friendly characters to align with children's interests [51,52]. Moreover, we adapted the difficulty of the game to enhance the learning possibilities of children by working on graphism and the instructions given to the children and by creating evolving tasks that gradually increased the level of difficulty [51,53,54]. With this second version, we adopted a user participatory design by inviting children, families, and professionals to test this version and send us feedback about their experience (feasibility study). User participatory design is a method that is currently gaining attention. Contrary to user-centered designs, which create games for a user, participatory design aims to construct the game with the users by collecting their experience and advice and then including them in the game [58]. It has been shown that participatory design promotes engagement of the user [52]. Indeed, collecting feedback both from families and children and from professionals is essential as professionals and families and children focus on different aspects of an SG and do not place the same importance on each feature [52]. We believe that this participative process helped us develop an SG that improved the experience within the game and the interest of families and children in Mila-Learn.

Regarding computational aspects, we also collected feedback that helped us resolve bugs and record the time spent on the game and the player's accuracy in each game. These features allowed us to follow children's interest in the game and their progression over time and demonstrate that progression occurred with Mila-Learn and was associated with age. Study 1 confirmed that children could engage with Mila-Learn for a rather long period and play at home without the need for an extra supporting person, suggesting that Mila-Learn was sufficiently motivating and adapted to this population. Children and their families appeared to be highly satisfied with the game.

Finally, following a third round of feedback from parents, children, and professionals, we developed a final version of Mila-Learn to improve accessibility and motivation for the player. We made structural modifications to the proposed tasks to ensure the fluidity of the game and improve motor interactions. We resolved most of the technical problems, which allowed us to conduct a real-life usability study of the Mila-Learn game during the second lockdown.

Comparison With Prior Work

In the usability study, we observed that children significantly improved their scores on the 6 games included in Mila-Learn. Although we cannot conclude that the rhythm abilities of the children improved based only on these results, we believe that the children learned how to use Mila-Learn and that they were increasingly accurate in responding to each game. However, the effect size was small, although it may have been underestimated as the difficulty in the games increased, which could have masked the children's progression. In addition, based on the diagnosis declared by the children's parents, we performed exploratory analyses to assess whether improvements over time were associated with the declared diagnoses. Linear mixed models showed that children's performance significantly increased over time, that scores were better for children with ADHD and dyslexia, and that performance improved significantly faster for children with ADHD and slower for children with dyslexia.

Regarding the average performance of children according to diagnosis, the results were very encouraging if we consider the

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relationship between reading impairments and diagnosis. On the basis of the literature, we expected reading impairments to be associated with dyslexia, attention deficit, and specific oral language impairment (dysphasia) [59,60]. In addition, we expected that severity would negatively influence performance. This is usually the case when children have dysphasia [61], executive function impairment [62], or multidimensional impairments [63]. The results were in line with these expectations. Children with dyslexia and ADHD showed a significantly better performance over time, whereas children with dysphasia, executive function impairment, and dysgraphia showed a worse performance. Of note, children with dysgraphia often have motor coordination disorders [64]. Finally, dyscalculia had no influence on Mila-Learn performance. In summary, the predictions according to diagnosis were in line with the hypothesis that Mila-Learn may improve performance in children with reading impairments. The fact that dyscalculia showed no specific effects and that the diagnoses associated with the highest severity (dysphasia and executive function impairment) showed less improvement followed our hypothesis [61-63,65]. We speculated that dysgraphia was associated with multidimensional impairments, including motor coordination disorder. This interpretation is based on the fact that recruitment for the study was based only on user reading impairments.

Regarding the average performance of children according to diagnosis over time (ie, the statistical interaction), the fact that performance improved significantly faster for children with ADHD and slower for children with dyslexia is not surprising as the perception of rhythm is impaired in children with dyslexia. In contrast, children with ADHD may have impairments in reading abilities but do not have specific deficits in rhythm and speech perception [57,66].

Strengths and Limitations

The exploratory studies presented in this paper have some limitations despite the promising results. On the one hand, some aspects of the game need to be improved.

First, we currently consider a “standard” latency of 20 ms, which corresponds to the estimated delay between the child’s real input and the input processed by the operating system. In reality, each tablet may have unique differences. In the next version of Mila-Learn, we need to consider this unique latency to get as close as possible to the real performance of children. This adjustment might lead to more accurate measurements of children’s interactions and, potentially, more tailored game experiences.

Second, the game gradually increases in difficulty with the progression of the player within the game. We integrated some specific pathways as a function of the difficulties that the children declared before starting the game (ie, children with motor difficulties do not start with games that require a high level of motor skills). However, the progression is predetermined and does not take into account the results of the player. In the next version of Mila-Learn, the difficulty of each game will automatically adapt based on the child’s performance in the previous games using a specific algorithm [53], allowing for much better stimulation. By doing so, the game could offer a more individualized experience, potentially leading to more sustained engagement and greater benefits for the children.

Third, the age range of 7 to 14 years is wide as children’s interests can vary greatly during these years. In a future version of Mila-Learn, the graphics and music will be adapted to the age specified by the child so that the game will be more suitable for their age. This may enhance the game’s appeal to players across the entire age range, fostering increased engagement and learning.

However, our study was only exploratory in nature. First, even if the lockdown gave us the opportunity to have a large sample for exploratory studies, diagnoses were not clinically grounded and were only declared by the children’s parents. Therefore, caution should be the rule when interpreting predictive models.

Second, there was no predefined design for the studies as the training was spontaneous and included no comparison with alternative treatment proposals. Therefore, the clinical interest of Mila-Learn for dyslexia cannot be established based on the results of the 2 exploratory studies presented in this paper.

Future Directions

To address the clinical relevance of Mila-Learn in relation to dyslexia, the next step will be to evaluate the effects of Mila-Learn in the context of a randomized controlled trial. Children with dyslexia based on objective clinical assessments will be randomized to Mila-Learn sessions or placebo game sessions that take place in the same universe but with different tasks. We will assess the evolution of reading skills from before to after training with the hope of greater improvements with Mila-Learn. On the basis of the exploratory studies, we calculated the number of patients per group that would ensure a statistical power of at least 85% for an effect size equal to 0.5 (moderate) when the changes in the experimental and control groups were compared. This calculation indicated that each group should have at least 73 children (ie, 146 children in total). This study started in September 2021 (Comité de Protection des Personnes registration 2021-A01709-32; ClinicalTrials.gov Identifier: NCT05154721).

Conclusions

We presented how we constructed Mila-Learn, an SG based on rhythm activities, to improve reading skills in children with dyslexia. We developed several versions of the game considering the literature, professionals’ experiences, and users’ feedback. We also conducted a usability and a feasibility study to evaluate each version of Mila-Learn. The results indicated that Mila-Learn was attractive and sustained the players’ motivation and engagement for several months. Moreover, children were able to learn how to use the game, and their performance in the games improved with training. Future research will include (1) adapting to the latency of the electronic devices, (2) automatically adapting the games based on the player’s performance, and (3) conducting a large randomized controlled trial to evaluate the impact of Mila-Learn on reading skills.

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Acknowledgments

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Data Availability

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

Authors' Contributions

FV conceptualized the study with DC and CG, managed data curation, acquired funding, undertook the investigation, and contributed to software development alongside AY. AY participated in data curation, formal analysis, and software development. HP was responsible for formal analysis and visualization. DC further contributed to conceptualization and was involved in methodology, supervision, and the review and editing process. CG also took part in conceptualization, formal analysis, writing of the original draft, investigation, supervision, and the review and editing process.

Conflicts of Interest

FV reports a relationship with bMotion Technologies that includes equity or stocks. AY reports a relationship with bMotion Technologies that includes employment and equity or stocks.

Multimedia Appendix 1
User survey on Mila-Learn.
[DOCX File , 26 KB - games_v12i1e42733_app1.docx]

Multimedia Appendix 2
Average scores from all games between April 2020 and June 2020 according to the children's age.
[PNG File , 22 KB - games_v12i1e42733_app2.png]

Multimedia Appendix 3
Feedback classification based on the criteria by Morville [55].
[DOCX File , 27 KB - games_v12i1e42733_app3.docx]

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
FFDys: French Federation for Learning Disorders
NDD: neurodevelopmental disorder
SG: serious game

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Original Paper

A Novel Casual Video Game With Simple Mental Health and Well-Being Concepts (Match Emoji): Mixed Methods Feasibility Study

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Abstract

Background: Adolescence is a crucial phase for early intervention and prevention of mental health problems. Casual video games are popular and have promise as a novel mechanism for reaching young people, but this potential has seldom been explored.

Objective: This study aimed to explore the acceptability, feasibility, and possible indicators of therapeutic changes after playing a purpose-built novel casual video game (Match Emoji) with simple mental health and well-being content among young adolescents.

Methods: We conducted a single-arm, nonrandomized trial of Match Emoji with 12- to 14-year-old school students (N=45; 26 [57%] New Zealand European, 12 [26%] Māori; 7 [15%] Asian or Pacific; 27 [60%] boys, 3 [6%] non-binary). Participants were invited to play Match Emoji for 15 minutes, 2-3 times a week over 2 weeks (a total of 60 minutes). Acceptability was assessed through the frequency and duration of use (analytics analyzed at the end of the 2-week intervention period and at weeks 4 and 6) and through participant reports. The Child and Adolescent Mindfulness Measure (CAMM), General Help-Seeking Questionnaire (GHSQ), Flourishing Scale (FS), and Revised Children's Anxiety and Depression Scale (RCADS) were assessed at baseline and week 2 to indicate possible effects. Focus groups were held in week 4.

Results: Most participants (n=39, 87%) used Match Emoji for at least 60 minutes over the 2-week intervention, with 80% (36/45) continuing to play the game after the intervention period. Mean change (from baseline to 2 weeks) on each measure was 1.38 (95% CI –0.03 to 2.79; *P*=.06) for CAMM; 0.8 (95% CI –2.71 to 4.31; *P*=.64) for GHSQ; –1.09 (95% CI –2.83 to 0.66; *P*=.21) for FS; and –3.42 (95% CI –6.84 to –0.001; *P*=0.49) for RCADS. Focus group feedback suggested that Match Emoji was enjoyable and helpful.

Conclusions: The casual video game with mental health content appeared to be acceptable and provided a promising indication of possible therapeutic effects. This approach is worthy of further investigation.

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KEYWORDS

adolescent; anxiety; casual video games; digital mental health interventions; gaming; mental health; micro interventions; serious game; teenage; video game; youth

Introduction

Mental distress and low well-being are common among adolescents [1-3] and appear to have increased over the past decade, at least in high-income nations [4-6]. Cognitive behavioral therapy (CBT) and psychotropic medications are recommended for young people experiencing mental health disorders [7,8]. Preventative programs that aim to buffer against higher levels of distress later in life also exist for young people

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[9]. Nevertheless, structural and attitudinal barriers inhibit access to mental health support for many young people [10].

Digital mental health interventions (DMHIs) refer to specialized content, support, or therapy for mental health conditions delivered electronically to treat, alleviate, or manage symptoms [11]. DMHIs encompass various technologies, including computerized CBT programs, chatbots, virtual reality for mental health conditions, games for mental health, apps, and interactive web pages [12]. Systematic reviews have shown promising effects for specific DMHIs across various age groups [13,14], such as CBT therapies for anxiety and depression [15,16]. Quality DMHIs can address some of the challenges often impacting face-to-face treatments [17,18]. For example, well-designed DMHIs can be used by young people irrespective of their level of distress, and they can be scaled up at a low cost due to their reduced reliance on clinically trained professionals [19,20].

Although this method of delivering mental health content is promising, engagement with DMHIs outside trial settings is typically lower than in trials [16]. Even playful interventions, such as Pesky gNATs [21] and SPARX [22], designed to appeal to young people's interest in computer games, have had limited evidence of engagement [16]. In part, these findings may reflect mismatches between how end users engage with technology and the way tools are provided (eg, sessions approximating weekly face-to-face therapies may be a poor match with contemporary patterns of internet use) [16,23,24]. Moreover, a lack of appealing options, lack of trust, or uncertainty about digital tools for mental health purposes may create additional barriers [22-24]. Therefore, while DMHIs have a great capacity to address mental health needs, it is important to keep exploring new opportunities to improve engagement [19,25,26].

Casual video games (CVGs) refer to simple games that can be played in short bursts of time, require no specialized skills, are often used for relaxation [27] and distraction purposes [28], and are generally free or low-cost to download and play. Well-known CVGs include "Rise Up" and "Angry Birds." "Rise Up" has been downloaded over 10 million times on the Google Play Store worldwide, and "Angry Birds" is played for approximately 200 million minutes daily [29,30]. Given their popularity and potential therapeutic effects, CVGs may be an approach that could be explored for delivering mental health and well-being content [28].

We systematically reviewed the effects of CVGs on anxiety, depression, stress, and low mood [31]. We found that 12 of the 13 trials reported promising results on their respective outcome measures. Following this work, we developed simple prototypes of CVGs with mental health concepts based on the puzzle, word, and match-3 genres and reviewed these in focus groups and interviews with young adolescents [32]. Young people indicated interest in this idea, with a match-3–style CVG being preferred. Subsequently, a game designer was contracted to develop the first version of Match Emoji, a simple match-3 CVG that includes brief text-based mental health and well-being messages, which have been previously described [33]. In brief, this includes short "micromessages," which were developed using psychological well-being literature and were sometimes linked to gameplay, for example, "Great job focusing and matching the emojis!" and "Phew! Take a short breath to help focus again." Subsequently, we held think-aloud interviews [34] with a small group of young adolescents to refine components.

In this study, we aimed to conduct a small open trial to explore the feasibility of using Match Emoji to strengthen the mental health and well-being of adolescents in a school setting. Findings from the study can help develop the literature on this new possible method for delivering mental health and inform processes for a possible future randomized controlled trial.

Methods

Design

The recruitment procedures, sample size, and analyses differed from those planned and published in our protocol paper [35] due to COVID-19 pandemic–related restrictions. Each departure from protocol is documented in the relevant section below.

This feasibility study used a mixed methods design. Adolescents attending New Zealand intermediate and high schools were recruited to participate in this study. They were shown how to use Match Emoji and then asked to play for 15 minutes, 2-3 times a week over 2 weeks (a total of 60 minutes). Analysis of game use, analytic data, and focus groups were held with all participants to explore the acceptability of Match Emoji. The therapeutic potential of the game was assessed by changes in mental health and well-being, which were assessed by 4 validated instruments.

Recruitment

Before the onset of the COVID-19 pandemic, we developed a protocol to outline the guidelines for conducting the trial, including how participants would be recruited [35]. Initially, as 1 local secondary school had expressed interest in participating, we aimed to recruit students between the ages of 13 and 15 years from this school across 2-4 classrooms. However, several teachers had become ill during the recruitment phase, and the secondary school could no longer participate in the study. As such, we approached 2 secondary schools (students aged 12-18 years) and an intermediate school (students aged 12-14 years), which all expressed interest in participating in the study.

In the secondary school, we described the study to an assembly of over 400 students in years 9 and 10 (aged 12-14 years). Those interested in participating in the trial and with access to a smartphone or tablet were asked to take home information, an assent form, and a consent form for their parent or guardian. Of the 42 interested students, only 6 returned both forms. When recruiting participants in each intermediate school, the New Zealand government implemented restrictions on indoor face-to-face gatherings. At this time, indoor gatherings of up to 100 people were allowed. As such, instead of recruiting participants in an assembly, we delivered a 10- to 15-minute face-to-face presentation to students in each classroom, explaining the theory and research underpinning Match Emoji. In total, 39 returned the assent and parental consent forms. Given the primary aims, the inclusion criteria were students aged between 12 and 14 years who had access to a phone that could

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download Match Emoji and provided written consent from a parent or caregiver.

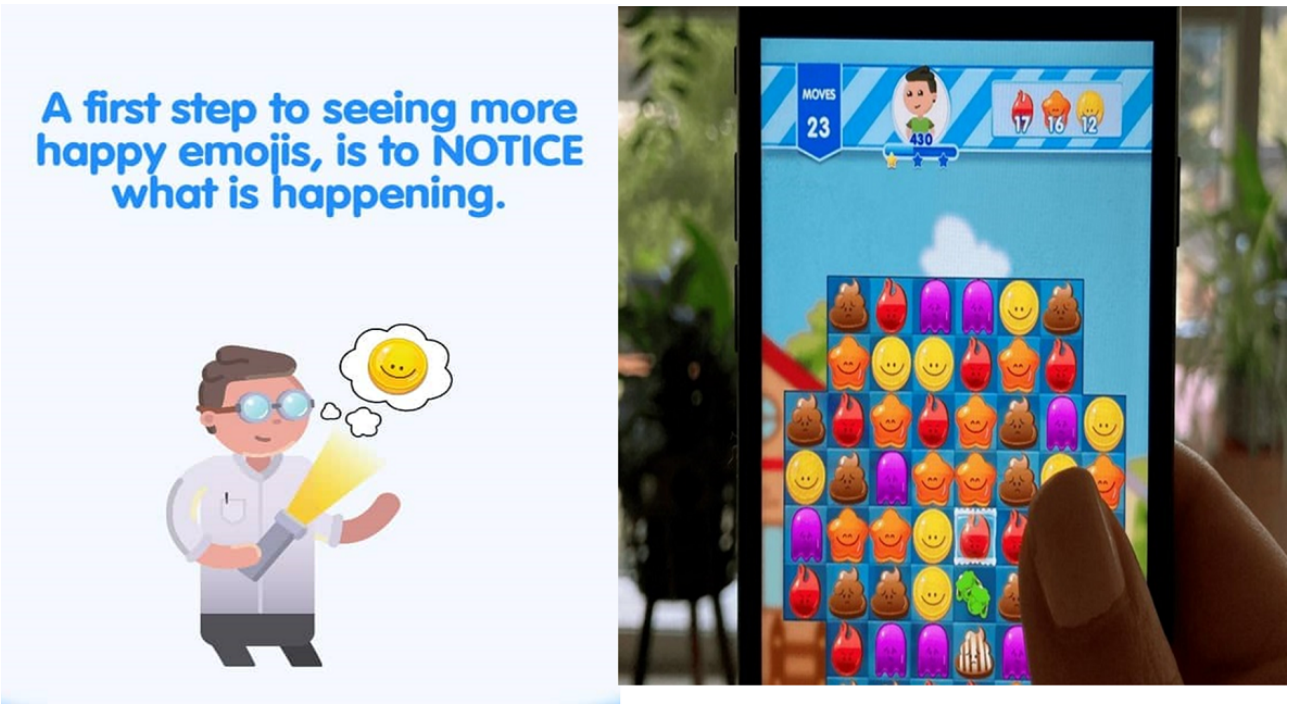
Study Procedure

Consenting participants completed the Child and Adolescent Mindfulness Measure (CAMM), General Help-Seeking Questionnaire (GHSQ), Flourishing Scale (FS), and Revised Children's Anxiety and Depression Scale (RCADS) at baseline. These assessments were completed in groups of 6 in the high school and 30 in the intermediate school. Students completed the questionnaires at their desks and were separated at least a meter apart from each other to protect privacy. Instructions on how to play and install the game were provided, and participants were given an opportunity to ask questions directly or email the primary researcher. Next, they were asked to play Match Emoji 2-3 times a week for a minimum of 15 minutes per session for 2 weeks (ie, a minimum of 60 minutes in total). Questions were repeated after the 2-week intervention period. All participants were invited to participate in focus groups held at each school 2 weeks later (4 weeks after the study began). After the study, *koha* (food and drink) was provided to acknowledge the student's effort. No financial incentives or gifts were provided.

The Intervention

The Match Emoji rationale, content, and processes have previously been described [33]. In brief, the micromessages in Match Emoji are based upon psychological well-being literature, specifically the *Five Ways to Wellbeing* [36]. As seen in Figure 1, these messages appear instead of in-game advertisements and function as prompts. For example, players are encouraged to read the message and practice skills including diaphragmatic breathing, noticing thoughts, or normalizing difficult emotions. In terms of the gameplay, users must identify and match 3 or more similar colored emojis together in rows or squares (a "match-3" game) to earn points. There are 6 different colored and shaped emojis, each representing an emotion or idea. The game has 99 levels, each designed to be completed within a few minutes, with a player advancing to the next level on completion of the current level. The gameplay becomes increasingly challenging as the player progresses.

Figure 1. Screenshot of the Match Emoji video game.



Measures and Outcomes

Demographic data were collected at baseline. Students who reported more than 1 ethnicity were categorized using the New Zealand Census ethnicity prioritization method [37].

Acceptability was assessed by the proportion of approached schools who agreed to participate, the number of participants who are able to download the game on their phone and those who fully participated in the study, and student feedback in focus groups. At week 4 (ie, after the intervention period), all participants were invited to take part in a 45-minute focus group at their school to explore their views of the intervention. Questions included (1) What parts of the game did you like? (2) What parts of the game could be improved? (3) What did you learn from playing the game? (4) Did you try and use any of the ideas from the game, and if so, which ones? and (5) Do you think you will continue to play Match Emoji? A general inductive approach was used to analyze the data from the focus groups [38]. The first author (RP) read participants' responses several times to identify emerging themes and categories from the raw data. A research assistant read through the raw data to ensure the themes reflected the essence of the category. Appropriate quotes that conveyed the key core themes were recorded and integrated into the results. Lastly, game analytics for minutes played and the number of sessions were recorded on the Unity platform [39]. Unity is a secure platform for creating and operating interactive games.

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The secondary outcome measures assessing therapeutic potential were changes from the pre- to postintervention (baseline and 2 weeks) time period on mental health and well-being domains calculated from the CAMM, a 10-item instrument measuring acceptance and mindfulness for use with children and adolescents aged 10 between 17 years; the GHSQ, which measures formal help-seeking intentions for nonsuicidal and suicidal problems; the 8-item FS, which measures self-perceived success in important areas such as relationships, self-esteem, purpose, and optimism as a single psychological well-being score; and the RCADS, a 47-item youth self-report questionnaire with subscales, such as separation anxiety disorder and generalized anxiety disorder.

The specific mental health and well-being domains assessed were mindfulness derived from the CAMM, help-seeking from the GHSQ, psychological well-being from the FS, and overall anxiety and depression score from the RCAD. Pretest and posttest summary statistics (mean, median, range, and SD) were computed using the R software (R Foundation for Statistical Computing) developer package. Data were assessed for normality using the Shapiro-Wilk normality test. Since data were not normally distributed, the nonparametric Wilcoxon signed rank test was used to compare the means between pairs of values (pre and post).

Ethical Considerations

This study received ethics approval from the New Zealand Health and Disability Ethics Committee (21/NTA/34) on May 28, 2021. Data was de-identified and all participants provided informed consent. No financial compensation was provided to the study participants.

Results

Participants

Of the 45 adolescents who participated in the study (mean age 12.5, SD 0.33; range 12-14 years), 26 (57%) were New Zealand European, 12 (26%) were Māori, and 7 (15%) were Asian or Pacific. As seen in Table 1, the majority (n=27, 60%) were boys, while 15 (33%) were girls and 3 (6%) were nonbinary.

Table 1. Demographics of participants (N=45).

Characteristic	Value
Age (years)	
Mean (SD)	12.5 (0.33)
Range	12-14
Gender, n (%)	
Boy	27 (60)
Girl	15 (33)
Nonbinary	3 (6)
Ethnicity, n (%)	
Asian	3(6)
Māori	12 (26)
New Zealand European	26 (57)
Pacific	4 (9)

Acceptability

On average, each participant played 7.5 sessions for 24 minutes across the 2 weeks, comprising 180 minutes in total. In addition, data recorded from the focus groups suggested that, on average, participants completed 50 out of the 99 available levels during the 2-week duration of the study. Most participants in the focus groups said they would continue playing the game after completing the study. A total of 38 (84%) participants said they “would” continue to play the game, while 5 (11%) said they “might” continue to play. Only 2 (4%) participants said they would not continue to play the game after the trial. In addition, 36 (80%) reported playing Match Emoji after week 4, and 32 (71%) were still playing after week 6, according to game analytics from the Unity Platform. Findings from the focus groups suggested that participants enjoyed playing Match Emoji for several reasons. First, participants enjoyed the convenience of the game. For instance, many participants reported playing Match Emoji across multiple environments, including waiting rooms at the dentist, bus stops, and long car rides. As no internet connection was needed, participants could access the game whenever they wished. A participant explained, “I could play the game even when there was no Wi-Fi,” while another said, “The game was really good when waiting for appointments (be)cause it could distract me for a bit and didn’t use up data.”

Second, many participants reported enjoyment from playing the game. They described this enjoyment as stemming from game features such as increasing levels of challenge, the variety of emojis, and clear goals: “it was fun (be)cause the game got harder, but you knew what you had to do.” While there was some level of challenge, the simplicity of the game allowed students to bypass traditional barriers to CVGs, such as instructional videos. One participant described Match Emoji as a “super easy game to understand and play.” A smaller group of participants also provided suggestions about game features. This group appeared to be more frequent users of CVGs, as they provided recommendations based on other games they had

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played. One participant suggested, "You could add more rewards or more characters and then get more power-ups like Fortnite," while another recommended, "coins, customization, themed music, and bonus rounds... add stuff like they have in other casual games."

In general, participants liked the subtle aspect of accessing mental health content. As 1 participant mentioned, "the messages are a nice way of getting mental health information out there that isn't in your face." There was a high consensus that they preferred micromessages over typical in-game advertisements. However, some were initially skeptical about their value, "the messages were cringe at first but got way better."

Of the intermediate and secondary schools approached to participate in the research, only 3 (25%) of the 12 took part in the study. Only 3 (7%) out of the 45 participants could not download Match Emoji onto their phones. In each case, this was because their phone had limited capacity to download the necessary software. All participants completed baseline and follow-up assessments, but several needed clarifications on wording related to the RCADS questionnaire items.

Indicators of Possible Effects

As seen in Table 2, a small positive change was observed on the CAMM (mean difference 1.38, 95% CI –0.03 to 2.79) and on the RCADS (mean difference 3.42, 95% CI –6.84 to –0.001). In focus groups, when asked, "What did you learn from playing the game," a number of participants answered that playing the game was helpful for their mental health and well-being: "I reckon playing the game for a bit of time was helpful for my mental health (be)cause it took my mind of stuff." When asked, "Did you try and use any of the ideas from the game, and if so, which ones?" Several participants reported using specific skills suggested in Match Emoji: "Once when I started to think about annoying stuff, I tried the breathing thing, and it was actually pretty helpful," and "I remember I got pretty mad at my brother and used the noticing a thought approach."

Table 2. Changes in mental health and well-being indicators of adolescents aged between 12 and 14 years after 2 weeks of playing Match Emoji (N=45).

Outcome	Baseline, mean (SD)	Postintervention, mean (SD)	Mean differences (95% CI)	*P* value
CAMM[a]	22.44 (8.35)	23.82 (8.93)	1.38 (–0.03 to 2.79)	.06
GHSQ[b]	62.89 (21.96)	63.69 (23.30)	0.8 (–2.71 to 4.31)	.65
FS[c]	41.71 (11.58)	40.62 (12.07)	–1.09 (–2.83; 0.66)	.22
RCADS[d]	46.24 (26.39)	42.82 (26.49)	–3.42 (–6.84 to –0.001)	.049

[a]CAMM: Child and Adolescent Mindfulness Measure (mindfulness).

[b]GHSQ: General Help-Seeking Questionnaire (help-seeking).

[c]FS: Flourishing Scale (psychological well-being).

[d]RCADS: Revised Children's anxiety and Depression Scale (overall anxiety and depression).

Discussion

Overview

In this study, we found that a CVG with psychological well-being concepts (Match Emoji) was a new and engaging mechanism of change that provided a promising indication of possible therapeutic impact. Most participants played more often and for a longer period than was requested for the study. Indeed, most participants continued to play in week 4. Small improvements in mindfulness assessed by CAMM and a small decrease in overall anxiety and depression assessed by RCADS were recorded. Given these promising changes, participants may have learned skills related to reducing their level of anxiety through playing Match Emoji. The findings of this small open feasibility trial indicate that the Match Emoji CVG was an acceptable way to support mental health and well-being in adolescents aged between 12 and 14 years.

Participants reported a high level of acceptability with Match Emoji, as evidenced by the game analytics, qualitative feedback, and the large portion of participants who were still playing the game in weeks 4 and 6. The percentage of participants who stated they continued to play Match Emoji even after week 6 of the study (n=32, 71%) is contrary to the poor retention rate typically found across the range of digital interventions. Real-world data on user engagement with popular mental health apps suggest that a small portion of users stay engaged with digital health interventions [16]. For example, once a health app is downloaded, approximately 4% of users continue to use the app after 15 days [24]. It is possible that the ongoing consultation with end users from the beginning of the development of Match Emoji, the simplicity with which CVGs can be played "on the go," across environments with no Wi-Fi, and how playing CVGs fits with adolescents' current behavior patterns may have been attributed to the high level of acceptability and engagement. That is, as many adolescents already play CVGs [32], there is less effort required to learn and change existing ways of engaging with technology. Data from the focus groups corroborated these findings. More specifically, participants mentioned they enjoyed playing for short periods across environments in comparison to computer games or those mobile phone games that require data to access. This is consistent with our previous work [32] and research [19], which suggests young adolescents tend to prefer brief therapeutic encounters. Moreover, Match Emoji enables large portions of the population to receive the same content irrespective of their proficiency with gaming or access to the internet, addressing a significant barrier to equity and engagement with DMHIs [11].

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Our finding that most participants preferred micromessages over typical in-game advertisements is consistent with research assessing how in-game advertising in the form of short videos is distracting and can lead to disengagement, particularly among young people who often have a relatively short attention span [40,41]. Although paid versions can avoid advertisements, young people are reluctant to pay for them [41]. Thus, Match Emoji represents an opportunity for public health interventions to provide appealing free CVGs that replace the advertising with health-related micromessaging that is not distracting, annoying, or potentially harmful, as is the case with in-game advertising.

Similarly, diverse preferences were found with gamification elements of Match Emoji. The various preferences toward micromessages and game features among participants are consistent with the literature that suggests adolescents have different opinions about the type of DMHI they are attracted to [42,43]. Thus, while some adolescents may be frequent CVG users and interested in gamification elements, others may be less focused on these features and more attracted to learning about mental health and well-being [44]. In essence, opportunities to embed therapeutic processes within game elements are plentiful when researchers and game developers collaborate and are creative.

The protocol and implementation of this study were completed during the COVID-19–lined social distancing practices, which resulted in frequent changes to the restrictions on the size of inside gatherings and how educational facilities operated. Apart from the implications of the pandemic, 3 participants in the study could not download Match Emoji. This was because their phones lacked the storage capacity required to download the latest software and the game. Future research could use methods to compress digital mental health apps such as Match Emoji. In this way, the size of the app may better align with the capacity of users' technology. In addition, some participants struggled to understand several questions on the RCADS. These questions were discussed in more detail with each participant to ensure they understood the meaning of each one. Despite these challenges, no significant issues occurred with conducting the study in a primary and intermediate school context.

Limitations

There are limitations to this study; these include departures from the protocol due to COVID-19 impacts, which resulted in a small exploratory open trial only. There were also limited resources to conduct the study; this meant that the first author (RP) introduced the game to participants, led the recruitment process, supported the completion of assessments before and after playing the game, and facilitated the discussions about the game. Thus, the interpretation of the students' feedback could be overly positive, and participants' opinions and thoughts could be influenced by social pressures, including normative and informative conformity.

Further, the self-assessment outcome measures relied on the comprehension skills of young participants. While some participants raised their hands when unsure of a question, others may have merely guessed. Nevertheless, the 4 assessments appeared to be easy to implement in a short amount of time. Third, when recruiting participants at the secondary school, only 6 (14%) out of the 42 participants who signed the assent form returned their parental consent form for reasons unknown, suggesting that a different process is needed to recruit older adolescents for future trials. Lastly, students were not recruited based on their level of mental distress. Therefore, the results may have been affected by floor effects, whereby their mental health and well-being scores were already good or optimal and thus unlikely to improve any further. Despite these challenges and preliminary results, these findings are of interest as this is the first study to assess the feasibility of a co-designed CVG with psychological well-being concepts.

Conclusion

Findings from this feasibility study suggest that Match Emoji, the purpose-built CVG with brief mental health messages, is promising as an acceptable and feasible approach for young adolescents. Future research should test clinical impacts through a randomized controlled trial. More broadly, the research also highlights the possibility of CVGs as a novel mechanism of delivering simple mental health and well-being messages.

Acknowledgments

We would like to acknowledge the young people who participated in the study and the teachers who helped with the recruitment process. This study was funded by Cure Kids (innovation seed fund: 3918).

Data Availability

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

Authors' Contributions

RP and TF were involved in the conceptualization of the game and study. LTM and JM were involved in the methodology and formal analysis. All authors were involved in writing the original draft and reviewing and editing the paper. All authors have read and agreed to the published version of the manuscript.

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Conflicts of Interest

TF is a codeveloper of SPARX, a computerized cognitive behavioral therapy program for adolescent depression. The intellectual property for SPARX is owned by Uniservices at the University of Auckland, and codevelopers can benefit financially from the licensing of SPARX outside of New Zealand.

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Abbreviations

CAMM: Child and Adolescent Mindfulness Measure
CBT: cognitive behavioral therapy
CVG: casual video game
DMHI: digital mental health intervention
FS: Flourishing Scale
GHSQ: General Health-Seeking Questionnaire
RCADS: Revised Children's Anxiety and Depression Scale

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Original Paper

A Smartphone-Gamified Virtual Reality Exposure Therapy Augmented With Biofeedback for Ailurophobia: Development and Evaluation Study

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Abstract

Background: To the best of our knowledge, no specialized research has been conducted to address ailurophobia (fear of cats) in Iran or globally. This has driven our project, along with the prevalence of ailurophobia and the absence of a gamified virtual reality exposure therapy (VRET) that incorporates affordable and easily accessible biofeedback (BF) tools. We hypothesize that a gamified VRET augmented with BF will yield more positive effects than a similar device lacking BF.

Objective: This study primarily focuses on the development and preliminary evaluation of a smartphone-gamified VRET integrated with BF, targeting animal phobia, with a specific case study on ailurophobia. The secondary objectives are using affordable and readily available BF found in devices such as smart bands and smartwatches and creating a mobile virtual reality gamified app to improve patients' adherence to treatments while simultaneously enhancing the app's accessibility, scalability, and outreach.

Methods: Evaluations encompassed 3 methods. First, we identified the tool's potential positive effects on phobia interventions, exploring 4 effects: intrinsic motivation, simulation of fearful situations, management of stressful circumstances without therapists' presence and mitigation of catastrophic thoughts, and preliminary effects on ailurophobia treatment. Participants were divided into BF and non-BF groups. Second, we gathered user preferences and opinions about the treatment. Third, we conducted heuristic evaluations using 44 heuristics from existing system usability scales assessing user interfaces, virtual reality platforms, and video games' playability. To interpret the data, mean scores; ANOVA, single factor; and ANOVA, 2-factor with replication were used. A total of 29 individuals were identified, of which 10 met the eligibility criteria or were accessible.

Results: The smartphone-gamified VRET augmented with BF exhibited better results on the identified effects compared with the non-BF version and contributed to normalizing encounters with cats. Moreover, 41 of the 44 heuristics achieved a percentage above 62%, indicating its potential as a therapeutic product and its ability to enhance patient adherence to treatments. Patient preferences on the treatment and its strengths and weaknesses were provided for further improvement.

Conclusions: The tool has the potential to evolve into a comprehensive solution by incorporating various types of cats and their behaviors, simulating environments in which they are commonly found, and enhancing its appeal through an increased sense of adventure without inducing unrealistic fears. By adapting fear elements, the game can be tailored to treat various animal phobias.

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Phobia-focused games should avoid action and combat scenarios to prevent reinforcement of fear responses. After rigorous evaluation, further exploration is required to provide remote use beyond clinical settings.

(JMIR Serious Games 2024;12:e34535) doi:10.2196/34535

KEYWORDS

animal phobia; specific phobia; ailurophobia; cat phobia; biofeedback; smartphones; virtual reality; gamification; mobile phone

Introduction

Specific Phobia and Available Therapies

Specific phobia is the most common anxiety disorder, with a lifetime prevalence of 12.5% [1]. It is characterized by an extreme and persistent fear of a specific object or situation [2], leading to substantial disruptions in daily life and heightened anxiety. Many individuals restructure their lives to evade their fears over extended periods [3,4]. Prolonged phobia detrimentally affects academic, social, and family aspects, compromising overall quality of life [5]. Situational (eg, fear of enclosed spaces and flying), natural environment (eg, fear of heights and storms), animal (eg, fears of snakes, spiders, and cats), and blood or injection or injury (eg, fears of medical procedures and seeing blood) fears are subtypes of specific phobias, with animal and natural environment phobias being more prevalent [3].

Phobia interventions are categorized into exposure therapies (eg, direct in vivo exposure, systematic desensitization, imaginal exposure, and virtual reality [VR]) and nonexposure approaches (eg, cognitive therapy and progressive muscle relaxation). There has been a trend toward adopting brief, intensive, or concentrated treatments to manage anxiety [5]. Among the available treatments, exposure therapies are the most commonly used approach for specific phobias [6]. However, although specific phobias are highly treatable, only 31% of patients seek treatment and, among those, only 43.4% seek mental health services [3]. Moreover, some patients might be unable to complete the treatment because of severe reactions, resulting in an attrition rate of 45% [3,7]. In total, 3 main factors contribute to this percentage [7]: (1) perceiving treatments as highly aversive and frightening; (2) the need to visit clinics throughout the treatment, causing relationship and ethical issues, such as perceived cruelty when therapists intentionally evoke fear; and (3) the lack of appealing treatments.

Gamified VR Exposure Therapies Augmented With Biofeedback

To overcome the limitations of exposure therapy methods, incorporating new technologies becomes imperative. Gamification, VR, and biofeedback (BF) are promising options. However, our research indicates that few studies have simultaneously used these technologies for specific phobias. Virtual reality exposure therapy (VRET) uses 360° computer-generated simulations [8,9] similar to traditional exposure therapies [2]. Meta-analyses have shown that VRETs are effective and their performance can rival standard exposure therapies [2]. VR's application in cognitive impairment, anxiety disorders, pain management, phobias, posttraumatic stress disorder, rehabilitation, and eating disorders, among others, has surged because of its immersive realism [8,10]. To treat phobias, VR is a safer, less embarrassing, and cost-effective solution by simulating fear-inducing situations in a controlled environment [8,9,11]. However, VR alone may not address all exposure therapy disadvantages, and enhancing the attractiveness of VRETs is crucial for treatment success. Researchers have explored the potential of gamified VRETs in treating phobias [2,12,13]. Gamification, a strategy derived from video game–based approaches, has proven successful in achieving serious objectives across various fields, including the workplace [14], education [15], marketing [16], mental health [17-19], learning disabilities [20,21], and lazy eye treatment [22]. The primary inherent feature of digital games is their high-level motivational potential [23]. Video games' appeal, engagement, and effectiveness encourage players and frequent use [18]. Attractiveness is beneficial for overcoming people's reluctance to seek treatment, broadening the reach of gamified interventions [18]. The engaging nature of gamification enhances users' experiences, as players are driven to win, explore stories, and ultimately reduce attrition rates [12,18,24]. The effectiveness aspect offers opportunities for achieving serious objectives such as behavior changes [18]. In a gamified product, elements such as scores, badges, and levels are integrated from games into nongame contexts, while not necessarily offering a complete gaming experience [18,25].

Human emotion recognition sensors or BF is another technology that can enhance gamified interventions. This technology serves 2 crucial purposes. First, it boosts their level of attractiveness by leveraging a strategy commonly used in video games to increase engagement [26]. Second, it addresses some of the limitations of traditional methods by potentially reducing or eliminating the need for therapists' constant presence. These sensors work by measuring various body parameters or electrical impulses in the nervous system to identify different emotions and track their changes [27]. Common techniques include electroencephalography, skin resistance measurements, blood pressure, heart rate (HR), eye activity, and motion analysis. With advancements in chipset manufacturing, BF has become more accessible, portable, efficient, and affordable. Users can easily access their data, thereby enabling self-regulation and monitoring. These technologies are incorporated into smart wristbands and watches to help individuals regulate anxiety in their daily lives. BF therapies have shown positive effects in treating conditions such as migraines [28] and attention-deficit/hyperactivity disorder in children [29].

Objectives

The primary aim of this study was to develop and conduct a preliminary assessment of smartphone-gamified VRET augmented with BF for the treatment of cat phobia (ailurophobia). We hypothesize that this tool will outperform

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gamified VRET without BF in various aspects. Limited evidence exists on animal phobia in Iran, particularly ailurophobia. Observations at the Cognitive and Brain Clinic in Tehran revealed a substantial prevalence of this phobia, as reported by the fourth author, who is a cognitive expert and psychologist attending to cat phobia patients daily. Owing to the abundance of cats in most Iranian cities, encounters are inevitable, resulting in daily challenges for patients walking on the streets and alleys. The secondary objectives were as follows:

1. Using affordable and accessible BF tools in devices such as smart bands and smartwatches to serve as both BF and a game mechanic, enhancing engagement and efficacy.
2. Developing a mobile VR–gamified app to enhance patients' adherence to phobia treatment and expand the app's accessibility, scale, and reach.

To evaluate the effectiveness of the tool, its potential positive effects on phobia interventions were examined. The tool's impact on the effects was examined by dividing the participants into BF and non-BF groups. In addition, we considered the playability and usability aspects of the tool, along with patients' preferences, to optimize its performance and enhance usability for future improvements.

Methods

Design and Development

Our primary objective was to present fear elements indirectly to the player, ensuring that interacting or not interacting with them would not affect the game's progress. The secondary objective was to create a general game design model that could be easily customized for specific phobias, particularly animal phobias. During the initial game development meeting, 2 game design experts (a game designer and a gamification expert) collaborated with 2 cognitive science experts (one of whom also specialized in cognitive games). They engaged in a discussion regarding the essential components required to simulate stress. Size, color, and behavior of the stimuli were introduced as fundamental elements for replicating the desired scenarios. The game team then devised the game stages using a maze design. In the second meeting, cognitive experts suggested simplifying the design to accommodate players of all ages. As it involved memory and problem-solving, it was rejected, leading to a more straightforward game plan that focused on finding lost objects in a park. In the third session, this plan received approval and was tested on a woman aged 40 years with cat phobia, who was selected based on her self-reported fear of cats. She stated, "I experienced a lot of fear during playing." In the fourth session, minor adjustments were made to the game. In total, 2 psychologists from Tehran University found the initial voice of the guide annoying, thereby hindering patient motivation. The overall view of the sessions is presented in Figure 1.

Our game's storyline was inspired by the "Hot and Cold" game. One group hides an object, and the other group should find it using verbal clues such as "colder" as they move away and "hotter" as they get closer. The experience is similar to that of a park with diverse paths. Players are on a quest to discover diamonds concealed within treasure boxes, all while walking along these pathways. Each game session comprises 4 short yet consecutive levels. At each level, players must determine their distance from each box by perceiving changes in the sound consistently played. Moreover, a hint ribbon shows the player's distance to the box for increased engagement. After locating the box, players must stay in front of it for a specific duration to open it, with the time increasing at later levels. The players must open the previous level's box to unlock the next challenge.

Regarding authors' concerns about spreading the game to individuals with phobias, smartphones were chosen as the primary platform. Using smartphones as a VR tool requires affordable mobile VR glasses, which are significantly cheaper than other options such as Oculus or HTC VR. The primary challenge in mobile VR is the user interaction limitations. The game uses Gaze, a pointer on the screen that allows users to interact through head movements, thus providing a mouselike experience. In addition, the game incorporates joysticks connected to the phone, thus offering more interactive possibilities.

The intensity of the fear elements must be balanced based on the game's progress and levels, as in previous studies [7,13]. The escalation of fear stimuli is determined by the following features, each with its own difficulty level. Moreover, these elements can be further amplified in tandem with player's advancement.

1. Visual elements: the fear-triggering elements include cat photos, fantasy cat models, low-poly cat models with minimal details, and high-poly cat models that closely resemble real cats. According to experts, individuals who fear something may also react to objects and shapes that resemble it. For instance, people who are afraid of cats might experience fear when encountering a cat picture or a furry object. This phenomenon is directly related to the degree and intensity of the individual's fear [30]. Figure 2 illustrates the game environment.

2. Fear elements' sound: the scary elements vary from silent to those with terrifying sounds. In intense situations, cats produce specific sounds that could heighten anxiety. The timing of when the sound is played also adds to the diversity. For example, when players are near a cat, the sounds it emits could intensify their fear.

4. The quality of fear elements' behaviors: studying the behavior quality of a stimulus is under investigation [31,32]. A cat jumping from one point to another evokes more fear than a cat simply standing still. Various animations were designed for 3D model cats. The fantastical cat playfully turns its head and randomly spins around. The low-poly cat remains stationary, solely turning its head. In the final level, the high-poly cat features 3 different animations. The first 2 animations portrayed the cat at rest, either shaking its tail and head or cleaning its paws. The third animation involves the cats' walking behavior.

5. Interactable elements: fear elements that respond to the player's presence add a sense of authenticity to the game, elevating immersion and allowing for anxiety manipulation. Cats may react by turning, approaching, or fleeing when a player gets closer. Both low-poly and high-poly cats respond to the

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player's presence. The manner in which the elements react was also classified. Although the fantasy cat remains unresponsive, the low-poly cat acknowledges players by turning their heads and looking at them when they enter the zone. At the last level, the realistic cat not only faces the players but also follows them until they exit from its zone.

6. Fear elements' size: element size could also amplify fear. In the final level, some cats are larger, preparing players to confront more intimidating situations.

7. Fear elements' numbers**:** seeing numerous cats creates a feeling of being surrounded, indirectly encouraging players to confront their fear. As players approach the boxes, fear intensifies, peaking around those areas.

The quantity and type of elements can be customized based on players' preferences and conditions (Figure 3), which is beneficial when they need to concentrate on a specific scary element. Furthermore, a player who does not fear an element can eliminate it from the game.

A VR Android game was developed using the Unity game engine, incorporating the Amazfit Bip smartwatch. In anxiety treatments, HR variability is a common BF technique for stress management [33]. However, because of limitations in receiving these signals through conventional smartwatches and wrist bands, HR was used instead of HR variability. HR data are accessible in smartwatches through Bluetooth low energy technology [33]. A plug-in for the Unity3D game engine was implemented to integrate smartwatch data into the game. The player's HR was incorporated into the experience as a game mechanic. The HR was displayed on the corner of the screen. A total of three BF techniques were used in this study: (1) displaying changes in players' bodies to inform and manage anxiety [33]; (2) keeping HR within specific limits allows players to earn the game's prize, a diamond, promoting relaxation skills for stressful situations [34]; and (3) maintaining a low HR for a period allowed players to open boxes and collect more diamonds [33,35].

Figure 1. The overall view of sessions between the game designers and other related experts.

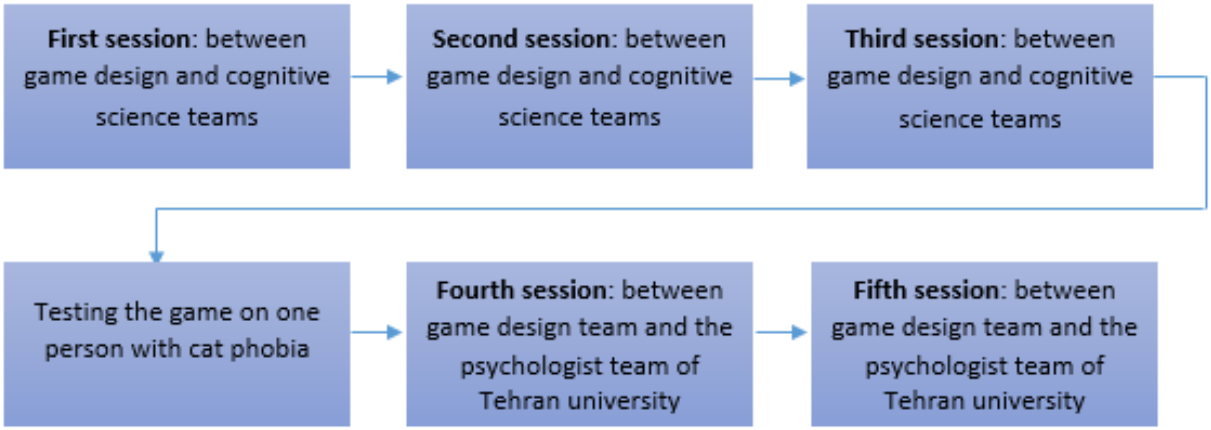

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Figure 2. Screenshots of the game's environment with all its cat types.

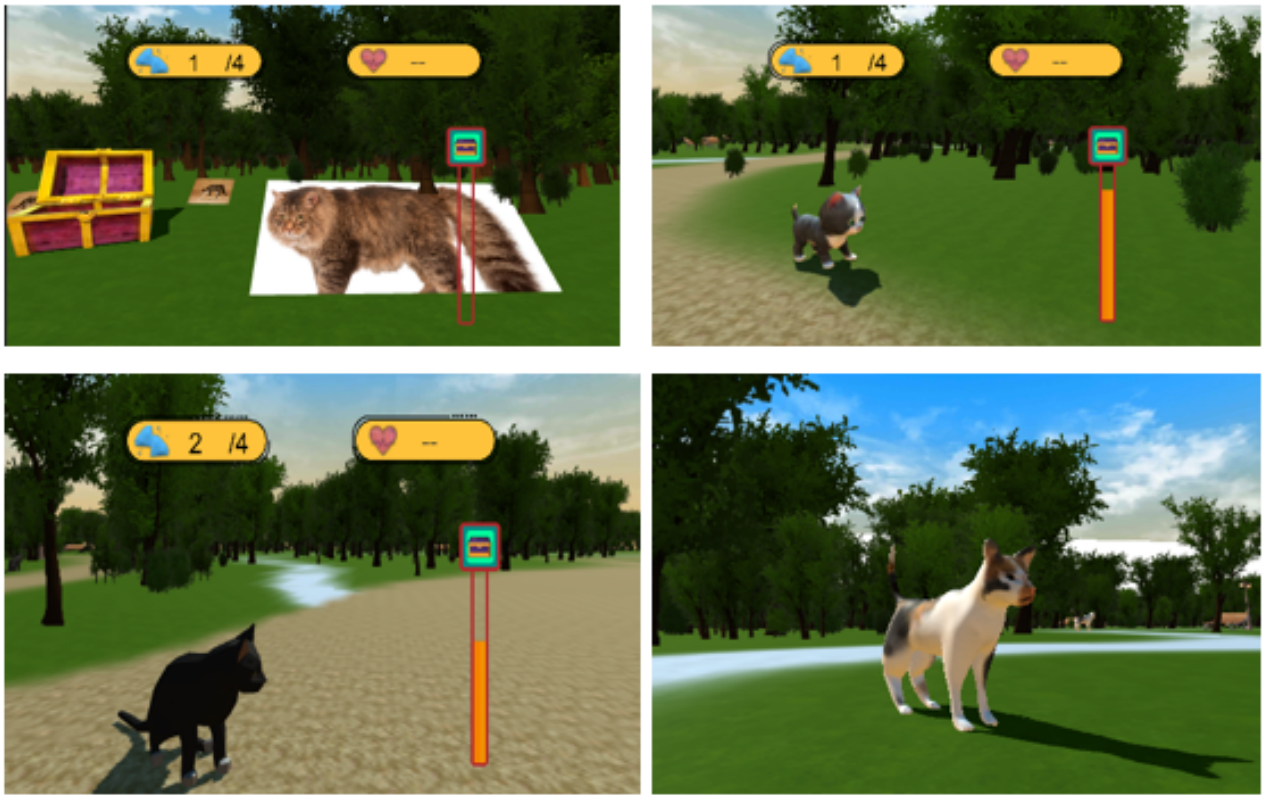

Figure 3. Images of the level customization menu.

Trial Design, Participants, and Procedure

Overview

In total, three methods were used to evaluate the tool: (1) identifying its potential positive effects it could have in phobia interventions. To assess the game's impact on these effects, participants were divided into BF and non-BF groups, with the only differences being the use of smartwatches; (2) gathering user preferences about the treatment; and (3) considering the tool's playability and usability aspects for subsequent optimization and improved usability.

Ethical Considerations

This study was approved by the Research Ethics Committees of the Institute for Cognitive Science Studies (IR.UT.IRICSS.REC.1401.047). Informed consent was obtained from participants. They had the freedom to withdraw from the study at any time. The participants' data were anonymized. To compensate for time, participants were informed that a smartphone-compatible version of the game would be provided free after its finalization.

Participants

The snowball method was used for recruitments. One attractive advertisement was prepared in Farsi and shared within various working, educational, and family groups on Instagram and

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WhatsApp. Receivers were asked to help by sharing the advertisement with their own groups. Recruitment took place from September 8 to October 14, 2022, in 2 provinces in Iran: Lorestan and Tehran. Each test session lasted up to 3 hours, and the participants had the flexibility to choose the test location. Random assignment was used to allocate the participants to the study arms.

Inclusion criteria were (1) providing informed written consent, (2) understanding and reading Persian, and (3) scoring ≥55 on the Fear of Cats Questionnaire (FCQ). Exclusion criteria were (1) currently receiving psychological treatment for ailurophobia; (2) having another severe mental disorder (alcohol or substance abuse, psychotic disorder, dementia, or bipolar disorder); (3) diagnosed with a severe personality disorder; (4) experiencing depressive symptoms or suicidal ideation; (5) heart disease; (6) vision or balance problems affecting the VR experience; (7) pregnancies exceeding 3 months; and (7) fear of cats only in a few and exceptional cases. An image of participants is presented in Figure 4.

Figure 4. Depiction of participants.

Identifying the Positive Effects of the Gamified VRET Augmented With BF

Effect 1: Intrinsic Motivation

One primary positive effect that the app could have on phobia interventions is its ability to enhance intrinsic motivation. By incorporating gamification, VR, and BF, the app effectively motivated patients to actively engage in their treatment. We hypothesize that combining gamified VRET with BF will significantly increase motivation compared with a similar tool without BF.

To assess their impact on intrinsic motivation, we used subjective and objective measures. After each level, participants completed a 10-item questionnaire that was previously used to evaluate subjective engagement [36-39].

Participants played a minimum of 5 levels and completed the intrinsic motivation questionnaire after each level, except for the first. First-level data were excluded because of participants' unfamiliarity with the experience. For the training step, the picture level of the game with 8 cat pictures was predetermined. The other settings regarding the type and quantity of stimuli for mandatory games are as follows:

- Game 1: fantasy model with 13 cats
- Game 2: low-poly model with 19 cats
- Games 3 and 4: high-poly model with 23 cats

We deliberately chose the last 2 steps in the same manner to examine the impact of repetitive tasks on the participants.

After the mandatory games, participants had the option to play the game for up to 4 additional times. During the voluntary sessions, participants were allowed to choose the type and number of cats, but the number of cats had to be selected in ascending order. In these sessions, we used a shorter version of the intrinsic motivation questionnaire with only 5 items, as used in Lumsden et al [36].

Effect 2: Simulating Fearful Situations

For phobia treatments to be effective, the game should evoke fear among individuals. To evaluate this, both groups were asked to rate their anxiety levels on a scale from 1 ("no anxiety") to 10 ("extreme anxiety") after any mandatory and voluntary sessions (except the first level).

Effect 3: Controlling Stressful Circumstances, Eliminating Therapists' Presence, and Mitigating Catastrophic Thoughts

The game enables participants to implicitly learn relaxation techniques while confronting their fears. The box-opening mechanism involves standing in front of the box for gradually increasing durations. This combined approach, along with BF, has the potential to reduce the need for therapists' presence.

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After the experiments, the participants were asked two questions: (1) How well do you think you could manage your stress when dealing with a real cat after using the gamified app? (2) To what extent can our game eliminate the need for operators? The app's attractive and fantasy environment was expected to alleviate catastrophic thoughts. Participants were also encouraged to share any positive signs of reducing their frequency of thinking about their fears.

Effect 4: Preliminary Effects on Ailurophobia Treatment

The study used before and after assessments with the State-Trait Anxiety Inventory (STAI) and FCQ to measure the game's impact on phobia symptom changes. The STAI questionnaire comprises 40 questions, measuring state (S-scale) and trait (T-scale) anxiety using a 4-point Likert scale. Only the S-scale was used in this study. The evaluation of state anxiety can be used for any situation with a time interval determined by a researcher or a clinical specialist. Mahram developed the Persian version of the STAI, and its internal consistency was confirmed for the S- and T-scales (Cronbach α of .91 and .90, respectively) [40]. Another Iranian study also reported high reliability for the S- and T-scales with Cronbach α values of .93 and .90, respectively [41]. The FCQ questionnaire was derived from the Fear of Spiders Questionnaire (FSQ) to assess cat phobia, with all instances of the word "spider" replaced by "cat." Furthermore, the question format was adjusted to suit the assessment of the cat phobia. The FSQ is an 18-item tool scored on a 7-point Likert-type scale to measure the level of spider phobia, yielding a total score ranging from 18 to 126. The FSQ demonstrates excellent internal consistency with Cronbach α ranging from .88 to .97 [42,43] and good test-retest reliability [42]. The FSQ has been used in previous studies for various phobias such as cockroaches [7,44,45], rats [46], and snakes [47].

After the games, each group of participants was instructed to play 2 levels of the game as the opposite group did. They were then asked to answer the following questions: (1) Which experiences do you prefer? (2) Which experiences had more novelty and were more attractive to you? (3) Which experience was more effective for improving your problem?

Patients' Preferences About the Designed Treatment

To gather patients' opinions on the implemented treatment, an adapted preference questionnaire [48] was used. This 6-item questionnaire focused on patients' preferences regarding the types of cat models, their behaviors, sounds, and sizes. For example, the questions related to cat models are as follows: (1) If you could choose among the cat models, which one would you prefer? (2) Which cat model do you think would be more effective in helping you overcome your problem? (3) Which cat model do you find more logical for aiding in your progress? (4) Which of these cat models do you perceive as more aversive? (5) Which cat model would you recommend to a friend facing the same problem? (6) Are there any cat models missing in the game?

Heuristics Evaluations

The playability and usability aspects of the tool were examined through heuristic evaluations designed as semistructured interviews to optimize its performance and enhance usability. Participants completed a 5-Likert questionnaire covering user interfaces, VR experiences, BF, and game playability. Participants had the opportunity to provide additional comments. The evaluations incorporated 44 heuristics from studies [49-52]. We used Nielsen heuristics [49,50] to assess the interfaces, along with modified Nielsen principles for VR platforms [51]. In terms of game playability, a comprehensive evaluation was necessary to assess additional features, including gameplay, story, and mechanics, which went beyond simple interface usability evaluation [52]. We used the heuristic principles of playability introduced in [52], which carefully examine the various components of a game in terms of playability and enjoyment for the player, encompassing gameplay, mechanics, usability, and game story. In this study, we used the first 3 heuristics from this set.

Statistical Analysis

We evaluated the differences in subjective ratings of intrinsic motivation and levels of anxiety using ANOVA: 2-factor with replication of the total score, with session number as the time factor and task variant (the tool with and without BF) as the between-subjects factor. In addition, we used 1-way ANOVA with task variant as the between-subjects factor to investigate the effects of the tool on mitigating phobia symptoms. For analyzing the semistructured interviews, mean and SD scores were used.

Results

Participants

Of the 17 participants, 7 were excluded for (1) heart disease (n=1); (2) vision or balance problems (n=1; participants with VR-induced dizziness and severe nausea); (3) pregnancy (n=1); (4) personality disorders (n=1); and (5) fear of cats in specific situations (n=3; one was afraid of direct eye contact with cats, whereas 2 others were scared of black cats). Among the 10 included participants (Table 1), 1 individual had 2 other phobias: fear of public toilets (paruresis) and birds (ornithophobia), especially their beaks and legs. Another participant displayed general phobia of animals; even touching chicks elicited an electric shock response. In addition, the sight of cats, dogs (cynophobia) especially when they bark, and foxes caused annoyance and discomfort for her. Interestingly, she was more afraid of kittens than fully grown cats. Another patient had cynophobia and ailurophobia. Finally, 1 participant had a phobia of space and galaxies (to the extent of avoiding space-themed movies) as well as chicks phobia and ornithophobia stating, "I am even afraid of a bird in a cage that might come out and harm me." This participant also avoided going to the park because of the fear of the animals. Given the prevalence of individuals experiencing multiple phobias, particularly fears related to various animals (zoophobia), such as cats, spiders, snakes, and dogs, it is crucial to explore the possibility of modifying the game to effectively address multiple types of phobias. The park environment appears to be conducive to addressing various animal phobias and specific phobias such as paruresis. Accessing 10 participants was hindered by the temporary filtering of Instagram in our country. In addition, 2 individuals declined to

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participate, expressing shyness and concerns about others noticing their phobia. Our observations suggest that men with ailurophobia conceal their fear more frequently. Notably, ailurophobia predominantly affected women, as 90% (9/10) of our participants were women (Table 1). Ailurophobia began in 70% (7/10) of the participants during childhood and 30% (3/10) during adolescence. The minimum and maximum ages of onset of phobia in the samples were 5 and 18 years, respectively. Regrettably, animal phobias in our country, particularly cat phobia, have been largely overlooked, leading individuals to live for many years in a completely curable condition without seeking treatment. Innovative and early interventions, for example, our tool, could treat patients from childhood when anxiety starts and reduce the negative impact of untreated phobias. There is a pressing need for screening and diagnostic games as a primary step, followed by therapeutic games. The main cause of participants' phobia stemmed from an unexpected childhood encounter with a cat.

Table 1. Participants' characteristics.

Characteristics	Non-BF[a]	BF
Age (years), mean (SD)	24 (7.31)	33.5 (7.16)
Female, n (%)	5 (100)	4 (80)
Video game playing hours per week, mean (SD)	6 (8.52)	1.5 (3.08)
Median level of education	Diploma degree	Master's degree
Years living with cat phobia, mean (SD)	15.6 (5.68)	21.6 (12.01)
Married, n (%)	2 (40)	2 (40)
The onset of phobia, n (%)		
Childhood	4 (80)	3 (60)
Adolescence	1 (20)	2 (40)
Youth	0 (0)	0 (0)
Adulthood	0 (0)	0 (0)
Age of onset of phobia (years), range	9-13	5-18

[a]BF: biofeedback.

Possible Positive Effects of the Gamified VRET Augmented With BF

Effect 1: Intrinsic Motivation

The average intrinsic motivation of the groups indicated better results for the BF group across all 4 mandatory games with 49 scores (the sum of motivation scores for BF vs non-BF in the first to fourth sessions were: 182 vs 174, 178 vs 169, 191 vs 160, and 182 vs 181). However, the results (P value [groups]=.15>.05=∝ and $F_{1,3}$=2.165) indicate no statistically significant difference. The analysis used a 2-factor ANOVA with replication.

On the basis of the results (P value [sessions]=.91>.05=∝; $F_{3,3}$=0.171), we can conclude that there were no significant differences in the effectiveness of the groups across the different sessions.

There were no significant differences in the interaction between groups and sessions (P value [interactions]=.61>.05=∝ and $F_{3,3}$=0.609).

Of the 5 participants in the non-BF group, 4 played 2 levels using BF. Two of them chose each game version, whereas the other 2 preferred the BF version exclusively.

Overall, BF had a greater effect on motivating patients. With greater efforts to leverage its potential within the game, the positive impact on motivation can be substantially enhanced. Nevertheless, it is essential to note that the non-BF version fosters motivation by incorporating 2 vital motivational elements: gamification and VR.

As participants enter new and especially challenging stages, their internal motivation to play tends to decrease, whereas their anxiety increases. However, with repeated attempts at this stage, motivation gradually increased, and anxiety levels tended to decrease.

Effect 2: Simulating Fearful Situations

The non-BF group had, on average, 40 points higher anxiety scores across all 4 rounds of the forced games compared with the BF group (the sum of anxiety scores for BF vs non-BF in the first to fourth sessions were: 11 vs 33, 22 vs 34, 29 vs 34, and 27 vs 28). There was a statistically significant difference between the 2 groups (P=.009<.05=∝ and $F_{1,3}$=7.805). The total anxiety score for the non-BF group was 129, whereas that for the other group was 89, indicating the beneficial role of BF in anxiety control. This finding also suggests that using BF could potentially reduce the need for a therapist's presence. Caution is advised when interpreting these data, as it may be influenced by individuals with severe phobias. The crucial point is that both game variants can evoke anxiety, as they simulate fearful situations. During the games, 5 participants (4 without BF and 1 with BF) experienced extreme stress, necessitating temporary pauses to help them calm down. One participant even reported an increase in blinking frequency when feeling nervous while playing the game.

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The P value (sessions)=.32>.05=∝ and $F_{3,3}$=1.204, indicating no significant differences in the effectiveness of the groups across different sessions. Many participants experienced anxiety even before the games began, which significantly impacted their anxiety levels during training (picture step). One participant even mistook pictures of cats in the training as real cats because of high tension. In addition, 6 participants (4 without BF and 2 with BF) responded to the cat pictures. On the basis of the data and participant feedback, the order of increasing anxiety levels followed the sequence of stages, starting from the trial game and progressing through the forced games in the following order: fantasy, low-poly, and high-poly cats. Similarly, the normalization of cats occurred in the following order: fantasy cats, pictures of cats, low-poly cats, and high-poly cats. For instance, anxiety levels increased as the number of cats increased. No significant differences in interaction between groups and sessions were observed (P value [interactions]=.20>.05=∝ and $F_{3,3}$=1.652).

Effect 3: Controlling Stressful Circumstances, Eliminating Therapists' Presence, and Mitigating Catastrophic Thoughts

Most participants about the positive signs of reducing their catastrophic thoughts expressed that encountering cats had started to feel somewhat normal. They noted that with continued play, their irrational fears could be replaced with more rational ones, and these positive changes could extend beyond the game to real-life environments. One participant shared, "Before playing the game, I couldn't even look at cats' stickers or images, and I used to throw my toy cat out of my room window into the street." Another participant expressed, "Encountering fantasy cats in small numbers has become normal for me, and I believe that over time, my fear of other types of cats will decrease." Follow-up data are required to verify the lasting impact of these positive changes.

A total of six noteworthy comments on the elimination of therapists using BF were suggested: (1) after a few sessions, the game can be played independently without therapists; (2) the treatment process can be shortened; (3) patients with milder phobias can benefit from playing without therapists. Otherwise, therapists' support is necessary during the initial sessions; (4) the game is more beneficial for therapists, offering a controlled environment free of danger; (5) combining virtual and face-to-face treatments is recommended, starting with the game to prepare patients for real-life cat encounters; and (6) BF cannot provide the psychological support therapists offer. One participant, Fatemeh, repeatedly reassured herself during gameplay, saying, "Fatemeh, it's just a cat, it's nothing, keep calm." The necessity of a virtual therapist to provide reassurance and guidance during moments of severe anxiety was evident. Participants either managed to calm themselves or received assistance from us. At times, we had to explain the unlocked stage scenarios to convince the participants to proceed with the remaining games.

To enhance the effectiveness, some participants suggested that the game should display their effort by showing the minimum and maximum HR and the time taken to complete a level. In addition, 2 positive comments regarding HR were as follows: "I noticed that my fear is higher before encountering cats, but my heart rate decreases when I face them" and "Before playing, I believed my fear of cats was overwhelming, but the game helped me realize it wasn't as intense as I thought."

Effect 4: Preliminary Effects on Ailurophobia Treatment

Using ANOVA single factor, we could not detect a difference between the groups ($F_{1,8}$=0.073, and P value=.79>.05=∝). The S-scale scores worsened by 50 and 33 points in the non-BF and BF groups, respectively (Table 2). Both variants induced anxiety, but the BF group showed lower anxiety levels, suggesting that BF was more effective in reducing stress.

No significant difference between the groups was detected (P value=.63>.05=∝, and $F_{1,8}$=0.256). The non-BF group improved by 67 points in the FCQ scores, whereas the BF group worsened by 42 points (Table 3).

The significant difference in scores can be attributed to one participant in the non-BF group who initially experienced high anxiety before and during the game. However, as she played more games, her scores on the S-scale (64-28) and FCQ (119-13) decreased dramatically. She mentioned that she used to be greatly bothered by cats being near her or hearing their voices, but after playing the game, she felt less anxious. The constant presence of cats in the game and being able to hear their voices helped her overcome her fears. It is noteworthy that this participant played the game more than all other players, completing 10 levels, including the training stage. In the last 3 stages, the participants specified an anxiety level of 1 out of 10. Initially, we considered this participant's data as an outlier, but because of the high number of games played, we retained her data. This observation clearly indicates that playing the game more frequently helps to normalize interactions with cats. Her anxiety scores (of 10) for playing 9 levels of the game were (the data related to training was excluded for all participants): 10, 10, 8, 3, 3, 2, 1, 1, 1. By replacing her score with a typical number, we obtained more reasonable scores. The non-BF and BF scores worsened by 9 and 42, respectively. Both game versions induced similar anxiety levels in participants. Some of the participants experienced symptom improvement. To assess the initial positive signs of phobia treatment using the FCQ, we should wait until the completion of 10 game stages on average. All participants completed this questionnaire shortly after the games (within a maximum of 10 minutes), and the effects of anxiety caused by fear were still evident. We had to reassure them that the game was not very scary and that the unpredictable event they feared would not happen in the next level, as 4 participants experienced extreme anxiety. These participants took longer breaks between the phases or temporarily stopped playing the game. This anxiety could adversely affect their grades. In addition, approximately 80% (8/10) of the participants mentioned that playing the game more often helped them become accustomed to seeing cats.

All participants expressed a preference for the gamified VRET with BF, stating that the experience was more novel and perceived as more effective in reducing fear.

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Table 2. Pretest and posttest scores of S-scales.

Groups	Pretest	Posttest	Difference
Non-BF[a] (control)	39	61	−22
Non-BF	64	28	36
Non-BF	38	67	−29
Non-BF	46	67	−21
Non-BF	33	47	−14
BF (experimental)	39	45	−6
BF	29	28	1
BF	42	65	−23
BF	39	37	2
BF	34	41	−7

[a]BF: biofeedback.

Table 3. Pretest and posttest scores of Fear of Cats Questionnaire.

Groups	Pretest	Posttest	Difference
Non-BF[a] (control)	71	100	−29
Non-BF	119	13	106
Non-BF	82	94	−12
Non-BF	112	92	20
Non-BF	101	119	−18
BF (experimental)	84	97	−13
BF	70	82	−12
BF	76	104	−28
BF	89	85	4
BF	89	82	7

[a]BF: biofeedback.

Patients' Preferences About the Designed Treatment

Most participants expressed that the game had a positive therapeutic impact and was capable of normalizing their interactions with cats. In total, 2 participants played the game 7 and 10 times and reported significant changes in their perception of cat-related fears. They shared that their perceptions of cat fear transformed, and encountering cats felt normal. Moreover, they believed that this effect could be extended to real-life situations. One participant shared, "I used to feel uneasy when cats were nearby, and the sound of cats was distressing for me. But now, as cats are consistently present in the game, and the sound of cats is played during the gameplay, being close to cats and hearing their sounds has become completely normal for me." In the last 2 stages, their anxiety levels were reduced to a rating of 1 of 10. Before playing, most participants anticipated that cats would appear in the forest and perch on the tree branches. They expected the paths where cats were located to have denser and more crowded areas, featuring an abundance of trees, wooden huts, and gazebos with cats nearby. One commented, "The space provided is too vast, and it could be made more intense to induce fear. It would be beneficial to create some narrower paths leading to a door where cats are positioned. This could instill more fear. Generally, the game's paths are not challenging situations, and a darker environment could make the cat's eyes more prominent." These comments contradict most participants, who appreciated the game's positive aspect of indirectly implementing treatment and displaying everyday interactions people have with cats. Incorporating various environments and cat behaviors could further normalize the interaction with cats from all angles. However, these changes must be introduced with caution to avoid reinforcing the perception that cats are scary. In addition, the suggested locations to be included in the game range from the park environment to urban settings, such as apartments, streets, alleys, markets, cafés, dark scenes, kitchens, and garbage cans.

Some participants preferred the fantasy cats, believing that they alone have the ability to normalize interactions with cats because they highlight the positive aspects of cats such as their beautiful eyes and portray them as attractive, safe, and less harmful. Designing different fantasy cats appears to be a reasonable way to encourage individuals. One participant said, "It bothers me

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that the cats' heads are small and their tails are long. In contrast, fantasy models had big heads and short tails. In different game levels, placing fantasy cats next to other cats conveys the feeling that all cats are harmless. Starting with images of rough and fat cats and gradually increasing the number of cats, and transitioning them to real models, helped me realize that the initial stage's image was merely in my mind and unreal. As the cats' numbers increased, I discovered that they did not pose any harm." These eye-opening opinions shed light on an overlooked aspect—the psychological impact of the game's difficulty levels and cat types.

Preferring fantasy cats indirectly revealed that low- and high-poly cats mostly evoke fear. Most participants found these cats to be more rational. Increased aversion and avoidance were observed in places with more cat voices and presence. Longer sounds also intensified fear.

On the basis of these findings, it is suggested to gradually introduce sounds, starting from cats with no sounds to short and pleasant sounds and then to real single and multiple sounds. The maximum fear was near the boxes where the number and noise of the cats were higher. Although this arrangement was found to be effective and logical in normalizing interactions with cats, high fear levels may have led some participants to avoid playing altogether. One participant preferred orderly and grouped cats for a calmer experience, whereas disorderly placement near the box increased fear. These reasons highlight the significance of using fantasy cats. Most participants found the size of the cats were found to be suitable. However, larger cat sizes, such as pictures of striped cats and low-poly cats, increased anxiety. The picture level, considered the easiest, induced anxiety and fear in most participants (6 of 10). Concerning cats' behavior, most preferred nonreactive cats, such as fantasy cats that simply look at the sky in a cartoony manner; cats sitting and grooming themselves; or cats moving along the path without any reaction. Most participants disliked black cats waving their hands or white cream cats turning and staring at the player.

Most participants expressed the need for the game's cat designs to closely resemble real-world cats. The following cats were not used based on their comments:

- Spotted (mainly black and white) and gray-striped cats, which are abundant in Iran.
- Kittens: Participants made three points: (1) kittens may not have a significant therapeutic effect, but they enhance the game's appeal and create a more lifelike environment; (2) the treasure finder can be replaced with a fantasy kitten, allowing for a more captivating display of less favored features of cats, such as their nails, tail, and head. Moreover, their beautiful eyes can be showcased as larger; and (3) the option of raising a kitten in the game.
- Fierce-looking cats with grabbing capabilities: adding them requires expert opinions. Although statistics on cat grabbing are limited, the actual occurrence is likely to be minimal. People's intense fears may exaggerate this concern.
- A mother cat breastfeeding her babies for a heartwarming and motherly touch.
- Sphynx cats: despite being rare in Iran, could enhance realism and normalize fear of diverse cat breeds.
- Fat or fluffy cats resembling a doll-like appearance.
- Placing cats amidst the greens and bushes along the paths.
- Injured (eg, cats with one eye or leg) or lifeless cats.
- Sudden movements of cats (eg, cats leaping out of trash cans): mentioned by most participants.
- Feeding cats: some participants did not agree with implementing this feature.

In conclusion, the game layout and models were considered logical by most of the participants. They stressed that fighting with cats in the game could worsen their fear, making a clear distinction between a therapeutic game and one designed solely for entertainment purposes. This opinion is in agreement with the clinical expert (the fourth author) who emphasized that the games for treating animal phobias should avoid action and fighting scenarios. For example, reducing the fear of cockroaches using scenarios where they stomp on or kill them may adversely affect.

Heuristics Evaluations

As presented in Tables 4-7, of the 44 heuristics adapted from the Nielsen user interface, VR, and playability, an impressive 41 principles obtained scores of 62% or higher, underscoring the tool's potential as a therapeutic product. Moreover, it enhances patient adherence to the treatment process.

Overall, 90% (9/10) of the participants found learning to play the game remarkably easy, particularly with the convenience of using just one button under VR glasses, which proved beneficial for those with mobility disabilities. Two suggestions emerged concerning in-game movement: (1) incorporating a back button and (2) movement through walking, potentially achieved with motion-sensing devices. However, careful consideration is necessary to ensure that they positively impact the player experience. Some individuals may prefer a less cumbersome setup. To enhance experience, it is crucial to incorporate a tutorial in a video or audio format for first-time users by introducing relaxation techniques to manage panic situations. Many participants required clarification that frightful situations would not occur at the subsequent levels. Providing detailed descriptions of new levels, including information about cats' types and behaviors, prevents players from creating self-made stories about cat attacks. Moreover, to improve clarity, players needed clearer instructions after opening each box, signaling that they should open 4 boxes per session. Although a ribbon in the corner of the screen displays the number of opened boxes, it does not adequately alert the players to this requirement. Among the VR principles, the navigation and orientation support principle excelled at 82%, with patients being well-informed about their in-game position. Notably, approximately 80% (8/10) of patients experienced no dizziness during extended gameplay. To increase the level of engagement and therapeutic impact, introducing a punishment mechanism, such as reducing players' points, could be beneficial. It might be worth reconsidering the features of allowing players to win the game without encountering cats. Game sounds and music received a relatively low score (51%), causing tension and unease, instead of promoting peace and happiness. The addition

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of soothing natural sounds was also suggested. In addition, consider a sound to indicate proximity to the box, reducing the need to check the bar constantly and improving the focus on gameplay. The game could benefit from a save and resume feature, especially during panic situations, allowing patients to take a moment to calm down. Some also raised concerns about the suitability of graphics for older adult audiences.

The principle of variety in the game's paths and challenges stands out as one of the main gameplay principles. Although it obtained a relatively good score (68%), most participants said that after a few stages, the game became monotonous. Players quickly realized that cats only appear in certain sections of the roads and near treasure boxes. Certain adjustments were recommended to enhance the game's appeal. Increasing the spacing between trees and raising their height can create a more immersive environment. Adding colorful elements such as flowers, toys, water views, and a gazebo in the park will infuse vibrancy into the game. In general, elevating the game's attractiveness can be achieved by introducing a greater sense of adventure without relying on unrealistic fears. One participant suggested that instead of having the treasure box as the game's goal, it could be placed in various locations within the forest, each rewarding the player with different prizes, such as food. Another suggestion was to replace the guide bar, which received positive feedback from the participants, with a map that indicated the approximate distance to the target. In addition, the introduction of a captivating and fantastical cat character instead of the current bar was recommended. In total, 2 participants pointed out that displaying HR in the corner might be somewhat distracting. It was suggested to show HR only when it was high or to remind players to reduce stress using a heartbeat's sound.

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Table 4. Results of the questionnaire designed based on [49-51] for evaluating user interfaces and virtual reality apps, respectively (Tables S1-S4 of Multimedia Appendix 1 provides the noncompressed version of Tables 4-7 containing the list of questions).

Usability heuristic and question	Question, mean (SD)	Heuristic, mean (SD)	Heuristic overall percent, %
1. Natural engagement			
Q1	3.5 (1.08)	3.7 (0.28)	74
Q2	3.9 (0.88)	N/A[a]	N/A
2. Compatibility with the user's task and domain			
Q3	3.7 (0.95)	3.7 (0.3)	74
Q4	4 (1.25)	N/A	N/A
Q5	3.4 (1.17)	N/A	N/A
3. Natural expression of action			
Q6	3.5 (1.27)	3.2 (0.42)	64
Q7	2.9 (1.20)	N/A	N/A
4. Close coordination of action and representation			
Q8	3.5 (1.27)	3.6 (0.1)	72
Q9	3.6 (1.17)	N/A	N/A
Q10	3.7 (1.25)	N/A	N/A
5. Realistic feedback			
Q11	3.7 (1.4)	3.7 (1.4)	74
6. Faithful viewpoints			
Q12	3.6 (1.2)	3.6 (1.2)	72
7. Navigation and orientation support			
Q13	4.1 (1.2)	4.1 (1.2)	82
8. Visibility of system status			
Q14	3.7 (1.25)	3.63 (0.75)	72.5
Q15	3.4 (1.17)	N/A	N/A
Q16	3.7 (1.49)	N/A	N/A
Q17	3.7 (1.16)	N/A	N/A
9. Consistency and standards			
Q18	3.7 (1.3)	3.7 (1.3)	74
10. Error prevention			
Q19	3.7 (1.34)	3.5 (0.28)	70
Q20	3.3 (2)	N/A	N/A
11. Recognition rather than recall			
Q21	3.6 (1.2)	3.6 (1.2)	72
12. Flexibility and efficiency of use			
Q22	3.8 (1.0)	3.8 (1.0)	76
14. Help and documentation			
Q23	2.9 (1.4)	2.9 (1.4)	58

[a]N/A: not applicable.

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Table 5. Results of the questionnaire designed based on gameplay part of the playability heuristics [52].

Question	Question, mean (SD)	Heuristic, mean (SD)	Heuristic overall percent
1. Player's fatigue is minimized by varying activities and pacing during game play.			
Q1	3.4 (1.6)	3.4 (1.6)	68
2. Provide consistency between the game elements and the overarching setting and story to suspend disbelief.			
Q2	3.4 (1.3)	3.4 (1.3)	68
3. Provide clear goals, present overriding goal early as well as short-term goals throughout play.			
Q3	4.3 (1.1)	4.3 (1.1)	86
4. There is an interesting and absorbing tutorial that mimics game play.			
Q4	4.5 (1.0)	4.1 (0.57)	90
Q5	3.7 (0.9)	N/A[a]	N/A
5. The game is enjoyable to replay.			
Q6	3.5 (0.7)	3.5 (0.7)	70
6. Game play should be balanced with multiple ways to win.			
Q7	3.8 (1.0)	3.8 (1.0)	76
7. Player is taught skills early that you expect the players to use later, or right before the new skill is needed.			
Q8	3.4 (1.5)	3.4 (1.5)	68
8. Players discover the story as part of game play.			
Q9	4 (0.8)	4 (0.8)	80
9. The game is fun for the Player first, the designer second and the computer third. That is, if the nonexpert player's experience is not put first, excellent game mechanics and graphics programming triumphs are meaningless.			
Q10	3.9 (1.2)	3.9 (1.2)	78
10. Player should not experience being penalized repetitively for the same failure.			
Q11	4.3 (0.7)	4.3 (0.7)	86
11. Player's should perceive a sense of control and impact onto the game world. The game world reacts to the player and remembers their passage through it. Changes the player makes in the game world are persistent and noticeable if they back-track to where they have been before.			
Q12	4.1 (1.0)	3.9 (0.28)	82
Q13	3.7 (1.3)	N/A	N/A
12. The game should give rewards that immerse the player more deeply in the game by increasing their capabilities (power-up), and expanding their ability to customize.			
Q14	3.5 (1.3)	3.7 (0.28)	70
Q15	3.9 (1.0)	N/A	N/A
13. Pace the game to apply pressure but not frustrate the player. Vary the difficulty level so that the player has greater challenge as they develop mastery. Easy to learn, hard to master.			
Q16	3.9 (1.2)	3.75 (0.21)	78
Q17	3.6 (1.2)	N/A	N/A
14. Challenges are positive game experiences, rather than a negative experience (results in their wanting to play more, rather than quitting).			
Q18	3.8 (1.1)	3.8 (1.1)	76

[a]N/A: not applicable.

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Table 6. Results of the questionnaire designed based on mechanic part of the playability heuristics [52].

Question	Question, mean (SD)	Heuristic, mean (SD)	Heuristic overall percent
1. Game should react in a consistent, challenging, and exciting way to the player's actions (eg, appropriate music with the action).			
Q1	2.8 (1.6)	2.8 (1.6)	51
2. Make effects of the AI[a] clearly visible to the player by ensuring they are consistent with the player's reasonable expectations of the AI actor.			
Q2	3.1 (0.9)	3.1 (0.9)	62.3
3. A player should always be able to identify their score/status and goal in the game.			
Q3	4.4 (0.5)	4.3 (0.14)	86
Q4	4.2 (0.9)	N/A[b]	N/A
4. Mechanics/controller actions have consistently mapped and learnable responses.			
Q5	4.4 (1.1)	4.15 (0.35)	83
Q6	3.9 (1.6)	N/A	N/A
5. Shorten the learning curve by following the trends set by the gaming industry to meet user's expectations.			
Q7	4.3 (1.3)	3.95 (0.49)	79
Q8	3.6 (1.6)	N/A	N/A
6. Controls should be intuitive, and mapped in a natural way; they should be customizable and default to industry standard settings.			
Q9	4.5 (1.0)	4.35 (0.21)	87
Q10	4.2 (0.9)	N/A	N/A
7. Player should be given controls that are basic enough to learn quickly yet expandable for advanced options.			
Q11	3.3 (1.3)	3.53 (0.32)	70.67
Q12	3.4 (1.7)	N/A	N/A
Q13	3.9 (1.4)	N/A	N/A

[a]AI: artificial intelligence.
[b]N/A: not applicable.

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Table 7. Results of the questionnaire designed based on usability part of the playability heuristics [52].

Question	Question, mean (SD)	Heuristic, mean (SD)	Heuristic overall percent
1. Provide immediate feedback for user actions.			
Q1	4.1 (1.5)	4.1 (1.5)	82
2. The player can easily turn the game off and on, and be able to save games in different states.			
Q2	2.3 (1.3)	2.3 (1.3)	46
3. The player experiences the user interface as consistent (in control, color, typography, and dialog design) but the gameplay is varied.			
Q3	3.7 (1.3)	3.35 (0.49)	67
Q4	3 (1.2)	N/A[a]	N/A
4. The player should experience the menu as a part of the game.			
Q5	3.4 (1.0)	3.65(0.35)	68
Q6	3.9 (1.0)	N/A	N/A
5. Sounds from the game provide meaningful feedback or stir a particular emotion.			
Q7	3.5 (1.2)	3.35 (0.35)	67
Q8	3.2 (1.1)	N/A	N/A
Q9	2.8 (1.6)	N/A	N/A
6. Players do not need to use a manual to play the game.			
Q10	4 (0.9)	4 (0.9)	80
7. Make the menu layers well organized and minimalist to the extent the menu options are intuitive.			
Q11	3.9 (1.6)	3.9 (1.6)	78
8. Get the player involved quickly and easily with tutorials and/or progressive or adjustable difficulty levels.			
Q12	4.1 (1.3)	3.95 (0.21)	79
Q13	3.8 (1.4)	N/A	N/A
9. Art should be recognizable to the player, and speak to its function.			
Q14	3.7 (1.2)	3.65 (0.07)	73
Q15	3.6 (0.7)	N/A	N/A

[a]N/A: not applicable.

Discussion

Principal Findings

We developed a gamified VRET augmented with BF to address ailurophobia. To our knowledge, no specialized research on ailurophobia treatment exists, either in Iran or internationally. Motivated by the high prevalence of ailurophobia and the lack of accessible gamified VR environments with BF, our main goal was to create and assess a smartphone-based VRET augmented with BF for animal phobia (cat phobia). We hypothesized that this tool would better motivate patients, manage stress, simulate fearful situations, treat phobia, and reduce therapists' involvement compared with a gamified VRET. The tool was designed based on expert sessions in video games, gamification, cognitive, and psychology. The results indicate its positive impact on specified features. Of the 44 heuristics, 41 scored above 62%, showing the potential for phobia interventions and motivating patients for treatment. Although tested on only 10 participants for a short duration (up to 3 hours without follow-up sessions), the results were reliable. Extensive data and feedback collection have been used to evaluate various aspects of the tool. On average, after 10 sessions, initial signs of improvement were observed, with slight variations depending on individuals' phobia levels. One intriguing finding was that most participants were content with the game's indirect approach to normalize interaction with cats and its nonviolent nature. They emphasized that action or combat scenarios would reinforce unrealistic fears and validate their phobia. Another significant finding was the progression of normalization in dealing with cats, tolerating their behavior, and hearing their voices, which gradually became more challenging. Although the current game normalizes communication with cats and holds good appeal, most participants suggested improvements, such as adding a variety of cats that closely resemble real-world characteristics, including voices and behaviors, to further enhance the normalization process. In addition, most participants expressed satisfaction with the game's easy movements and minimal learning curve. To enhance the experience, adding diversity and adventure while minimizing unrealistic violence was recommended. Moreover, during the evaluations, the participants strongly felt the need for a virtual therapist to provide calming guidance and support during moments of severe anxiety.

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Comparison With Prior Work

To our knowledge, no study has simultaneously used BF, VR, and gamification for the treatment of animal phobia. However, various studies have used VR and game concepts to address specific animal phobias, for example, spider phobia [12,32] and snake phobia [47]. Similar to these studies, our tool successfully induced anxiety and led to a reduction in fear levels, avoidance behaviors, and catastrophic thoughts related to phobias. In addition, it positively boosted their motivation for treatment adherence. Unlike previous studies, our unique feature was the initial evaluation, showing that participants preferred a gamified VRET with BF. It has proven to be more effective in reducing symptoms and increasing internal motivation. These findings align with recent reviews highlighting the significant anxiety-reducing benefits of combining VR and BF, along with the advantages in motivation, user experience, involvement, and attentional focus [53,54]. In contrast to our study, where more participants preferred interacting with safe stimuli such as fantasy cats, studies such as those by Dibbets and Schruers [55] and Pittig et al [56] reported that selecting riskier options led to a stronger decrease in self-reported spider fear and disgust, whereas safe choices increased these emotions. The differing outcomes could be attributed to the use of VR and 3D images. VRETs are widely recognized as an appealing treatment modality because of their perceived naturalness in the automated format. However, Albakri et al [57] suggested that augmented reality exposure therapies offer a better experience and increased realism by seamlessly integrating digital information into the real world rather than creating a completely new virtual environment. We plan to explore the implementation of our designed tool with augmented reality and compare the outcomes in future studies. Dibbets and Schruers [55] found that the number of spiders encountered did not correlate with declines in aversive feelings and avoidance behaviors. However, our study concluded that a higher number of stimuli were more effective in normalizing interactions with cats. In addition, we observed that the action and combat scenarios were not beneficial for individuals with phobias. Interestingly, snake phobia treatment in a nearly action genre format [47] lacks a rationale for its selection. Further research is required to determine and devise appropriate scenarios for individuals with phobias. Throughout this study, the need to conduct similar research was highlighted. It was not feasible to make precise comparisons with prior studies in every detail.

Limitations

The initial study on treating ailurophobia using VRETs with gamification and BF had limitations, primarily a small number of respondents. A total of 10 potential participants were inaccessible after Instagram's temporary filtering in our country. The sample was skewed toward educated participants in their twenties and thirties, indicating the need to include diverse educational backgrounds, children, adolescents, and older adults. Owing to time constraints, we did not use any statistical method to calculate the required sample size. The study by Mor et al [48] recommended a minimum of 20 participants in each study arm for feasibility pilot studies on treating flying phobia using 360° images. Certainly, a larger number of patients is needed in each arm for the primary assessments. One future work is to replicate the study quantitatively and more rigorously while also introducing another arm that uses standard and clinical exposure therapies, enabling us to evaluate the tool and showcase more applications. In addition, the small sample sizes prohibited us from examining dropout rates. The results are exploratory, and long-term effects remain unknown due to the lack of follow-up data. Only one self-rating scale, the FCQ, has been used to diagnose individuals with ailurophobia. However, it is advisable to supplement such questionnaires with a telephone or face-to-face diagnostic interview conducted by an expert clinician, typically lasting approximately 30 minutes [2,12,32]. These interviews not only boost diagnostic reliability but also enable descriptive analysis [2]. It is worth mentioning that the patients were initially asked to explain the origin and signs of their ailurophobia. Participants were randomly divided into groups; however, the equality of their stress levels was not considered. It appears that by preserving randomness, the stress levels of individuals in the study groups should be nearly equal. For example, if one group has 2 extreme cases, the other groups should also have 2 similar cases to ensure transparency and enhance the reliability of the results. Creating a real-world game proved challenging owing to the limitations of the smartphone platform. Although playability and system usability questionnaires were not rigorously assessed, they were designed based on popular usability scales, including Nielsen [49,50], VR [51], and playability [52] heuristic evaluations. Changes in the individual's physiological status, particularly HR, influence their experience. Unfortunately, this feature could not be assessed in the BF arm owing to the small sample size. Understanding its effectiveness in high-tension situations and its role in reducing anxiety remains a top priority.

Conclusions and Future Work

The gamified VRET incorporating BF for treating cat phobia could be effective and has the potential to evolve into a comprehensive tool. One way to enhance its utility is by expanding the variety of cat types and behaviors, simulating different environments where cats are commonly found, and boosting its appeal through increased adventure while avoiding the use of unrealistic fears. After modifying the tool and using more robust study designs with ample sample sizes, further investigation can explore how this tool can be used in treatments without the presence of a therapist or combined (virtual and real simulation of fear), both in clinics and remotely. The park environment has the potential to effectively treat various animal phobias and other specific phobias. Implementing a gradual progression of sound stimuli could improve the therapeutic process. Starting with serene and pleasant sounds and gradually advancing to more challenging and potentially distressing voices, like cats squealing (inspired by a participant's recollection of hearing a cat giving birth) or their aggressive vocalizations during fights. The final suggestion is to add the possibility of interacting with cats during more challenging stages, thereby bridging the game environment with the real world.

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Data Availability

The data presented in this study are available from the corresponding author upon request.

Authors' Contributions

AK contributed to the conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, software, supervision, validation, visualization, writing the original draft, and reviewing and editing. AN contributed to conceptualization, data curation, formal analysis, investigation, methodology, resources, software, validation, visualization, writing the original draft, and reviewing and editing. ZA contributed to the conceptualization, data curation, formal analysis, methodology, project administration, resources, validation, visualization, writing the original draft, and reviewing and editing. AKB and PHA contributed to conceptualization, formal analysis, funding acquisition, investigation, resources, software, validation, and reviewing and editing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Questionnaires were designed based on user interfaces, virtual reality, and playability heuristics, along with their results.
[DOC File , 136 KB - games_v12i1e34535_app1.doc]

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Abbreviations

BF: biofeedback
FCQ: Fear of Cats Questionnaire
FSQ: Fear of Spiders Questionnaire
HR: heart rate
STAI: State-Trait Anxiety Inventory
VR: virtual reality
VRET: virtual reality exposure therapy

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Original Paper

Using a Virtual Reality Tool to Provide Primary Prevention Training in the Construction Field Following a Periodic Medical Visit: Cross-Sectional Study

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Abstract

Background: The construction field is highly concerned with the risk of work-related accidents, and training employees is difficult due to their small numbers in most companies.

Objective: This study aimed to study the impact of a virtual reality (VR) training tool following a periodic occupational health medical visit on the feeling of personal effectiveness in preventing occupational risks related to co-activity on a construction site.

Methods: We conducted a cross-sectional study with employees who had a periodic medical visit between April 1, 2022, and October 13, 2022, in a French occupational health service specializing in the construction field (Services Médicaux Interentreprises Bâtiment Travaux Publics [SMIBTP]). The employees were divided into 2 groups according to the training received: a medical visit alone or coupled with a session with a VR tool. We compared the scores for a “feeling of self-efficacy in occupational risk prevention” using the Fisher exact test.

Results: Of the 588 employees included, 210 had a medical visit alone, and 378 had a medical visit coupled with VR training. Training with the VR tool was associated with an increased “feeling of self-efficacy in occupational risk prevention.” The employees who benefited from the training reported a willingness to apply the advice given on prevention to a greater extent than those who did not, and they believed that risks on the worksite could be reduced using this tool.

Conclusions: Using VR training as a complement to periodic medical visits in an occupational health service improves the feeling of personal effectiveness in occupational risk prevention at the end of the training. If this trend is confirmed over a longer period of time, it could be an easily accessible prevention lever for employees in the future.

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KEYWORDS

virtual reality; virtual training tool; prevention; occupational medicine; construction

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Introduction

Overview

The building and construction field is one of the most hazardous occupations in France. The main risks identified are the risk of road accidents, chemical risks, and musculoskeletal disorders, as well as risks related to the work environment and working with equipment. There are numerous work-related accidents, both fatal and nonfatal, with a major medicosocial impact on the individual and the community (long and costly medical care, prolonged absence from work negatively affecting the employer) [1]. In France, it is the leading field in terms of the frequency of work-related accidents, and the prevention of occupational risks remains difficult to achieve [2].

These difficulties are specifically related to collective prevention, which needs to be applied to a wide variety of tasks, sometimes in varying conditions and subject to change. Co-activities may be performed with employees from other companies in locations regularly situated very far from the company's head office. Small and medium-sized construction companies are the most affected by the lack of accessible risk prevention [3]. They also represent 99.8% of the companies and 45.7% of the jobs in France [4].

Health Monitoring of Employees in France

In France, all employees must undergo a periodic medical visit (at least every 5 years) in an occupational health services center. The main mission is to avoid any alteration in the employees' health due to their work. Thus, during these visits, employees receive advice to prevent occupational risks [5].

The Services Médicaux Interentreprises Bâtiment Travaux Publics (SMIBTP) is an occupational health service in charge of medical visits in the field of building and construction activity. In 2018, the SMIBTP monitored 2001 companies and 15,176 employees, mostly working in small and medium-sized companies. These companies work on a large number of sites throughout northern France. Since February 2022, the SMIBTP has been experimenting with a virtual reality (VR) training tool to train employees in the primary prevention of occupational risks related to co-activities on construction sites at one of its 2 consultation centers. The VR training is always preceded by a medical visit.

Virtual Reality

VR is a computer technology that involves real-time simulation and interaction through visual and auditory sensorial channels [6]. Computer-based 3D environments provide sensory information in a form similar to that received from the real world. VR allows individuals to experience and interact with or within environments with enhanced feedback [7-9]. To do this, users are required to be equipped with a VR headset that uses the principle of a stereoscopic 3D display connected to a computer interface to enable reproduction of the sensation of interaction with the artificial environment. The SMIBTP is the first occupational health service in France to have used a VR tool to provide additional prevention training for employees undergoing periodic medical visits. The goal of the SMIBTP is to provide employees with additional training in occupational risk prevention, with the aim of reducing the risk of accidents on site.

Objectives

No study has yet been conducted on periodic medical visits in an occupational health service coupled with a VR educational tool. A study in Finland compared VR with lecture-based safety training and found that the feeling of personal effectiveness in occupational risk prevention was increased by VR at the end of the training [10]. On a more general note, a review of the literature was carried out in 2023 on VR training and its impact on prevention, focusing in particular on the construction sector and its risks, highlighting that, although there appeared to be a positive impact, there was a lack of experimental studies in this field [11]. This was also highlighted in a meta-analysis published in 2023 [12]. However, it's important to keep in mind that these reviews pool together studies with different methods. Some studies are based on immersive technologies such as head-mounted displays, which rely on a computer connection [13], and mobile VR, which relies on the use of a smartphone [14]. Others have used less immersive techniques such as the Cave Automatic Virtual Environment, which involves virtual reality spaces where the walls, floor, and ceiling act as huge projection surfaces [15]. For the same method, the tools may vary (eg, headset brand), and above all, the context of the serious game may be very different (eg, risk prevention specific to certain trades vs risk prevention linked to co-activity on construction sites here).

The main objective of our study was to determine whether VR training had an impact on the feeling of self-efficacy in occupational risk prevention compared with a medical visit alone.

As a secondary objective, we wanted to know how the employees rated this additional VR training compared with the medical visit alone.

Methods

Design

This cross-sectional study included employees coming for a periodic medical visit to the SMIBTP who presented between April 1, 2022, and October 13, 2022, at one of the 2 centers.

The employees received 2 types of prevention training depending on the center in which they were examined. The employees in the first group had a medical visit coupled with VR (MV+VR group) training at the end of their periodic medical visit (Site A). The employees in the second group (Site B) had a medical visit alone (MV group).

Only employees performing manual work on construction sites were included in the study (engineers or secretaries were not included). In addition, in the VR group, only employees who completed the entire training (eg, no interruption due to motion sickness) were included.

The only exclusion criteria were an employee's past or present refusal of personal data collection and an insufficient knowledge of French.

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Periodic Medical Visit

The role of occupational health services in France is to prevent any damage to workers' health caused by their work. The periodic medical visit is a preventive training tool used to this end. During these visits, workers can receive individual advice adapted to the workstation they occupy within their company. This involves oral advice, for example, on wearing personal protective equipment or using collective protective equipment. It may also, for example, involve a physical examination to assess the way employees bend over to pick up items from the floor. Finally, it may involve the delivery of paper documentation specific to the risks and workstations concerned.

Virtual Reality Tool

The VR training tool used by the SMIBTP is a serious game entitled SRC-Bâti VR (ViRtual Création), which aims to improve the occupational risk prevention skills of construction workers using VR digital simulation. SRC-Bâti VR emphasizes the co-activity aspect of construction sites and therefore the interaction between employees with very different workstations. Relative to a typical medical visit, it is less theoretical and more closely approaches real work, which is expected to have a positive impact in terms of prevention [16]. ViRtual Création was created in 2018 to develop software as an educational tool to improve worker safety.

The training sessions lasted between 7 minutes and 10 minutes, and a technician was present to equip the employee and explain how the device works. The training took place in a dedicated area of more than 10 m². The technician did not interfere during the training, except, for example, to prevent the employee from colliding with the equipment in the room.

During the training, the employees moved freely on a construction site. Workstations were clearly identified by markers. When the employee went to a workstation, a multiple choice question appeared about an accident risk at the workstation. If the employee did not answer correctly, the accident occurred, and a correction was provided. When an accident occurred, the employee's senses were stimulated to raise awareness of the risk. Workstations at which there was a risk of falling made a strong impression, as the impression of falling was real, as were situations in which there was a risk of being crushed. SRC-Bâti VR therefore offered a realistic simulation that served to teach skills in the prevention of occupational hazards linked to on-site co-activity. This realistic aspect gave a dimension of play to the VR simulation, with employees positively reacting to these virtual accidents, sometimes providing them with a simulation of what would happen (employees were never evaluated on their performance in the questions, which served only as an introductive teaching aid).

Depending on the employee's profession, 2 types of VR training were possible: one focused more on road work, and the other focused on building construction. Of the 20 possible workstations, 7 were randomly presented during the training, and 1 had to be present (possible workstations are shown in Table 1). No other customization was implemented in addition to the basic tool. Employees moved around the site by teleporting from one workstation to another over short distances, rather than gliding along, using joysticks. Although the training is short, the involvement of participants and interactivity and immersion offered by VR distinguish it from a simple paper questionnaire with the same questions (certainly greater involvement). The risks addressed were representative of the major risks on a construction site. Figure 1 illustrates how an employee is notified of a workstation, and an example of a workstation is shown in Figure 2. Figure 2 shows, on the left, the initial risky situation in which a truck backs up toward the employee in training and, on the right, the correction involves the employee moving away from the truck (green proposal). The red proposal indicates that the employee made the wrong choice before the correction and was run over by the truck. Demos can be viewed online [17]. The headset was a VIVE Focus 3 because, at the time the training was set up in 2021, it was the headset recommended by ViRtual Création and ViRtual Création was, at the time, the only French company identified by the SMIBTP that offered ready-made training material for building construction and road works. Since then, another solution dedicated to on-site risk prevention has appeared in France: VIRTUAL CONSTRUCT (Mimbus).

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Table 1. Possible workstations depending on the training scenario in the Bâti VR serious game.

Scenario	Workstations common to both scenarios	Scenario-specific workstations
Road work	• Putting on personal protective equipment upon arrival on site[a] • Handling an unstable catwalk • Putting safety caps on the ends of iron bars • Waiting for trench walls to be reinforced to avoid being buried and limit machine traffic nearby • How to limit the risks associated with the vibrations from a jackhammer • How to deal with a truck backing up on a worksite • In front of an area cluttered with equipment, clearing a passageway without the possibility of falling objects before carrying out work in this space • In front of a colleague passing close to a load-lifting machine, informing the driver of the presence of the colleague to avoid any accidents • Using safety barriers when passing near holes in the ground	• Not driving past construction machinery but going around it by following the markings on studs • Using appropriate personal protective equipment when operating a circular saw • Using available handling equipment to carry loads instead of carrying them yourself • Replacing defective site signage • When laying asphalt on the road, wearing gloves, long sleeves, and pants for protection • Not working on a running construction machine engine • Using antipollution kits in the event of an accidental chemical spill on site • Bypassing work areas and following safe paths when moving around the site • When a construction machine reaches a buried network, stopping the machine and continuing work by hand • Warning a truck driver if he is going to hit a power cable when reversing • When climbing into a construction machine, always maintaining 3 points of support
Building construction	• Putting on personal protective equipment upon arrival on site[a] • Handling an unstable catwalk • Putting safety caps on the ends of iron bars • Waiting for trench walls to be reinforced to avoid being buried and limit machine traffic nearby • How to limit the risks associated with the vibrations from a jackhammer • How to deal with a truck backing up on a worksite • In front of an area cluttered with equipment, clearing a passageway without the possibility of falling objects before carrying out work in this space • In front of a colleague passing close to a load-lifting machine, informing the driver of the presence of the colleague to avoid any accidents • Using safety barriers when passing near holes in the ground	• How to avoid injury when carrying a heavy load • On scaffolding, limiting the risk of accidents by avoiding the presence of people working on several levels • Ventilating and vacuuming when using a sander • Before working on a pressurized water pipe, turning off the water supply completely • When using electrically-powered machines, never repairing the machine or its connections yourself • Using appropriate personal protective equipment when working near a colleague using a grinder • Disposing of rags soaked in chemical products after use • Reducing noise exposure by enclosing the compressor in dedicated rooms • Wearing appropriate gloves when welding • Alerting the colleague in charge of any abnormalities in load-bearing equipment • Using rolling scaffolding for occasional work at height

[a]Workstation mandatory for all training sessions.

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Figure 1. Representation of a workstation accessible by the employee in the Bâti VR serious game.

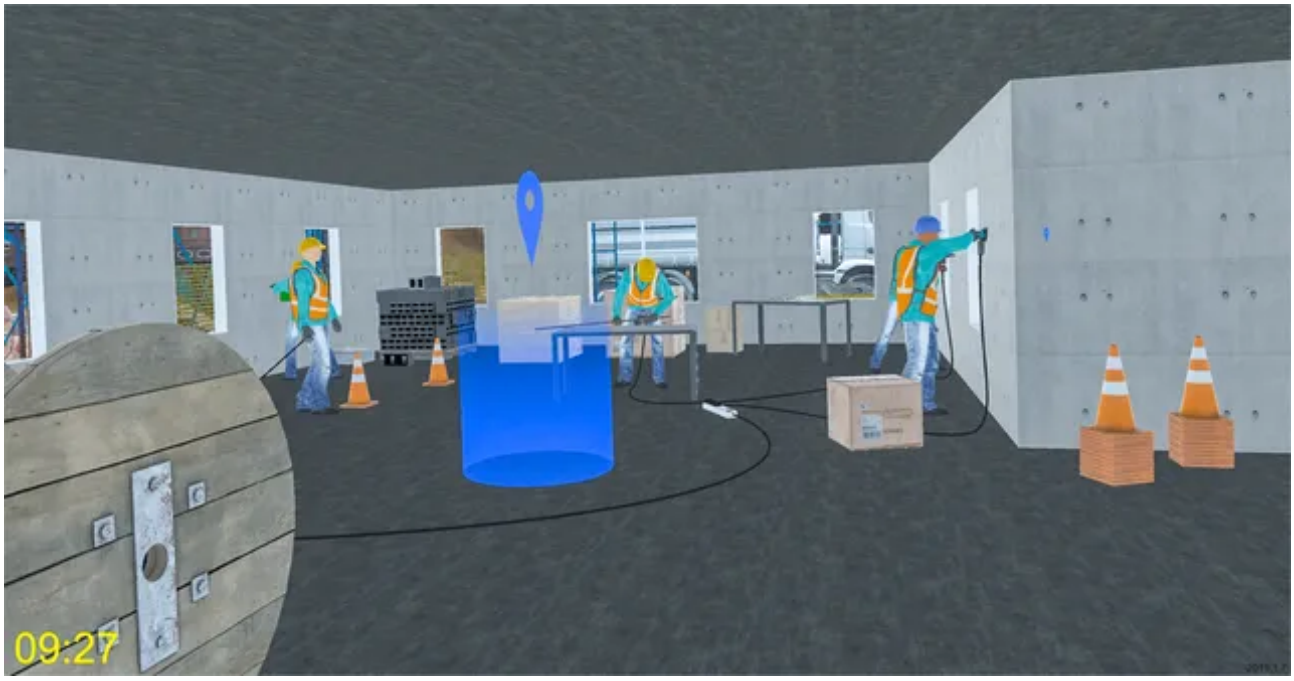
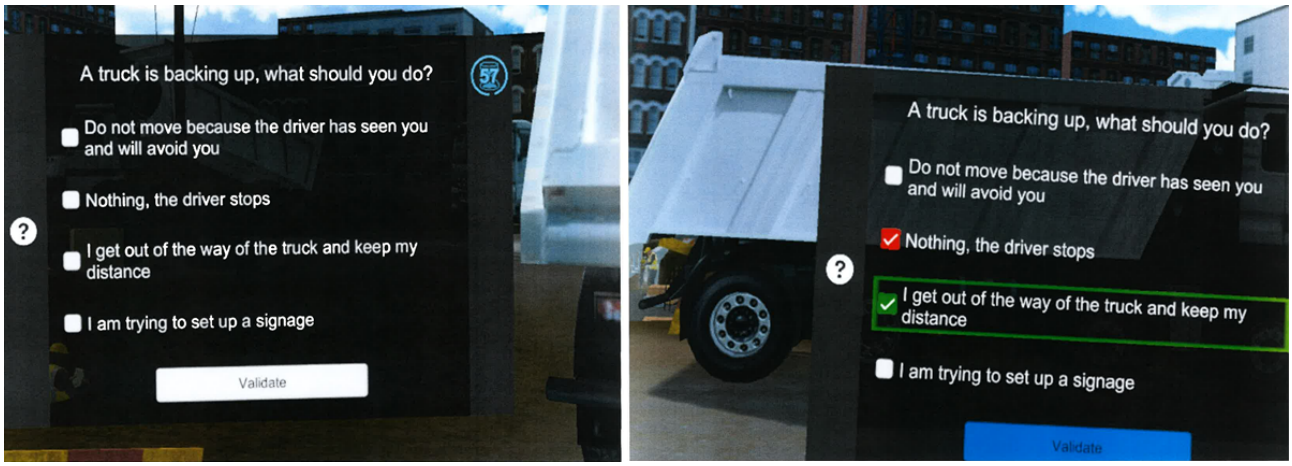


Figure 2. Example of a workstation in the Bâti VR serious game in which an employee is at risk of being run over by a truck.



Ethical Considerations

As this was a cross-sectional study evaluating current practice in the use of virtual reality, it did not require review by an institutional review board. Virtual reality was used independently of the study, with only an anonymous virtual reality evaluation questionnaire added by our teams. The study was carried out in compliance with good data protection practice, with the agreement of the data protection officer of the Université de Picardie Jules Verne. Our study was not funded by ViRtual Création and we did not collaborate with the company in the conduct of the study.

Data Collection and Variables

We collected data using a questionnaire built using the LIMESUVEY tool provided by the University of Picardie Jules Verne. The questionnaire was completed directly following the intervention (site A) or after the medical visit (site B). The data collected were demographics (age, gender, size of the company in which the employee worked), type of medical visit (with or without VR), and questions related to the feeling of self-efficacy and their rating of the training using 5-point Likert scales. These questions have not been validated and were defined by the authors. The questionnaire we used, based on the LIMESUVEY tool, also did not undergo a prior validation study. It was, however, partially based on the model for self-efficacy questions by Kirkpatrick and Kirkpatrick [18], which is a training evaluation method based on 4 levels: reaction, learning, behavior, and results. It enables assessment of the effectiveness of a training program at different levels, from participant reactions to concrete results for the employer. This model is widely used in training and human resources development to measure the impact of training programs. We only studied reactions, as our study design did not allow for employees to be contacted at a later date. The immediate reaction was assessed by the statement “I feel more effective in prevention.” We wished to address the question of what employees felt they could apply in practice just after their training, in particular regarding on-site co-activity, using the following 2 statements: “I am ready to apply these prevention rules” and “I think that

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these prevention rules can reduce the risks with regard to other colleagues on the site." The other 2 questions were aimed at evaluating the training received in itself: "My visit to the SMIBTP was worth it" and "I learned about prevention."

To explore gender, we asked employees to indicate whether they defined themselves as male or female.

Statistical Analysis

Employees were divided into 2 groups based on the 2 types of prevention training (MV *vs* MV + VR). The primary endpoint was a difference (as a percentage) between the responses of the 2 groups for each item (on our Likert scale) on questions relating to "feelings of self-efficacy in the prevention of occupational risks." The secondary endpoint was the difference (as a percentage) between the responses of the 2 groups to questions relating to the rating of the training. Responses measured on the Likert scales were not transformed into a quantitative variable, to not distort the nature of this mode of questioning.

Baseline demographics and clinical characteristics are expressed as means (SDs) or medians (IQRs) for numerical variables and frequencies (percentages) for categorical variables. Between-group comparisons were performed using the Mann-Whitney *U* test (for age) and Fisher exact test for categorical variables (size of the company and gender). The chi-squared test could not be used because the number of participants for certain response modalities was <5. The Fisher exact test was used to assess the association between the type of prevention training and the primary and secondary endpoints. A *P* value of .05 was considered significant for all tests.

All statistical tests were performed using R software (version 4.0.0, R Core Team, R Foundation for Statistical Computing). The data and R scripts are available on MENDELEY [19].

Results

During the study period (April 1, 2022, to October 13, 2022), 588 employees were recruited.

The baseline participant characteristics by type of prevention training are summarized in Table 2. The study population was predominantly male (571/588, 97.1%). The mean age was 33.15 (SD 12.1) years. By comparison, in 2019, men represented 87.89% of employees in the construction industry in France, and the mean age was 42 years [20,21]. There was not a statistically significant difference between the 2 groups in terms of gender, but there were statistically significant differences for age and company size. Of the 588 employees, there were 210 employees (35.7%) who had the medical visit alone (MV group) and 378 employees (64.3%) who had the medical visit coupled with VR training (MV+VR group). There were no missing data.

The results for the "feeling of self-efficacy in occupational risk prevention" are shown in Table 3. The MV+VR group had a greater feeling of self-efficacy in prevention than the MV group. For each question, there was a statistically significant difference at the 5% risk level, indicating that the MV+VR group felt more effective in prevention in general and, more specifically, in co-activity on worksites and would be more inclined to apply the prevention rules learned during their visit to the occupational health service.

The results of the ratings of the interventions received by the 2 groups are shown in Table 4. Employees in the MV+VR group found the intervention to be more useful and to provide more knowledge in terms of prevention than those in the MV group.

Table 2. Study population characteristics by type of prevention training at the Services Médicaux Interentreprises Bâtiment Travaux Publics (SMIBTP).

Characteristic	Overall (n=588)	MV[a] (n=210)	MV+VR[b] (n=378)	*P* value
Age (years), median (IQR)	32 (23-42)	38 (28-47.75)	29 (21-37)	<.001
Male, n (%)	571 (97.1)	201 (95.7)	370 (97.8)	.19
Size of the company				.01
1-10 employees	214 (36.4)	60 (28.6)	154 (40.7)	
11-49 employees	224 (38.1)	91 (43.3)	133 (35.2)	
50-299 employees	129 (21.9)	53 (25.2)	76 (20.1)	
≥300 employees	21 (3.6)	6 (2.9)	15 (4)	

[a]MV: medical visit.

[b]MV+VR: medical visit coupled with virtual reality training.

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Table 3. Distribution of answers relating to the "feeling of self-efficacy" statements.

Questions	Responses, n (%)					*P* value
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	
I feel more effective in prevention.						.002
MV[a] (n=210)	77 (36.7)	87 (41.4)	32 (15.2)	3 (1.4)	11 (5.2)	
MV+VR[b] (n=378)	139 (36.8)	197 (52.1)	36 (9.5)	2 (0.5)	4 (1.1)	
I am ready to apply these prevention rules.						<.001
MV (n=210)	118 (56.2)	70 (33.3)	16 (7.6)	2 (1)	4 (1.9)	
MV+VR (n=378)	277 (73.3)	96 (25.4)	5 (1.3)	0	0	
I think that these prevention rules can reduce the risks with regard to other colleagues on the site.						<.001
MV (n=210)	117 (55.7)	66 (31.4)	20 (9.5)	2 (1)	5 (2.4)	
MV+VR (n=378)	282 (74.6)	90 (23.8)	5 (1.3)	0	1 (0.3)	

[a]MV: medical visit.

[b]MV+VR: medical visit coupled with virtual reality training.

Table 4. Distribution of answers relating to the evaluation of the training.

Statements	Responses, n (%)					*P* value
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	
My visit to SMIBTP[a] was worth it.						.002
MV[b] (n=210)	129 (61.4)	65 (31)	13 (6.2)	1 (0.5)	2 (1)	
MV+VR[c] (n=378)	268 (70.9)	104 (27.5)	6 (1.6)	0	0	
I learned about prevention.						<.001
MV (n=210)	75 (35.7)	93 (44.3)	19 (9)	4 (2)	19 (9)	
MV+VR (n=378)	186 (49.2)	158 (41.8)	25 (6.6)	3 (0.8)	6 (1.6)	

[a]SMIBTP: Services Médicaux Interentreprises Bâtiment Travaux Publics.

[b]MV: medical visit.

[c]MV+VR: medical visit coupled with virtual reality training.

Discussion

Principal Findings

The results of our study show that the use of a VR training tool at the end of periodic occupational medical visits had an impact on the feeling of self-efficacy in terms of occupational risk prevention in the construction field. This is an important finding, suggesting that the use of VR could have a significant impact on the occupational risk prevention practices of construction site employees. This is a useful finding, given that all employees in France systematically and regularly have such medical visits. Our results highlight a potentially important lever for the prevention of occupational risks in the construction field in the future through the improvement of employee competence.

Other Uses of Virtual Reality in the Health Field

Eiris et al [22] sought to validate safety training using 360-degree augmented reality panoramas. Their study showed the interest in the use of this method in the identification and recognition of hazards on construction sites. However, the rate of hazard identification was quite low, as only 30% of the hazards were identified by the participants. They explained this by the fact that their population was composed of students specializing in construction management (n=30) and were not building and construction professionals. They also emphasized the constructive comments concerning the ease of use of the platform, feedback that we also had in our study using VR. In our study, we did not analyze the responses to the questions asked during the VR training, as this did not correspond to our research question.

Nykänen et al [10] evaluated both the effectiveness of an immersive VR-based safety training program and a participatory human factors safety training program. The study was conducted with 119 employees working on 8 construction sites in Finland. The employees evaluated the training with questionnaires at the start, immediately after the intervention, and at a 1-month follow-up. They considered VR to be a serious tool for improving prevention skills and found that it motivated them to apply prevention rules more than after safety training based on passive learning methods. This study was conducted only with employees of medium-sized and large companies.

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Simeonov et al [23] investigated the value of reducing mechanical vibration of support structures used as walking or working surfaces when performing construction tasks at height (falls from height account for one-third of fatal accidents in construction). Employees (n=12) used instrument-carrying gel insoles connected to a VR system to test sensory perception of the feet. The study did not show any effectiveness for this technology in 2008, but given the evolution of VR technologies, it is possible that the results would be different today.

We also found studies that assessed the use of VR as a prevention and training tool in fields other than construction.

The mining industry is a field in which the risk of serious accidents and fatalities is very high. Filigenzi et al [24] highlighted the value of using VR to train surface and underground mine employees and rescue personnel in hazard recognition and evacuation routes and procedures. This study, carried out in 2000, was innovative, demonstrated possibilities, and generated interest in extending such an approach to other fields of high-risk activity, such as construction, agriculture, and the oil industry.

In the logistics field, the use of handling equipment is responsible for a large number of occupational accidents, in particular to third parties. Choi et al [25] focused on forklift drivers, conducting a study with 20 students at Hong Kong Polytechnic University specializing in construction engineering. Their goal was to investigate how a forklift driver's situational awareness of others around him can be influenced by the type of subtasks he performs. A VR environment was used as the experimental environment in which participants performed a series of subtasks, such as driving, turning, reversing, loading, and unloading: the more concentration that was required for the tasks, the higher the risk of an accident. The authors concluded that it would be beneficial to not only use additional safety devices (such as person detection devices) but also have more detailed safety training, making VR meaningful.

In the area of electrical risk training, in 2015, Zhao and Lucas [26] reported that human error was responsible for approximately 50% of all electrical-related fatalities in multiple industries in the United States. They hypothesized that effective employee safety training programs, including VR, would be the most direct approach to mitigate such errors. Their study showed the success of using VR, highlighting training that effectively visualizes invisible risks without endangering employees. Such training increases awareness of the risk and trains employees to use the necessary protective equipment.

In the health care field, VR interventions appear to be an effective tool to boost the intention to be vaccinated [27-29].

The results of our study, as well as those of others in various fields, show that VR training tools hold great potential and should be further developed to improve the prevention of occupational risks, particularly in the construction field.

Strengths and Limitations

One of the strengths of our study is that it was conducted with a large population and 2 groups who were similar in terms of gender. In addition, the completion rate was 100% due to the use of a short and acceptable questionnaire.

However, the study population was mainly composed of men, which did not allow us to obtain data on the female population in the construction field. Women are not as well represented as men in the national population of construction employees. In addition, this intervention was intended only for certain construction jobs, mainly on construction sites, where women are much less present. The female population is mainly present in the administrative field of construction and public works companies and is therefore not subject to the same occupational risks.

Employees in the MV+VR group were younger than those in the MV group, which is similar to the overall population of construction employees in France. This result was expected, given the appetite of the younger generation for new technologies, such as VR. This age difference suggests that, if this tool is deployed on a larger scale, the older portion of the construction employee population might not benefit from it, as they may not want to use it.

The employees in the MV+VR group were also more often from small companies, which can be explained by the fact that they were the target population for the occupational health service. It is possible that this influenced our results, as larger companies have more resources for prevention. The employees of larger companies might therefore find this training less useful, but we believe that this does not affect the interpretation of our results.

It should also be noted that the use of VR is already a common practice in occupational health services and that our study did not change these practices, apart from the addition of the questionnaire. We therefore believe that our intervention did not bias our results.

On the other hand, we excluded individuals with the least mastery of the French language from our study. Individuals in this group are among those most at risk of having an accident at work due to the language barrier, in particular because of difficulties in understanding safety instructions. This does not call into question the validity of our results but highlights this group's limited access to prevention through this tool. A translated version could be envisaged.

All the employees who participated were only seen once by the SMIBTP. It was therefore not possible to evaluate the impact of repeating these VR training sessions. Similarly, the design of the study did not allow an evaluation of the impact of this training at a later date. This was a major limitation of our study. Although these results are encouraging, other studies are needed to evaluate the long-term impact of VR training on the knowledge and perception of personal effectiveness in preventing occupational hazards. Longer-term studies are also needed to study the tool's impact in terms of reducing the occurrence of occupational accidents.

In the context of our study, no data were collected that could be used to identify employees. Our objective was to reproduce, as closely as possible, the real-life conditions of using the tool, and we knew that collecting identification data could have significantly reduced participation in our study. If we were to

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carry out an evaluation at a later time point, it would logically be conducted under the normal conditions of periodic medical visits in occupational health services and therefore completed within 2 years to 5 years following our study. We would ask the employees coming for a visit whether they had already received training via VR. If so, we would request that they complete a questionnaire.

Further studies will be needed to assess the acceptability of VR. Indeed, one of the classic side effects of VR is motion sickness, and some VR sessions had to be interrupted because of symptoms such as nausea [30]. VR can also alter sensorimotor and perceptual abilities, with effects that can last several hours after exposure, and cause visual fatigue and headaches [31].

The routine use of VR during medical visits by occupational health services could have an impact on occupational risk prevention in the construction field. It could be a tool of major importance, given its accessibility, but its long-term impact and accessibility need to be assessed.

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Conflicts of Interest

None declared.

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Abbreviations

MV: medical visit
SMIBTP: Services Médicaux Interentreprises Bâtiment Travaux Publics
VR: virtual reality

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Original Paper

Impact of Virtual Reality–Based Group Activities on Activity Level and Well-Being Among Older Adults in Nursing Homes: Longitudinal Exploratory Study

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Abstract

Background: In addition to illness, inactivity is a risk factor for high mortality in nursing homes. Using innovative technology, such as virtual reality (VR), for meaningful group activities could provide new opportunities for solving this problem. VR interventions have already been approved as a promising method for enhancing the health of older adults.

Objective: In this study, we examined whether VR-based group activities can have a positive impact on activity level and group interaction among older adults living in nursing homes.

Methods: We conducted a longitudinal study and provided VR interventions as a group activity once a week for 4 consecutive weeks in nursing homes. Participants were recruited based on the experience of the nursing staff members and the natural decisions of the older adults. Within a virtual cottage, designed according to the needs of the target group, older adults were able to perform daily tasks that they were no longer able to do in real life, such as gardening and making pizza. Overall, 2 psychologists measured the psychosocial capacities, activities of daily life, and well-being before and after the interventions using standardized instruments.

Results: The results focus on a total of 84 older adults from 14 nursing homes who completed at least 3 VR interventions. The results indicate that several psychosocial capacities among the older adults improved, including adherence to regulations ($P<.001$; $\eta^2=0.122$), flexibility ($P<.001$; $\eta^2=0.109$), and group integration ($P<.001$; $\eta^2=0.141$). Problems related to competence also showed a slight decrease ($P=.04$; $\eta^2=0.039$). In addition, the VR intervention promoted their proactivity ($P<.001$; $\eta^2=0.104$) and mobility ($P=.04$; $\eta^2=0.039$). During the VR group intervention, older adults' well-being could be maintained at a high level. The results highlight the beneficial effects of VR intervention as a meaningful activity in nursing homes, showcasing the potential of VR applications in this setting.

Conclusions: This study provides a novel and naturalistic perspective, offering new insights into the use of VR in nursing homes. The VR intervention was well accepted and fulfilled the aim of enhancing capacity and well-being. It could be a meaningful group activity in nursing homes to improve social group interaction. To provide stronger evidence, randomized controlled trials are necessary.

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KEYWORDS

virtual reality; group activity; aging care; older adults; meaningful activity; mental health; well-being; social interaction; psychosocial capacities; activity of daily living

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Introduction

Background

As a result of demographic changes and the development of physical and mental illnesses in the older adult population, residing in a nursing home for assisted living is a commonly chosen solution in later life. The perspectives of older adults residing in nursing homes are characterized by a prevailing sense of awaiting death and a dearth of activities that foster a sense of purpose and fulfillment [1]. Vossius et al [2] conducted a longitudinal study involving 690 older adults living in nursing homes over a span of 3 years. The median survival time in nursing homes was approximately 2.2 (95% CI 1.9-2.4) years. The annual mortality rate was approximately 30% [2,3].

On the one hand, the high mortality rate can be explained by the baseline health situation and comorbidity of the residents [3,4]. On the other hand, there is a loss of activities of daily living (ADLs). It is possible to reduce the risk of mortality by improving ADLs to maintain physical functioning [2]. ADLs encompass essential daily activities and mobility, such as eating and using the toilet. Ouden et al [5] observed a significant number of inactive older adults in nursing homes. Most of them were observed to be in a lying or sitting position [5]. A considerable proportion (67%) of the older population engaged in sedentary behavior for >8.5 hours per day [6]. This sedentary behavior and lack of communicative activity have critical implications for the prevention of physical, psychological, and social health problems [7]. This phenomenon also indicates social isolation and loneliness among older adults in nursing homes [8,9]. Older adults in nursing homes tend to be lonelier than community-dwelling older adults, even though they are often surrounded by other residents and caregivers [9-11]. Connecting with individuals with varying cognitive fitness levels is challenging in nursing home settings [10].

Several studies have been conducted regarding how loneliness and social isolation in nursing homes negatively affect mental and physical health, well-being, and mortality [12-15]. Studies have consistently shown that both loneliness and social isolation are associated with various mental health issues, including depression, feelings of hopelessness, and cognitive impairment [16,17]. Older adults residing in nursing homes experienced elevated levels of loneliness and anxiety during the COVID-19 pandemic compared to those receiving home care [18]. Overall, 69% of older individuals in nursing homes reported feelings of loneliness and 63% reported anxiety. On the other hand, among those receiving home care, 53% reported loneliness and 47% reported anxiety [18]. In addition, these conditions have been linked to impaired motor function, cardiovascular health problems, disrupted sleep, and increased frailty [13,19]. Zhao et al [20] found that higher engagement in activities was associated with lower levels of loneliness and frailty among older adults in nursing homes. The authors emphasized the importance of developing strategies to increase social and activity engagement in this population. Higher levels of activity engagement and meaningful relationships have been linked to greater satisfaction, well-being, and quality of life [15,21,22].

Therefore, there is a need to develop strategies that focus on improving ADLs, promoting engagement in activities, and enhancing social interactions among nursing home residents. These strategies have the potential to enhance overall well-being and quality of life and potentially reduce loneliness, social isolation, and mortality among older individuals residing in nursing homes [1,20,23].

Enhancing activity and social interaction among older adults can be effectively supported through meaningful daily group activities [24]. Participating in group activities fosters a sense of belonging, promotes social engagement, and contributes to overall well-being [24]. It provides opportunities for increased social interaction with fellow residents and emotional support through participating in games and identifying with teams [24]. It is also important that these activities are “meaningful” to the residents. Research by Tak et al [25] demonstrated that if activities are not relevant or meaningful to the residents, they may prefer to do nothing or passively watch television. Meaningful group activities are described as those that hold significance or provide enjoyment for individuals, aligning with their current and past interests, routines, habits, and roles and improving their mental or physical function [26-29]. It has been shown that meaningful activities enhance social engagement and well-being and reduce loneliness among older adults living in nursing homes [30]. Nevertheless, there are several barriers to providing meaningful group activities in nursing homes. One major challenge is the shortage of personnel. Nursing homes are already facing difficulties in filling nursing home positions due to a shortage of skilled workers [31], and this is expected to persist and worsen in the coming years. Insufficient staffing limits the capacity to organize several meaningful activities [32,33]. In addition, there may be constraints related to limited space and equipment within nursing homes [33]. Therefore, there is a need to develop new, low–resource dependent, easily applicable, meaningful group activities [34,35]. Moreover, the demands of older adults in need of care are evolving, including their expectations regarding the technical equipment in nursing homes. On the basis of a population survey conducted in Germany between 2009 and 2014, only a small percentage of older adults aged >65 years used smartphones, but by 2019, more than half of them were already using these devices. In addition, internet use has also experienced significant growth since 2009, with 74% of the older adult population using the internet in 2019 [35]. Therefore, introducing innovative, technology-based interventions such as virtual reality (VR) [36] for group activities could be a promising solution to improve social connections and activities for older adults in nursing homes [12,37,38].

Fully immersive VR has emerged as a feasible method of intervention in older adults’ rehabilitation and aging care [36,39]. By using head-mounted devices (HMDs) and controllers, VR technology provides users with a fully immersive experience and a sense of presence. The unique characteristics of VR offer a viable solution to the barriers faced in nursing homes [33]. These barriers include the health status of older adults, limited physical space in the environment, and organizational challenges such as staffing shortages and funding constraints. First, VR proves to be accessible and

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accommodating for older adults with limited mobility. For example, individuals can remain seated in a wheelchair while experiencing the sensation of being on a mountain surrounded by stars. This enables older adults to engage in activities that would otherwise be physically challenging or impossible. Moreover, VR interventions ensure safety as they eliminate environmental risks and can be paused at any moment, which is particularly important for populations considered vulnerable such as older adults [40]. Second, VR interventions are flexible and require minimal physical space, similar to the space requirements for small-group activities [41]. This flexibility empowers the staff members to efficiently organize activities, while also reducing the costs associated with transportation. Moreover, the effectiveness of VR interventions for older adults has been demonstrated. The immersive and presence-inducing nature of VR has shown evidence comparable to that of traditional interventions in mental health [42]. Using VR as a medium to improve ADLs for older adults has already shown promising effects [43], and it was found to be effective in reducing loneliness and social isolation [44-47]. In the field of mental health, VR is considered an effective method for training and therapy for cognitive functions and for enhancing the well-being of older adults [48-50]. In addition, several studies have reported high acceptance of VR experiences among older adults [39,51,52].

However, recent interventions have primarily focused on singular concepts such as training or entertainment, and there is a lack of studies exploring VR interventions as daily group events in nursing homes that provide opportunities for older adults to connect and interact socially. In this study, we developed and evaluated a series of VR interventions, aiming to enhance the overall health and well-being of older adults in nursing homes. The VR interventions combine training activities and entertainment to create meaningful group ADLs in nursing homes. As discussed previously, meaningful activities should align with older adults' current and past interests, routines, habits, and roles [28,29]. Studies have shown that older adults who engage in daily and household activities experience less decline in mobility [53]. For example, gardening has been recognized as a promising activity for reducing loneliness and improving socialization [54,55]. Building upon these findings, our VR group intervention focuses on providing older adults in nursing homes with virtual environments that allow them to engage in daily tasks they may no longer be able to perform, such as baking a pizza, handcrafting, and gardening. Through these simulated activities, older adults have the opportunity to experience the fulfillment of completing familiar tasks, while preserving and enhancing their physical and mental functioning. By using tasks that are familiar to them, we aimed to reduce fear or demotivation, which might occur when being confronted with new technology. The meaningful activities chosen for the VR game offer older adults an enjoyable experience and contribute to their overall well-being. Organizing these daily activities in a virtual environment incurs lower costs in terms of time and equipment compared to real-life implementation. In addition to the VR scenario, we developed an aid system and an automated program that enable staff members to easily facilitate VR group sessions with older adults.

In summary, this exploratory study investigated the effectiveness of implementing VR interventions as meaningful group activities for older adults in nursing homes. The primary focus was on evaluating the older adults' activity and mobility levels, well-being, social interaction, and mental capacities over the course of a 4-week VR group intervention. By supporting well-being and psychosocial capacities, these interventions have the potential to address key challenges faced by older adults in nursing homes.

Research Question and Hypotheses

This observational intervention study examines the following question: Does VR-based group activity have any positive impact on the daily lives of older adults living in nursing homes? The following hypotheses were tested:

- Hypothesis 1: Over the course of a 4-week VR intervention, psychosocial capacities and ADLs of older adults in nursing homes will remain stable or even improve.
- Hypothesis 2: Over the course of a 4-week VR intervention, older adults' well-being will remain stable or even improve.

Methods

Study Design

This longitudinal study using pre-post measures was conducted in naturalistic settings in nursing homes in a city with 250,000 inhabitants in Germany. After contacting all 31 local nursing homes, a total of 15 (48%) nursing homes chose to participate in the project.

Selection of Participants

We contacted all nursing homes by telephone. Subsequently, those nursing homes expressing interest were provided with a comprehensive briefing via email outlining the selection criteria. Participants were selected from the nurses in the nursing homes, who considered both the basic data (eg, medical history) about the older adults from the nursing home information system and their extensive experience in assisting older adults with their daily living, while also assessing the older adults' willingness to participate. The selection criteria were as follows: (1) older adults were aged >60 years; (2) they had at least 1 arm and 1 hand that they were able to use (this ensures their interaction with the virtual environment); (3) they were still able to see and hear, and the use of audio aids or glasses was permitted; (4) they were able to participate in an oral interview with the researchers and did not have severe dementia; and (5) they did not have diseases, such as epilepsy, that are contraindications for VR activities.

We set a control group that underwent the same measurement procedure as the intervention group, except that they did not undergo the VR intervention phase. The control group participants were chosen based on the advice from the nursing staff members. The older adults in the control group had a low willingness to participate in the VR intervention and expressed a preference for interviews. Of the 15 nursing homes, 1 (7%) chose to solely participate in the control group due to low willingness to organize new group events and expressed a

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preference for participating in the project only through interviews with older adults.

Procedure and Data Collection

The interventions were conducted for approximately 3 months in each participating nursing home. During this period, the intervention group went through 3 phases: premeasurement phase, 4 weeks of VR group intervention, and postmeasurement phase (Table 1). During the premeasurement phase, each older adult was offered an individual initial appointment. During this appointment, a psychologist explained the schedule, privacy agreement, and consent form to the older adult. One week after the initial appointment, the older adult underwent the first pretest interview (T0; baseline) with a psychologist. This baseline assessment covered mental capacity, ADLs, and well-being. In the following week, a brief, second pretest (T1) was conducted to familiarize the older adults with the well-being assessment. This served as a warm-up assessment and was repeated after each subsequent intervention session. The intervention phase began after the premeasurement phase. Group interventions were conducted every week for 4 weeks (T2-T5). These sessions were facilitated by a project psychologist and a technical assistant. Their role was to introduce the older adults to the VR program and provide support throughout the VR sessions. There were always 3 to 5 older adults in a group for an intervention. During each VR intervention session, the older adults were presented with tasks to solve in a virtual environment. After completing the tasks, the older adults participated in a 3-minute virtual tour of a landscape to relax. Following each VR group session, the older adults' individual well-being was assessed. One week after completing all 4 VR group interventions, the same psychologist who conducted the pretest interviews assessed the older adults' mental capacities, ADLs, and well-being in the posttest phase through a postintervention interview (T6). A follow-up interview (T7) with the same content was conducted 3 weeks after the posttest phase to assess the stability of the posttest results.

Table 1. Procedure of the virtual reality (VR) group intervention study in a nursing home (as per the focus of this paper)[a].

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 10
Event	• Preintervention assessment 1 (T0)	• Preintervention assessment 2 (T1)	• VR activity 1 (T2)	• VR activity 2 (T3)	• VR activity 3 (T4)	• VR activity 4 (T5)	• Postintervention assessment 1 (T6)	• Follow-up (T7)
Content	• Baseline demographic information • Mini-ICF-APP[b] • ADL[c] • WHO-5[d]	• Warm-up • WHO-5	• VR group activity • WHO-5	• VR group activity • WHO-5	• VR group activity • WHO-5	• VR group activity • WHO-5	• Postintervention interview • Mini-ICF-APP • ADL • WHO-5	• Follow-up-interview • Mini-ICF-APP • ADL • WHO-5
Implementation	• Psychologist	• Psychologist	• Psychologist and technical assistant	• Psychologist and technical assistant	• Psychologist and technical assistant	• Psychologist and technical assistant	• Psychologist	• Psychologist

[a]Some procedures such as a questionnaire for feedback and obtaining perceptions from the older adults are not presented in this table.

[b]Mini-ICF-APP: Mini-ICF-Rating for Impairment in Psychological Activities and Capacities [56].

[c]ADL: activity of daily living [57].

[d]WHO-5: World Health Organization–Five Well-Being Index [58].

The study was conducted during the COVID-19 pandemic, and the safety of our older adult participants was our top priority. From our initial contact with the nursing homes, we inquired about and strictly adhered to the COVID-19 guidelines governing group events. Our team members underwent COVID-19 testing at public testing institutes within 24 hours before each visit to a nursing home. Even if a team member exhibited symptoms similar to those of COVID-19 but obtained a negative test result, they were not allowed to enter the nursing home as an extra precaution. During individual interviews, all team members wore masks, and regular hand disinfection was practiced throughout their stay in the nursing homes. During the VR interventions, we maintained a safe distance between the older adults, and the VR equipment was thoroughly disinfected after each use to ensure the highest level of safety for all participants.

VR Intervention and Equipment

In collaboration with the technical company, VirtuaLounge, we developed a virtual vacation home to facilitate VR interventions for the older adults. We designed the meaningful VR activities in the virtual vacation home with an older adult–centered approach, drawing upon our understanding of older adults' daily routines and incorporating the valuable suggestions received

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from older adults during the pilot program testing phase while developing the VR intervention. The central aspect was to make the VR intervention as accessible as possible to the older adult population, while minimizing the barriers to use. For example, we ensured that older adults, including those using wheelchairs, could actively participate in the entire intervention by setting up the VR experience in a sitting format. We optimized the interaction with the VR environment to be easily manageable with only 1 finger, and all the tasks were designed to be completed using only 1 hand.

The interventions were conducted over a period of 4 weeks in regional nursing homes, with each session lasting approximately 30 minutes. Within each VR session, participants engaged in 4 or 5 tasks that were no longer possible for them to perform in real life. These tasks were integrated into a cohesive storyline, resulting in an immersive experience for the older adults. Our storyline revolved around 4 classic settings within a vacation home: living room, crafts station, garden, and kitchen (Figures 1 and 2). The tasks encompassed various routine activities, such as building furniture, gardening, and cooking in the kitchen. We devised a tablet control system specifically for those conducting the procedures to address the challenge of assisting older individuals wearing the nontransparent HMD. This system enables remote connectivity between the tablet and HMD. Through the tablet interface, a live view of the older adults' perspective is displayed, allowing the technical support personnel to monitor the progress of individual tasks for all participants. In addition, the tablet allows supporters to adjust the sound settings and remotely initiate or terminate the program on each HMD (Figure 3). This innovative solution enhances the ability to provide real-time assistance and control during the VR interventions.

Figure 1. Example task—gardening.

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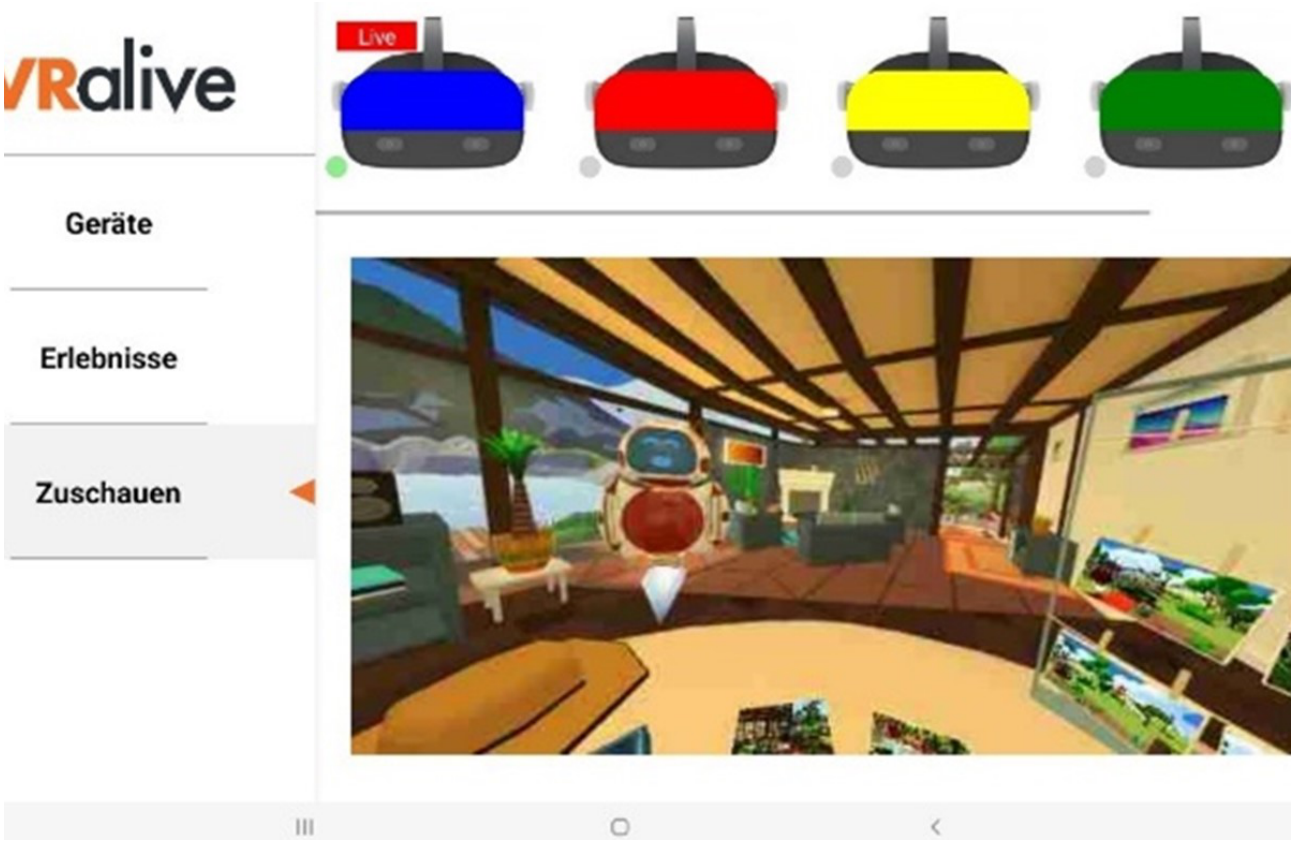
Figure 2. Example task—baking a pizza.

Figure 3. Screenshot of the tablet system.



The VR setup used in this study involved the use of the stand-alone VR Headset Pico Neo 3 Pro along with the Pico Neo 3 controller (Pico Technology Co, Ltd). The resolution of the VR headset was set at 1832 × 1920 per eye. The headset operated at a refresh rate of 72 Hz and featured 6 dfs inside-out tracking capabilities. In addition to the VR equipment, a Samsung Galaxy Tab S6 Lite (Samsung Electronics Co, Ltd) with an Android 12 operating system served as the remote tablet for the study. The system was programmed using .Net and C# programming languages.

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Instruments

Consistent with our hypotheses, *psychosocial capacities* (hypothesis 1) included the mental capacities to adapt to daily life in a nursing home, which was assessed using the Mini-ICF-Rating for Impairment in Psychological Activities and Capacities (Mini-ICF-APP) scale [56]. This scale encompasses 13 psychosocial capacities, including proactivity and mobility. *ADLs* (hypothesis 1) included physical activity and mobility of the participants, which were assessed in more depth using the ADL-Barthel Index [57] that encompasses basic ADLs. *Well-being* (hypothesis 2) was measured using the World Health Organization–Five Well-Being Index (WHO-5) [58]. These measures were administered to both the intervention group and the control group, allowing for a comprehensive evaluation of the outcomes in both groups (Table 1).

The *Mini-ICF-APP capacity rating* [56] is an established instrument for describing a person's psychosocial capacity status. It has been translated internationally into many languages and is recommended in social medicine guidelines [59]. Among other settings, it is commonly used in settings of psychosocial rehabilitation. It is internationally recognized and has proven to be manageable, reliable, and valid in clinical practice [60-63]. In this study, the Mini-ICF-APP rating was designed to assess the psychosocial capacities for living in the nursing home, that is, performing certain basic activities on their own. The scale covers the following capacity dimensions: (1) adherence to regulations, (2) planning and structuring of tasks, (3) flexibility, (4) competence and knowledge application, (5) capacity to make decisions and judgments, (6) proactivity and spontaneous activities, (7) endurance, (8) self-assertiveness, (9) contact with others, (10) group integration, (11) intimate relationships, (12) self-care, and (13) mobility. Each dimension is rated using an 8-point rating scale (0=this is a strength of me to 7=this is impossible for me). The Mini-ICF-APP interview guide and questionnaire were adapted for the older adults by focusing on activities that individuals in need of care could still perform independently while residing in a nursing home. In a pilot study, 8 participants were interviewed by both project psychologists. Of the 2 psychologists, 1 conducted the interview, and both the interviewers completed Mini-ICF-PP rating sheet based on the responses provided by the older adults. On average, the interrater reliability over all 13 capacity dimensions was r=0.857. Psychosocial capacities were measured at 3 measurement time points (T0, T6, and T7).

ADL [57] was measured before the first VR intervention (T0), after the intervention (T6), and at a 3-week follow-up after the posttest phase (T7). It includes 10 dimensions of daily activity: (1) eating, (2) washing and showering, (3) body care, (4) dressing and undressing, (5) stool control, (6) urine control, (7) toilet use, (8) transfer from bed to chair, (9) movement and mobility, as well as (10) climbing stairs. The total score on the Activity of Daily Living-Barthel Index (ADL-BI) ranges from 0 to 100, with higher scores indicating greater independence in performing daily activities. A score of 0 indicates complete dependence on assistance for all activities, whereas a score of 100 indicates complete independence. An ADL score <80 indicates a need for care of >2 hours a day [64]. In the interview with the study participants, the psychologists asked about the activities one after the other and checked the plausibility of the answers of the older adults were. In cases of doubt, supplementary external judgments were obtained from the caregivers to ensure data validity.

The third instrument used in this study was the *WHO-5* [58], which is a concise self-report measure of current mental well-being. The assessment of well-being using the WHO-5 was conducted at baseline, after each VR intervention session, and during the postintervention and follow-up interviews. Numerous studies have demonstrated the validity of the WHO-5 as a screening tool for depressive mood and as a measure of treatment outcomes in clinical trials, and it has also shown good construct validity for assessing well-being in both younger and older populations [65,66]. The WHO-5 has been translated into >30 languages [66]. It consists of five statements that assess the individual's (1) good mood and cheerfulness, (2) relaxation, (3) activity and energy, (4) regenerative capacity through sleep, and (5) enthusiasm. Each statement is rated on a scale ranging from 1 ("at no time") to 5 ("all the time"). For example, 1 statement reads as follows: "Last week, I was happy and in a good mood." These statements are straightforward and nonintrusive in nature [66]. Typically, the questionnaire covers a 14-day period; however, considering the older adult participants and the study's weekly interventions, a 7-day period was deemed appropriate. Therefore, the assessment inquired about the individual's well-being, relaxation, activity level, quality of sleep, and interest in life over the past 7 days. Well-being was measured at each of the 8 measurement time points (T0-T7; Table 1).

Statistical Analyses

The data collected from the study were entered into the statistical software SPSS (IBM Corp) [67] for analysis. A repeated-measures ANOVA was conducted to analyze the data obtained from the 84 older adults in the intervention group who had participated in at least 3 interventions. The analysis focused on psychosocial capacities (Mini-ICF-APP), ADL, and well-being (WHO-5).

Owing to unequal sample sizes, a 2-factor, repeated-measures ANOVA between the intervention group and the control group could not be performed. However, the data from the control group (consisting of 11 participants) are presented descriptively, enabling a comparison with the values obtained from the intervention group.

Ethical Considerations

This study was funded by the German Federal Ministry of Education and Research (BMBF) (project number: 16SV8561 VRalive). This study was approved by the ethics committee of Technische Universität Braunschweig (FV-2020-18). Before the study, informed consent, confidentiality, and informed data protection were obtained from the participants or their life caregivers under the supervision of nursing staff. The older adults were informed of their ability to opt out at any time. The VR activities were provided as daily activities in the nursing home, and there was no compensation provided. All activities carried out in the nursing home were in strict compliance with the current nursing home COVID-19 prevention and treatment

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policy. For secondary analyses using existing data, we specified that the original consent approval covers secondary analysis without additional consent. The collected data were anonymized and deidentified.

Results

Participants and Demographic Information

A total of 116 older adults aged ≥60 years initially participated in the VR intervention group. Of these 116 participants, 31 (26.7%) discontinued their involvement in the VR group. The primary reasons cited for dropping out were concerns related to data protection and illness or death (Table 2).

Table 2. Reasons for dropping out (n=31).

Reasons	Values, n (%)
No more interest, without reasons	5 (16)
Several events are occurring	4 (13)
Incapable of participating due to illness or death	12 (39)
Virtual reality–related sickness (“cybersickness”)	5 (16)
No interest in interviews	1 (3)
Alternative events are preferred	2 (6)
Leaves retirement home	1 (3)
Cancellation of the group owing to very few participants	1 (3)

Sociodemographic information was collected at baseline and included older adults’ age, sex (male, female, or intersex), and educational and working history. The intervention group (N=116) had an average age of 80.74 (SD 8.49) years. The age range at the time of the intervention varied from 60 to 97 years. There was a higher proportion of female participants (81/116, 69.8%). Most participants (107/116, 92.2%) in the intervention group had no previous experience with VR. Table 3 presents more detailed demographic information.

We decided to consider only the data from older adults who participated in a minimum of 3 VR interventions to ensure that the analysis focused on the impact of the VR intervention. This resulted in a final sample size of 84 older adults to be analyzed statistically. Hence, for the purpose of this paper, statistical evaluation will be conducted on the data obtained from 84 older adults from the VR intervention group.

Furthermore, 12 older adults participated in the control group. One of the participants discontinued due to death (this has already been accounted for in the dropout statistics, as indicated in Table 2). The age range of the control group participants spanned from 61 to 94 years, with an average age of 83.75 (SD 8.97) years, and 10 (83%) of the 12 participants were women. It is important to note that the selection of participants for the control group was based on the perceptions of the nursing staff members and the natural decisions made by the older adults themselves. Consequently, the sample size of the control group in this study is notably small, rendering it insufficient for a robust comparison with the intervention group. Therefore, detailed information about the control group, which is presented alongside the intervention group data, is provided in Multimedia Appendices 1-3. The limitations associated with the small control group sample size are discussed further in the Strengths and Limitations section.

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Table 3. Sociodemographic data about the older adults participating in the virtual reality (VR) intervention (N=116).

Features	Values
Age (y), mean (SD; range)	80.74 (8.49; 60-97)
Sex, n (%)	
Female	81 (69.8)
Male	35 (30.2)
Education, n (%)	
None	7 (6)
Special school	2 (1.7)
Primary school	1 (0.9)
Secondary school	17 (14.7)
Primary school or grade 9 or 10	79 (68.1)
Abitur	10 (8.6)
Professional qualification, n (%)	
None	37 (31.9)
Craft profession or skilled work	67 (57.8)
Master	7 (6)
University studies	5 (4.3)
Longest professional activity in working life, n (%)	
Craft, industry, or production	37 (31.9)
Research and development	3 (2.6)
Agriculture	3 (2.6)
Office or management activities	24 (20.7)
Service, gastronomy, or customer service	26 (22.4)
Practical health care (nurse, physician, therapist, or similar)	10 (8.6)
Housewife	12 (10.3)
Missing indication	1 (0.9)
Frequency of visits from trusted people, n (%)	
Several times a week	63 (54.3)
Weekly	27 (23.3)
Every 2-3 weeks	8 (6.9)
Monthly	2 (1.7)
Less frequently than monthly	2 (1.7)
No regular contacts	14 (12.1)
Previous experience with VR, n (%)	
No	107 (92.2)
Yes	9 (7.8)

Outcomes

Tables 4 and 5 present a summary of the results for the Mini-ICF-APP, ADL, and WHO-5 measures at specific measurement time points for both the intervention group and the control group. A macrolevel analysis indicates significant differences in the mean scores of Mini-ICF-APP (P<.001; η^2=0.150) and WHO-5 (P=.04; η^2=0.032) and the sum score of ADL (P=.02; η^2=0.050) within the intervention group.

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Table 4. Comparison of the older adults' scores at baseline, at the end of the intervention, and 3 weeks after the postintervention assessment.

	Baseline (T0), mean (SD)	Postintervention assessment (T6), mean (SD)	Follow-up (T7), mean (SD)	rANOVA[a] (n=84)	
				P value	η^2
Capacities (Mini-ICF-APP[b])					
Adjustment to rules and routines	2.57 (0.88)	2.15 (1.05)	2.04 (1.08)	<.001[c]	0.122
Planning and structuring tasks	3.13 (1.82)	2.95 (1.92)	3.13 (2.08)	.56	0.007
Flexibility and adaptability	2.38 (0.90)	1.86 (1.19)	1.87 (1.22)	<.001[c]	0.109
Competence and knowledge application	2.25 (1.25)	1.99 (1.55)	1.94 (1.52)	.04[d]	0.039[e]
Capacity to make decisions and judgments	2.57 (1.12)	2.42 (1.40)	2.48 (1.35)	.57	0.007
Proactivity and spontaneous activities	2.39 (1.19)	2.04 (1.25)	1.90 (1.26)	<.001[c]	0.104
Resilience and perseverance	2.54 (1)	2.25 (1.18)	2.29 (1.14)	.07	0.032
Self-assertiveness	2.60 (1.09)	2.43 (1.15)	2.40 (0.96)	.30	0.014
Capacity to talk with and contact third parties	2.39 (1.41)	2.14 (1.35)	2.25 (1.42)	.15	0.023[e]
Group integration	2.71 (1.39)	2.26 (1.36)	2.04 (1.21)	<.001[c]	0.141
Capacity to form close relationships	2.61 (1.58)	2.45 (1.66)	2.49 (1.75)	.57	0.007
Self-care and self-sufficiency	3.29 (1.76)	3.18 (1.84)	3.11 (1.86)	.63	0.006
Mobility and transportability	2.39 (1.46)	2.37 (1.59)	2.40 (1.54)	.95	0.001
Average score	2.60 (0.75)	2.35 (0.85)	2.33 (0.88)	<.001[c]	0.150[e]
ADL[f]					
Food	9.29 (1.76)	9.46 (1.56)	9.64 (1.30)	.11	0.027[e]
Bath	1.85 (2.43)	1.73 (2.39)	2.02 (2.47)	.42	0.010
Washing	4.52 (1.48)	4.58 (1.39)	4.64 (1.30)	.76	0.003
Dressing and undressing	7.20 (3.41)	7.38 (3.68)	7.32 (3.51)	.84	0.002
Stool control	7.92 (3.74)	8.04 (3.72)	7.80 (3.75)	.83	0.002
Urine control	6.31 (4.40)	6.55 (4.25)	6.90 (4.31)	.27	0.016[e]
Using the toilet	8.27 (3.76)	8.63 (3.41)	9.11 (2.71)	.03[d]	0.040
Bed or wheelchair transfer	12.74 (4.93)	13.15 (4.58)	12.98 (4.66)	.22	0.018[e]
Movement or mobility	9.11 (4.40)	9.46 (4.39)	9.64 (4.16)	.04[d]	0.039
Climbing stairs	4.35 (4.40)	4.76 (4.17)	4.88 (4.46)	.28	0.015
Total score	71.55 (23.19)	73.75 (23.32)	74.94 (22.29)	.02[d]	0.050[e]

[a]rANOVA: repeated ANOVA.

[b]Mini-ICF-APP: Mini-ICF-Rating for Impairment in Psychological Activities and Capacities; the scale ranges from 0 ("clearly a strength of mine") to 7 ("I cannot do at all").

[c]$P<.001$.

[d]$P<.05$.

[e]The value was corrected according to Greenhouse Geisser.

[f]ADL: activity of daily living; the scale ranges from 0 to 15.

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Table 5. Comparison of older adults' scores regarding their well-being (World Health Organization–Five Well-Being Index [WHO-5][a]) before the intervention (T0 and T1), during the intervention (T2-T5), after the intervention (T6), and 3 weeks after the postintervention assessment (T7).

	Time points, mean (SD)								rANOVA[b]		
	T0	T1	T2	T3	T4	T5	T6	T7	*F* test (*df*)	*P* value	η^2
Good mood and cheerfulness	4.08 (0.95)	3.90 (1.04)	3.78 (1.13)	3.94 (1.02)	3.90 (0.99)	3.85 (1.03)	3.83 (0.98)	3.90 (1.04)	1.893 (5.51)	.09	__[c]
Relaxation	4.02 (0.01)	3.89 (1.22)	3.98 (1.09)	3.90 (0.96)	3.94 (1.04)	3.93 (1.02)	4.06 (1.09)	3.89 (1.22)	0.554 (7.00)	.79	0.008
Activity and energy	3.54 (1.27)	3.27 (1.25)	3.32 (1.33)	3.52 (1.21)	3.57 (1.18)	3.23 (1.26)	3.60 (1.11)	3.27 (1.25)	2.050 (7.00)	.048[d]	0.029
Regenerative capacity through sleep	3.49 (1.35)	3.65 (1.36)	3.71 (1.26)	4.03 (1.05)	4.03 (1.21)	3.89 (1.36)	4.01 (1.12)	3.65 (1.36)	3.867 (5.85)	.001[e]	0.054[c]
Enthusiasm	3.64 (1.17)	3.72 (1.28)	3.60 (1.17)	3.73 (1.22)	3.85 (1.22)	3.68 (1.29)	4.12 (1.12)	3.72 (1.28)	3.541 (7.00)	.001[e]	0.049
WHO-5 (total)	3.75 (0.75)	3.69 (0.83)	3.68 (0.83)	3.82 (0.79)	3.86 (0.82)	3.72 (0.84)	3.92 (0.78)	3.91 (0.87)	2.235 (5.85)	.04[d]	0.032[c]

[a]A 5-point Likert scale ranging from 0 ("at no time") to 5 ("all the time").

[b]rANOVA: repeated ANOVA.

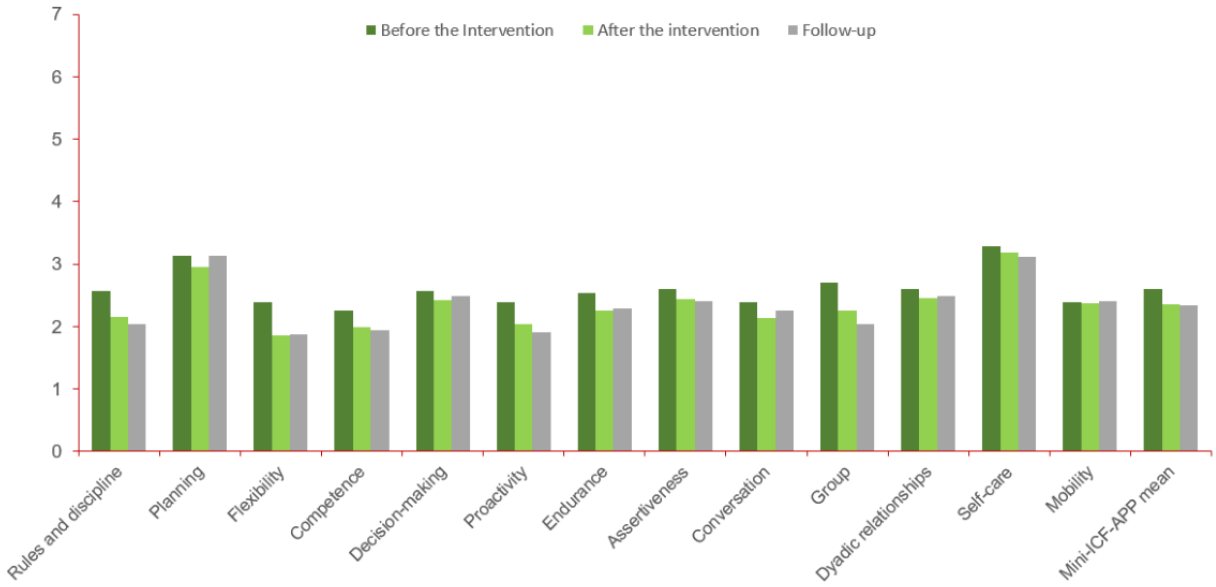
[c]The value was corrected according to Greenhouse Geisser.

[d]*P*<.05.

[e]*P*<.01.

Specifically, the data from the Mini-ICF-APP indicated slight reductions in some psychosocial capacity impairments within the intervention group (Table 4 and Figure 4): adherence to regulations (*P*<.001; η^2=0.122), flexibility (*P*<.001; η^2=0.109), proactivity (*P*<.001; η^2=0.104), and group integration ICF (*P*<.001; η^2=0.141). Problems related to competence also showed a slight decrease (*P*=.04; η^2=0.039).

Figure 4. Changes in older adults' scores for the ability dimensions (Mini-ICF-Rating for Impairment in Psychological Activities and Capacities; Mini-ICF-APP) across the measurement time points: before the intervention, after the intervention, and follow-up during the intervention.. 0=This is clearly a strength of person, 1=Person is better than many others, 2=Person can do this well, 3=Person can somehow work with this, 4=Person does not always get this to work, 5=Person has problem with this, 6=Person needs help in this regard, and 7=Person is fully unfit.



Overall, 2 ADLs seemed to improve over the course of the VR intervention (Table 4): "Using the toilet" (*P*=.03; η^2=0.040) and "mobility" (*P*=.04; η^2=0.039).

In terms of well-being (WHO-5), 3 of 5 items in the WHO-5 showed significant changes (Table 5 and Figure 5): "feeling active" (*P*=.048; η^2=0.029), "sleeping well" (*P*<.001; η^2=0.054), and "being full of interest for life" (*P*<.001; η^2=0.049). This indicates a slight variation in well-being over the course of the 4-week VR intervention period.

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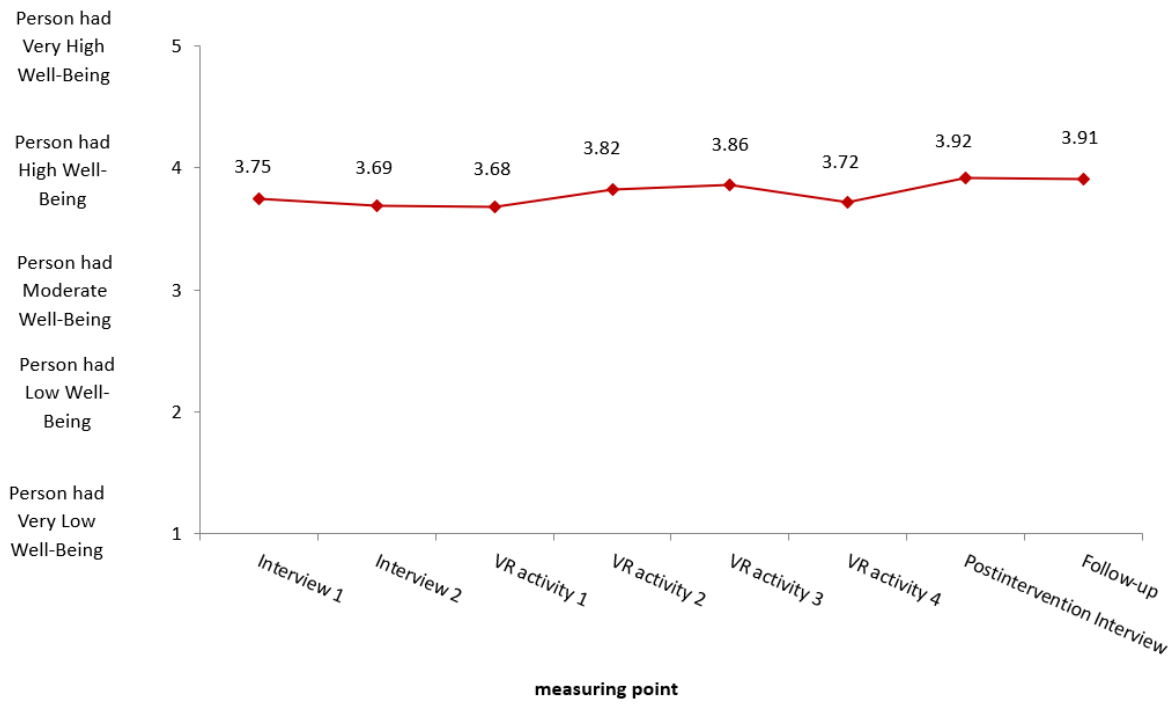
Figure 5. Mean of the World Health Organization–Five Well-Being Index for the intervention group at 8 weekly time points. VR: virtual reality.



Side Effects of VR

Throughout the VR intervention, there were no reported instances of older adults falling or accidentally colliding with nearby objects based on their sitting poses. In addition, there was no indication of potential interference with medical devices. While a few cases of cybersickness (5/31, 16%; Table 2) were reported, these were promptly addressed and resolved.

Discussion

Summary

The study aimed to determine whether a specifically designed VR intervention had a positive impact on nursing home inhabitants in terms of psychosocial capacities, activities, and well-being. In general, some dimensions of psychosocial capacities, activity, mobility, and well-being of older adults in the intervention group showed a slight positive improvement over the course of the intervention. Improvements were observed in adherence to regulations, flexibility, proactivity, competence, and group integration. The older adults showed improvement in their ability to use the toilet and physical mobility. The older adults reported feeling active, experiencing better sleep, and displaying greater interest in daily life.

Principal Findings and Comparison to Previous Studies

Psychosocial Capacities

The results of the study demonstrate an improvement substantially in the older adults' capacity to adhere to daily routines in the nursing home. This indicates that they have become more proficient in following schedules and maintaining self-discipline. In addition, the older adults show a greater willingness to adapt to and switch between different tasks or activities, both within the group setting and in public. Studies have shown that VR interventions can enhance the cognitive abilities of older adults, and these improvements are often correlated with their intrinsic motivation for training. This motivation can be triggered either by the engaging nature of the game itself or by the immersive experience facilitated by VR technology [68,69]. In addition, the study conducted by Fan et al [46] demonstrated that using VR as a form of entertainment for older adults can enhance their achievement motive and self-esteem, leading to improved mental health outcomes and reduced isolation, particularly among community-dwelling older adults. It is reasonable to assume that similar benefits could be experienced by older adults residing in nursing homes as well. In our case, the older adults' intrinsic motivation may stem from their own desire to participate in meaningful VR activities and engage with others, whereas extrinsic motivation could arise from the supportive environment provided by the staff members and the positive experiences associated with the VR group activity. The combination of intrinsic and extrinsic motivation appears to have contributed to the observed improvements in discipline and flexibility among the older adults; with these improvements, the older adult could fit better with daily life in the nursing home. However, it should be acknowledged that flexibility may also have been influenced by factors such as the visits from and relationship with the VR project psychologist. Over time, as the psychologist became more familiar with the older adults, they could have corrected any initial bias in the older adults' self-assessment, leading to more accurate evaluations based on their pragmatic experience.

The study findings indicate that the older adults' use and retention of competence and knowledge have improved. This outcome aligns with the study's design, which focused on implementing VR interventions with meaningful activities based on the older adults' familiar daily tasks. The positive impact of this approach is evident in the results obtained. The older adults

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were able to engage with the new VR activities, thus increasing their competence. Moreover, the result of improved capability of group integration indicated that after the VR intervention, the older adults gradually developed an interest in the group activity and expressed a desire to retry the task in the following week. A previous study by Padilha et al [70] found that VR offers a learning experience from interaction with the virtual environment and enhances knowledge acquisition in nursing education. It is plausible that VR can also be a promising tool for older adults to enhance these mental capabilities. Multiple studies have demonstrated that VR interventions have a positive impact on the memory and information-processing abilities of older adults [68,71,72]. VR video games could enhance the working memory and reasoning abilities of older adults [68]. The authors also suggested that VR interventions may improve problem-solving and planning skills, which are findings that align with those of our own study.

In summary, the VR group activity incorporating daily life tasks has shown to be a promising method for improving psychosocial capacities, including adherence to regulations, flexibility, and competence retention, among older adults in nursing homes.

Activity and Mobility

The results of the study demonstrate significant enhancement in the older adults' proactivity (Mini-ICF-APP). This suggests that the older adults experience less boredom and express a desire to engage in more daily activities that interest them while living in the nursing home. They are better prepared and motivated to initiate activities on their own. Furthermore, the ADL score, particularly in the mobility domain, also showed a significant improvement. This improvement in proactivity can be linked to the enhanced mobility observed in the ADL scale. The nursing home already provides gymnastic courses and physical therapy to help older adults maintain or rebuild their physical functioning. When older adults are more willing to participate in these activities, it can lead to better mobility and daily activity (eg, using the toilet) outcomes, aligning with the theoretical background that meaningful group activities can improve activity and mobility in nursing homes. Previous studies have investigated the impact of VR interventions on ADLs and instrumental ADLs among older adults, yielding different results. One of these studies aligns closely with our own study. Liao et al [47] conducted a VR cognitive training program that involved tasks such as locating stores and acting as a virtual kitchen chef, which is similar to our approach. Their results demonstrated a significant improvement in older adults' activity levels, with the effect size being larger than that observed with traditional cognitive training methods. Moreover, the improvement in the activity of older adults in nursing homes through VR intervention was also demonstrated by Saredakis et al [73]. In contrast, Optale et al [43] conducted a VR memory training program that consisted of repeated memory tasks focused on objects and orientation. Their study did not find a positive impact on ADL. This discrepancy suggests that the content of the VR intervention may play a crucial role in determining its effectiveness in enhancing older adults' daily activities. Overall, these findings highlight the importance of considering the specific content and nature of VR interventions when assessing their potential impact on the daily lives of older adults.

On the basis of the exploratory findings of this study, conducting an experimental study to provide evidence about the impact of VR interventions on proactivity and mobility would be valuable. Such a study can further validate the potential benefits of VR interventions in promoting proactivity and improving mobility among older adults in nursing homes.

Group Integration and Social Interaction

There was significant improvement in the group capacity of the older adults, indicating their increased willingness to participate in group activities and enjoy the benefits of group engagement. Thus, VR intervention could be used as a meaningful group activity that contributes to reducing social isolation. Staff members in some care homes also reported that older adults were pleasantly surprised by the VR technology and were more open to group activities after participating in the VR project. These findings are consistent with the results reported by Fan et al [46], who conducted a VR intervention involving horticultural group activities such as gardening for community-dwelling older adults, aiming to reduce social isolation. In addition, other previous studies involving VR horticultural activities in nursing homes have also demonstrated a reduction in older adults' loneliness and an improvement in their social interaction [44,74]. However, it is important to note that, unlike our study, these previous studies did not specifically focus on VR interventions as group events. Therefore, these studies have not reported about the impact of VR interventions specifically on group capacities of older adults. In addition to the VR horticultural activities implemented in nursing homes, the study by Saredakis et al [73] examined the effectiveness of VR reminiscence therapy in reducing older adults' loneliness but did not observe significant effects. This suggests that VR horticultural activities may hold greater potential in reducing loneliness among older adults. Engagement in meaningful activities, such as virtual gardening or horticultural group activities, might have a more profound impact on addressing the issue of loneliness in this population.

It is important to note that the project spanned periods of the COVID-19 pandemic and the winter and summer seasons, which could potentially act as confounding factors. While there was generally limited availability of group activities during the pandemic, the introduction of VR group sessions may have enhanced older adults' interest in social interaction.

Well-Being

Although there are statistically significant differences in the changes in well-being over the course of the intervention, it is important to note that the VR group activity has not yet demonstrated its full potential in consistently improving the well-being of older adults. The results indicate that there have been very small, incremental improvements in the well-being curve. The statistically significant difference observed may be attributed to the number of measurement points used in the study. We do not have a sufficient, practically relevant effect to confirm an increase in well-being.

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The well-being of the older adults was already good at the beginning of the VR intervention study, which makes significant and consistent additional improvements less likely. Furthermore, well-being is influenced by various situational factors, particularly among older adults with health problems or disabilities considered vulnerable. Another factor to consider is the frequency and duration of the VR intervention, which may not have been sufficient to produce further improvement in well-being. Other VR studies that have demonstrated improvements in well-being often involve more frequent and longer VR interventions [44,50,74] or are only measured once after a 1-time intervention [48,75,76]. Furthermore, recent entertainment-oriented VR interventions targeting well-being or quality of life among older adults have predominantly used a passive interaction approach, for instance, virtual travel in Hong Kong [75]. These studies consistently achieved their research goals in terms of enhancing older adults' mood and well-being. In contrast, VR interventions that primarily focus on functional training with hand interaction have generally shown limited improvement in overall well-being, such as the one conducted by Brito et al [77]. The learning process associated with using the hand console can act as a barrier for older adults, potentially hindering their ability to improve their well-being through functional training. Consequently, it is crucial to approach the didactic process of VR devices with care to ensure that older adults are not discouraged at the initial stages of training. Furthermore, when developing VR interventions for older adults, it is important to consider the design and usability of the console or device being used. Older adults may have specific needs and challenges when it comes to interacting with technology. Therefore, the console or device should be tailored to accommodate their physical abilities, cognitive capabilities, and potential sensory impairments [78].

In summary, the well-being of older adults could be maintained at a high level over the course of the VR group intervention. It would be interesting to see if a more frequent intervention could further improve the impact of VR intervention on the well-being of older adults.

Strengths and Limitations

This study explored VR group activities in nursing homes, adopting a naturalistic approach to gain a deeper understanding of technology's role for older adults in the digital age. Our findings revealed the potential of VR as a tool in meaningful activity programs for older adults residing in nursing homes. Notably, this intervention leads to an enhancement in older adults' abilities and engagement in activities, while sustaining a high level of well-being. Our study offers novel insights into the transformative possibilities of VR for enriching the lives of older residents within nursing home settings. Despite the significant findings of this study, it is important to acknowledge several limitations.

First, the impact of the COVID-19 pandemic on the effectiveness of VR interventions cannot be ignored. During the pandemic, there were restricted group activities and increased vulnerability among older adults, which may have magnified the positive impacts of the VR group intervention. It is crucial to consider this unique context when interpreting the results.

Second, there may be a selection bias in the sample of participants. The selection of participants in the nursing home was based on defined and standardized selection criteria, which the nurses applied in the field. This is the most natural, accepted, and standardized way to select participants for psychosocial activities in nursing homes. There can be a slight selection bias due to the various individual interaction processes of the nurses with the participants. The selected sample may not accurately represent the range of responses in the population, but it represents older adults with complex disabilities who are nevertheless able to cope with specially designed VR tools. Moreover, recruitment was also based on older adults' willingness to participate in the study. The older adults who chose to participate in the study may be more open to new experiences compared to those who declined. Furthermore, the findings indicate that the older adults initially reported good well-being and had regular contact with family or friends, suggesting a limited scope for improvement in well-being and social interaction. It is essential to find ways to extend the reach of VR group interventions to a wider range of older adults, particularly those who are more isolated and lonely. Using a VR session to introduce the intervention to these older adults may be a potential solution.

Third, there is a possibility that the older adults may have overestimated or underestimated their own capacities. This could be addressed by staff members closely monitoring the older adults' daily behavior. However, due to limited personnel resources, this was not feasible in this study.

Finally, another weakness of this study is in its study design. This was not a randomized controlled trial. Although a control group was included, the sample size was very small, making it challenging to establish a valid comparison with the intervention group. Participation in the control group was based on the natural decisions of the older adults. Therefore, the results should be interpreted as a point of reference rather than indicative of a causal "effect." Nevertheless, it is important to note that this longitudinal study is naturalistic and externally valid. It offers a novel perspective on the pragmatic application of VR intervention as a group event in nursing homes.

Future Studies

On the basis of the findings of this exploratory study, a randomized controlled experimental trial that specifically focuses on VR group interventions within the daily lives of older adults in nursing homes should be conducted. Without the specific conditions during the COVID-19 pandemic, a more favorable social environment will be available, resulting in fewer hindering factors such as limited group interventions. In addition, in this study, large variation was observed in the basic cognitive functions of the participating older adults, according to age and type of disease. However, it is important for researchers to be mindful about the competencies and skill levels of older adults when introducing VR interventions [79]. Some older adults may feel socially excluded if they lack the necessary skills to participate in these digital activities [80]. Therefore, it is crucial to prioritize accessibility and provide adequate support

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and training to ensure inclusivity. This can involve tailoring the VR experiences to accommodate older adults with varying cognitive functioning, such as providing different levels of difficulty based on individual capabilities. In our study, we received diverse feedback from older adults regarding VR tasks. The highly independent older adults expressed that the VR tasks were very easy for them, whereas those with cognitive impairments or dementia found the tasks challenging to complete. In the next phase, it would be beneficial to group older adults based on their cognitive capacities and provide tailored VR interventions at different difficulty levels. Exploring an older adult–centered VR design is another intriguing direction for further investigation. This could involve studying the optimal form of interaction that minimizes the learning curve associated with using VR devices, ultimately enhancing the overall user experience for older adults.

Conclusions

In conclusion, the project successfully explored the benefits of a VR-based group intervention in nursing home settings. The results indicate that the VR intervention could be a meaningful group activity in nursing homes to support social group interaction, activity level, and well-being. The 4 sessions of the VR group intervention—with tasks that the older adults were unable to perform in their current environment— led to significant improvements in adherence to rules, flexibility, competence, proactivity, group integration, and mobility. Future research could benefit from conducting a randomized controlled trial to provide stronger evidence.

Acknowledgments

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Data Availability

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

Authors' Contributions

BM and IS conceptualized the study and acquired the funding. BM designed the research question. IS and her team developed the virtual reality software. YL and CW conducted and implemented the study with technical support from IS in nursing homes. YL and CW collected and analyzed the data and prepared the tables for this paper. YL wrote the paper. BM supervised the research process and contributed to the writing and revision of the paper.

Conflicts of Interest

IS is the cofounder of the company, VirtuaLounge, which developed the virtual reality program used in this study. The developed program may be used commercially in the future.

Multimedia Appendix 1
Sociodemographic data of the participating older adults in the virtual reality intervention for the control group and the intervention group.
[DOCX File , 35 KB - games_v12i1e50796_app1.docx]

Multimedia Appendix 2
Comparison of the scores of the older adults from the control group and the intervention group at baseline, at the end of the virtual reality intervention, and 3 weeks after the postintervention assessment regarding their psychosocial capacities.
[DOCX File , 20 KB - games_v12i1e50796_app2.docx]

Multimedia Appendix 3
Comparison of the scores of the older adults from the control group and the intervention group regarding their well-being before the intervention (T0 and T1), during the intervention (T2-T5), after the intervention (T6), and 3 weeks after the postintervention assessment (T7).
[DOCX File , 18 KB - games_v12i1e50796_app3.docx]

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Abbreviations

ADL: activity of daily living
HMD: head-mounted device
Mini-ICF-APP: Mini-ICF-Rating for Impairment in Psychological Activities and Capacities
VR: virtual reality
WHO-5: World Health Organization–Five Well-Being Index

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Original Paper

A Serious Game (MyDiabetic) to Support Children's Education in Type 1 Diabetes Mellitus: Iterative Participatory Co-Design and Feasibility Study

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Abstract

Background: Serious games, which are gaming applications used for purposes beyond entertainment to educate users on, and address, specific issues, may present a timely approach to promote healthy diabetes management behaviors among children with type 1 diabetes mellitus (T1DM). The lasting benefits associated with these serious games encompass improved patient education; enhanced glycemic control; the reinforcement of bonds within the community of people with diabetes; the facilitation of meaningful dialogues with caregivers, especially within the familial setting; and a significant reduction in the economic burdens associated with subsequent complications.

Objective: This paper primarily aims to provide a detailed overview of the iterative design process and the associated evaluation methods used in the development of the educational game. Furthermore, this study aims to enhance motivation for sustained and extended engagement with the game over time. The MyDiabetic game design aims to educate children on various aspects, including the connections among food, insulin, and physical activity. Furthermore, it seeks to impart knowledge related to the operation of a glucometer and an insulin pen, as well as more advanced technologies such as administering glucagon, measuring ketoacidosis, and continuous glucose monitoring.

Methods: The co-design methodology was applied, involving interviews, design workshops, and prototype feedback sessions. A combination of several approaches, such as tailoring, observational learning, social and family support, decision-making practice, and reward systems, was used to support children's compliance. Moreover, incorporating the literature, guidelines, and current practices into the design ensured that the game was aligned with established health care pathways and included relevant information and best practices for diabetes management.

Results: The game was tested on 32 children in 3 iterations. Positive responses were received from children who tested the game as well as their parents. The game was also presented to 5 schoolmates of children with T1DM who appreciated a better understanding of the disease and the opportunity to support their friends more efficiently in T1DM compensation. The involvement of children and clinicians in participatory co-design contributed to to the game's high acceptance. With regard to the game's impact on education, 1 week of testing revealed an enhancement in educational outcomes.

Conclusions: The game is especially suitable for children newly diagnosed with T1DM because it acquaints them in a fun way with new terminology; for example, they can try to measure glycemia levels in an interactive way. The game also caters to children who still need to develop reading skills by including an audio guide. The guide ensures that children of all literacy levels can benefit from the game's educational content and interactive experiences. The game is available for download on Google Play and the Apple App Store.

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KEYWORDS

diabetes mellitus; serious games; mobile app; co-design; user-centered design; serious game; gaming; diabetes; child with diabetes; child; children; insulin; glucometer; glucose; patient education; insulin; mobile phone

Introduction

Background

Type 1 diabetes mellitus (T1DM) is the most common form of diabetes in children. Poor blood glucose control increases the risk of chronic microvascular complications, including renal and retinal complications. When T1DM starts in childhood or young adulthood, the course of the disease is long, and metabolic control is essential to prevent such complications [1]. Advances in the treatment of T1DM have decreased the risk of complications and delayed their occurrence, with a resultant overall increase in the quality of life of patients. Nutritional education, with systematic assessments of carbohydrate intake and the use of the insulin-to-carbohydrate ratio, has allowed for optimizing insulin dosage [2]. The basal-bolus scheme with multiple-dose insulin injections, continuous subcutaneous insulin infusion, and multiple capillary blood glucose measurements allow for better metabolic control. For this, adequate and continued diabetes education for patients and families is required [3].

In general, mobile phones are a natural choice for use in increasing the efficiency of medical care and patient motivation [4,5]. The development of monitoring technologies and designing systems for improving diabetes mellitus compensation based on a mobile platform is increasing and widespread [6,7]. In the field of diabetes mellitus, there are already several pilot studies that validate the effectiveness of this new technology [1,8-10]. The biggest problem so far is the motivation of patients, as many stop cooperating after a few weeks or months. Furthermore, some authors state that the noncooperation of patients is one of the most common reasons why we encounter failure in education outcomes [4,11,12].

Well-designed serious games can improve children's learning, skills development, attitudes, emotions, motivation, and many other factors that encourage children to work together with family members and health professionals on treatment [13]. The long-term benefits of the serious game are improved patient education; better diabetes compensation; increased connections with the community of people with diabetes; stimulation of discussion with caregivers, especially within the family; and a significant reduction in the economic costs of subsequent complications. Furthermore, due to the widespread use of technology among children, using serious games to educate and support health behavior for children with diabetes self-management is an emerging and promising practice [14,15].

Some examples of previous approaches are Packy & Marlon (Super Nintendo) [16], Balance [17], Mario Brothers [18], Monster Manor (Nintendo) [19], and mySugr Junior [20]. Carb Counting with Lenny [21] is geared toward teaching users valuable information about healthy food choices and allowing them to apply that knowledge during gameplay. Jerry the Bear [22] seeks to educate children about T1DM by getting them to take care of the game's avatar, check the avatar's blood glucose level, manage insulin dosage by administering the doses using a pen or a pump, and feed the avatar with various food items. Except in the case of Jerry the Bear, the games show only the relationship among food, blood glucose level and physical activity. Some diabetes management games tested in small populations have never been brought to market and have no scalability. In addition, no studies were identified examining T1DM educational games' impact on user behavior, knowledge, or clinical indicators. Further research is needed to better understand the sustainability of T1DM gaming as a tool for promoting adherence and the effect of education.

Objectives

This paper primarily aims to provide a thorough overview of the iterative design process and the accompanying evaluation methods applied in the development of the educational game, MyDiabetic. Furthermore, this study aims to enhance motivation for sustained and prolonged engagement with the game.

MyDiabetic aims to not only teach children the relationship among food, insulin, and physical activity but also pass on knowledge related to working with a glucometer and an insulin pen, as well as more advanced technology such as continuous glucose monitoring (CGM), insulin pump, glucagon administration, and ketones urine test. The game is designed for children aged between 5 and 12 years. It is especially suitable for children newly diagnosed with T1DM because it acquaints them in a fun way with new terminology; for example, they can try to measure glycemia levels in an interactive way.

Methods

Overview

A participatory iterative co-design approach was adopted. Participatory design in each iteration was guided by the fundamental principles from both traditional game design elements (eg, user flow and the mechanics, dynamics, and framework approach) and behavioral theory tailored for diabetes support. Figure 1 illustrates an approximate timeline for the MyDiabetic project, depicting key components of the participatory co-design methodology, along with the predominant principles used in each iteration indicated by the red bars.

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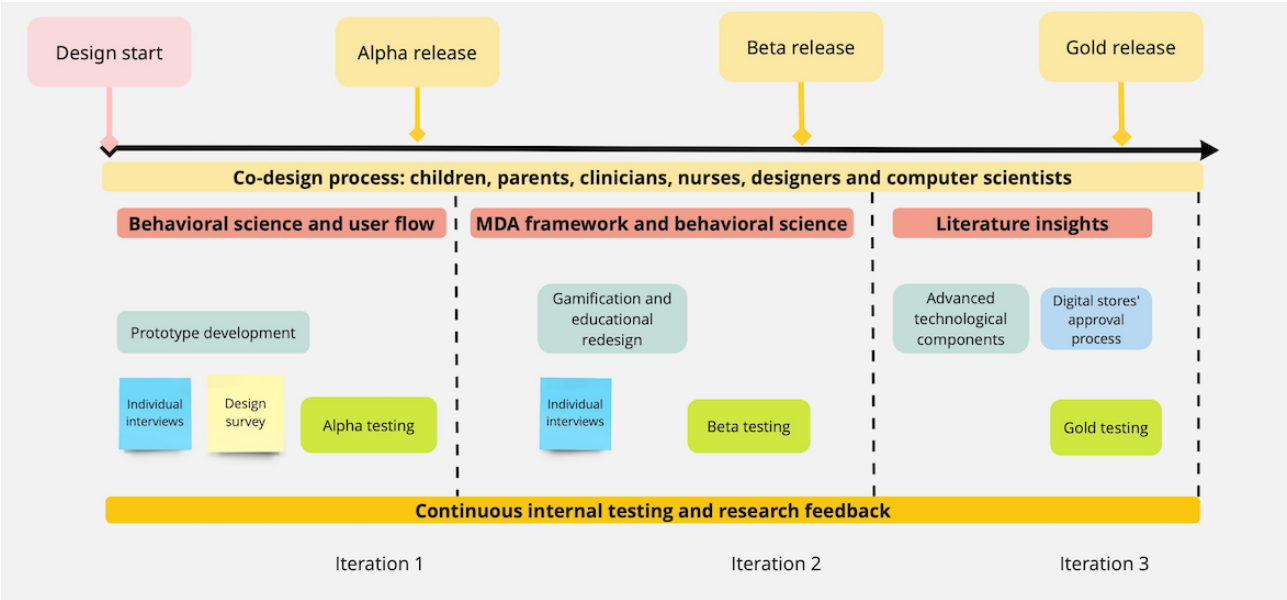
Figure 1. Approximate timeline for the MyDiabetic project showing the principal elements of the participatory co-design methodology along with the predominant principles used in each iteration indicated by the red bars. MDA: mechanics, dynamics, and aesthetics.



Participatory Iterative Co-Design

The game was continually developed, resulting in the 3 iterations of the co-design phases applying participatory co-design principles. Figure 1 presents the timeline of the co-design process. Co-design process is intrinsically incorporated into the research. Co-design is a research methodology that actively engages diverse stakeholders to initiate, create, and validate solutions by adding creative and participative principles and tools [23]. Participatory co-design establishes that the necessary features of person-centered design, clinical acceptability, and health IT feasibility are accounted for, with each process needed for the ultimate success of the serious game. Table 1 describes user statistics during the co-design process.

The design team included several types of participants:

- Children in the user group and their parents, who were recruited through collaborating institutions, such as patient organizations, or Facebook groups
- Researchers with backgrounds in behavior change, informatics, and design
- Designers and developers (external and from the in-house IT system development group)
- Clinicians with vast expertise in T1DM management and nutrition nurses who are part of the project's advisory group

The first iteration of the MyDiabetic game was based on qualitative and quantitative research with children with T1DM diabetes, which led to the requirement for a game to help educate these children and help them cope with their new diagnosis. The outcome of the co-design research was the concept of continuous care of an avatar (based on the Tamagotchi principle) that is represented as a 3D avatar, including technical modules illustrating glucometer and insulin pen use. Subsequently, the co-design of the second iteration focused on incorporating educational material, such as an educational library and audio guidance provided by a physician's avatar, as well as developing other gamification features, such as game levels, minigames, and storyline extension. In addition, a model for measuring blood glucose levels was added. The third iteration addressed new technologies and methods, such as CGM and insulin pump modules, glucagon administration, and an explanation of ketoacidosis. Each iteration ended with usability testing. We followed software release cycle terminology. The alpha usability testing was focused on the evaluation of the main game concept, while the beta usability testing was the most detailed, concentrating on educational and adherence aspects. The gold usability testing evaluated new technological components only. The depiction of screens can be seen in Figure S1 in Multimedia Appendix 1.

Detailed information regarding the characteristics of the children for each iteration can be found in Tables S1-S6, S9-S10, and S12-S13 in Multimedia Appendix 2.

The clinical team was composed of experts who possessed diverse experience in various aspects of T1DM. Throughout the development process, these clinicians consistently provided invaluable feedback during presentation workshops conducted at the conclusion of each iteration.

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Table 1. Description of iterative design and user statistics.

Iteration and activity	Users	Age (years), mean (SD)	T1DM[a] duration (years), mean (SD)	Stage of development	Features introduced
Iteration 1					Basic gaming concept, design of control elements, taking care of the avatar concept, carbohydrate counting, insulin pen administration, measurement of glycemia level, and performing exercise
Interviews	Boys: 4; girls: 0	12.8 (1.3)	5.5 (2.6)	Mock-up	
Design survey	Boys: 15; girls: 12	10.2 (2.1)	4.8 (3.0)	Mock-up	
Alpha testing	Boys: 8; girls: 4[b]	10.5 (2.7)	3.7 (2.2)	Alpha release	
Iteration 2					Education elements, such as an educational library or simulations of blood glucose, minigames, storyline, and levels design
Beta testing	Boys: 2; girls: 4	9.6 (4.5)	4.8 (2.9)	Beta release	
Iteration 3					Advanced topics such as CGM[c] and insulin pump illustration, measurement of ketoacidosis, and glucagon administration
CGM testing	Boys: 7; girls: 2	12.8 (1.7)	7.0 (3.7)	Gold release	
Glucagon testing	Boys: 4; girls: 4	13.2 (2.6)	6.4 (1.8)	Gold release	
Keto-acidosis testing	Boys: 2; girls: 5	12.2 (2.7)	8.9 (3.2)	Gold release	

[a]T1DM: type 1 diabetes mellitus.

[b]Of the 12 users, 5 (42%; n=2, 40% boys and n=3, 60% girls) did not have diabetes.

[c]CGM: continuous glucose monitoring.

Serious Games and Behavioral Theory Foundations

Methodological aspects of user flow [24]; the mechanics, dynamics, and aesthetics framework [25]; and behavioral theory (tailoring [26,27], observational learning [27-29], decision-making practice [13], social and family support [30,31], and reward systems [27,32]) were used during the design of MyDiabetic. Theoretical backgrounds are summarized in the Theoretical Background and Game Design section in Multimedia Appendix 1.

On the basis of literature research, guidelines, and current practices [13,19,21,22,33], the characteristics that are important for a successful serious game were further identified (Textbox 1).

Textbox 1. Characteristics that are important for a successful serious game.

Important characteristics

1. The main avatar should be empathetically connected to the player. One possibility is to use avatars that reflect the player in the game [34]. Customizing the avatar in game should also be possible (refer to the Avatar Tailoring subsection under Theoretical Background and Game Design and Figure S2A in Multimedia Appendix 1).
2. The game should have an incentive and customizable reward system that supports the player's learning. As a reward, the game can offer trophies or new *unlocked* game content (refer to the Level Progress Design subsection under Theoretical Background and Game Design and Figure S2B in Multimedia Appendix 1).
3. The game should aim to develop the player's skills by setting clear but challenging goals related to changing the player's behavior in real life (mainly all educational and technical features developed in iterations 1-3: iteration 1 [main game concept], iteration 2 [educational and gamification features], and iteration 3 [advanced features]).
4. The difficulty should gradually increase and adapt to gradually improving the player's skills, giving the player further opportunities for improvement (refer to the Level Progress Design subsection under Theoretical Background and Game Design in Multimedia Appendix 1).
5. The game should have a realistic and health-related story. This attractive design includes high-quality graphics, sounds, and animations to immerse the player in the game (refer to the Scenes Description subsection under Theoretical Background and Game Design and Figure S1 in Multimedia Appendix 1).

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A summary of the game and the methodology is provided in Multimedia Appendix 3. In addition, Multimedia Appendix 4 contains a video highlighting the game's main features.

Participant Recruitment

The whole concept was iteratively validated throughout the 3-stage iteration design process. Children were recruited through the project website [35], at diabetes summer camps, and via Facebook groups and through nonprofit organizations dealing with treatment support. The eligibility requirements were as follows: (1) fluency in Czech, (2) possession of a smartphone for a minimum of 2 weeks, (3) a confirmed diagnosis of T1DM for at least 1 year, and (4) aged between 5 and 16 years.

Ethical Considerations

The design process was approved by the committee for research ethics at the Czech Technical University in Prague, Czech Republic (0000-01/24/51902/EKČVUT). Written study information was provided, and written informed consent was obtained from parents. All users agreed to provide anonymized data for research and data analysis during the sign-up process, which was required for app use.

Development Approach

Agile principles [36] were used for the rapid development of various components and for iteratively integrating. Undergraduate and graduate students (computer science and biomedical engineering students) participated in developing new functionalities over 8 semesters. The game was prereleased on Google Play at the end of each iteration design process for feasibility testing. User feedback and bug fixes were communicated in weekly core team meetings and daily written discussions (via email and Slack). During the academic term, student meetings were also held once a week. A cross-platform solution, Unity software (Unity Technologies) [37], was used for game development; a free and open-source platform, Blender, was used for 3D modeling [38]; the GitHub tool [39] was used for versioning; and the Trello project management tool (Atlassian) [40] was used to track bugs and for project management. Furthermore, each task was developed in a separate branch on GitHub before being tested and approved by another team member and then merged into the master branch.

Results

Herein are presented the results of the design and development phase that gave rise to the MyDiabetic game as a person-centered education tool, along with details of the contributions provided by each iteration of the participatory co-design methodology.

Iteration 1: The Main Game Concept

Overview

In the first phase, the main game framework was outlined, focusing on carbohydrate counting and elementary technological tools for the measurement of glycemia levels and insulin administration. In addition, the basic gamification concept was proposed. The main aim of the usability study was the determination of user experience.

Individual Interviews and Design Survey

The co-design methodology was applied throughout the whole game design process. The main gaming concept was built in the first co-design iteration. First, qualitative (individual interviews) and quantitative research (design survey) methods were used to collect game design requirements. The additional documents for interviews are described in Multimedia Appendix 1 (refer to the Screener, Session Guide, and Design Survey subsections under Alpha Release). In addition, research was performed among parents, who are very important stakeholders in T1DM management. The questionnaire for parents is presented in the Questionnaire for Parents subsection under Alpha Release in Multimedia Appendix 1; a summary is presented in Table S1 in Multimedia Appendix 2.

User needs were specified, for which an informal interview was conducted. Four users with T1DM were invited to the interviews. Two observers were present during the interviews. One observer moderated the session, while another took notes, kept track of the time, and made observations. This was followed by rapid prototyping using the user-centered design methodology. The prototype used the basic paradigm mentioned in the Theoretical Background and Game Design section in Multimedia Appendix 1. The summary of the interviews is presented in Table S2 in Multimedia Appendix 2.

Parents play a big role in diabetes compensation. In this study, in children diagnosed at a young age, parents took care of insulin administration, the measurement of blood glucose levels, meal preparation, and writing in the diabetes diary. Parents would check their children regularly, some excessively, especially if they were physicians themselves. All participants used paper diabetes diaries because it was almost always the participants' mothers who took up the responsibility of maintaining the diaries, and they did not seem to be very confident about using mobile app technology (if the children were to enroll, they would have preferred to use a mobile app). The children learned about managing the disease by observing their parents' actions. Initially, when they were at school, they had to call their parents, who told them the appropriate insulin dose to inject. In time, the children became confident, and consulting their parents was no longer necessary. Quantitative research was carried out at diabetes summer camps (refer to the Design Survey subsection under Alpha Release in Multimedia Appendix 1 as well as Table S3 in Multimedia Appendix 2). In total, 27 questionnaires were collected among children aged 7 to 13 years. The main interest centered around where children obtained most of their information about diabetes and if they had ever encountered a game about diabetes. Other topics of interest were current favorite games among the children and how independent the children were in terms of counting bread units (BUs) and insulin administration.

On the basis of the results (refer to Tables S1-S3 in Multimedia Appendix 2), the main requirements for the game can be summarized as follows:

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- Teaching the relationship among food, insulin, and physical activity to children with diabetes
- Teaching children with diabetes how to count bread exchange units
- Demonstrating the symptoms of hypoglycemia and hyperglycemia and their solutions
- Demonstrating insulin administration, including technical skills and dose adjustment, and explaining how to assess diabetes compensation by blood testing
- Explaining the nature of the disease
- Motivating children to exercise
- Being available free of charge and to as many people as possible
- Being both educational and fun so that children can continue playing it for as long as possible

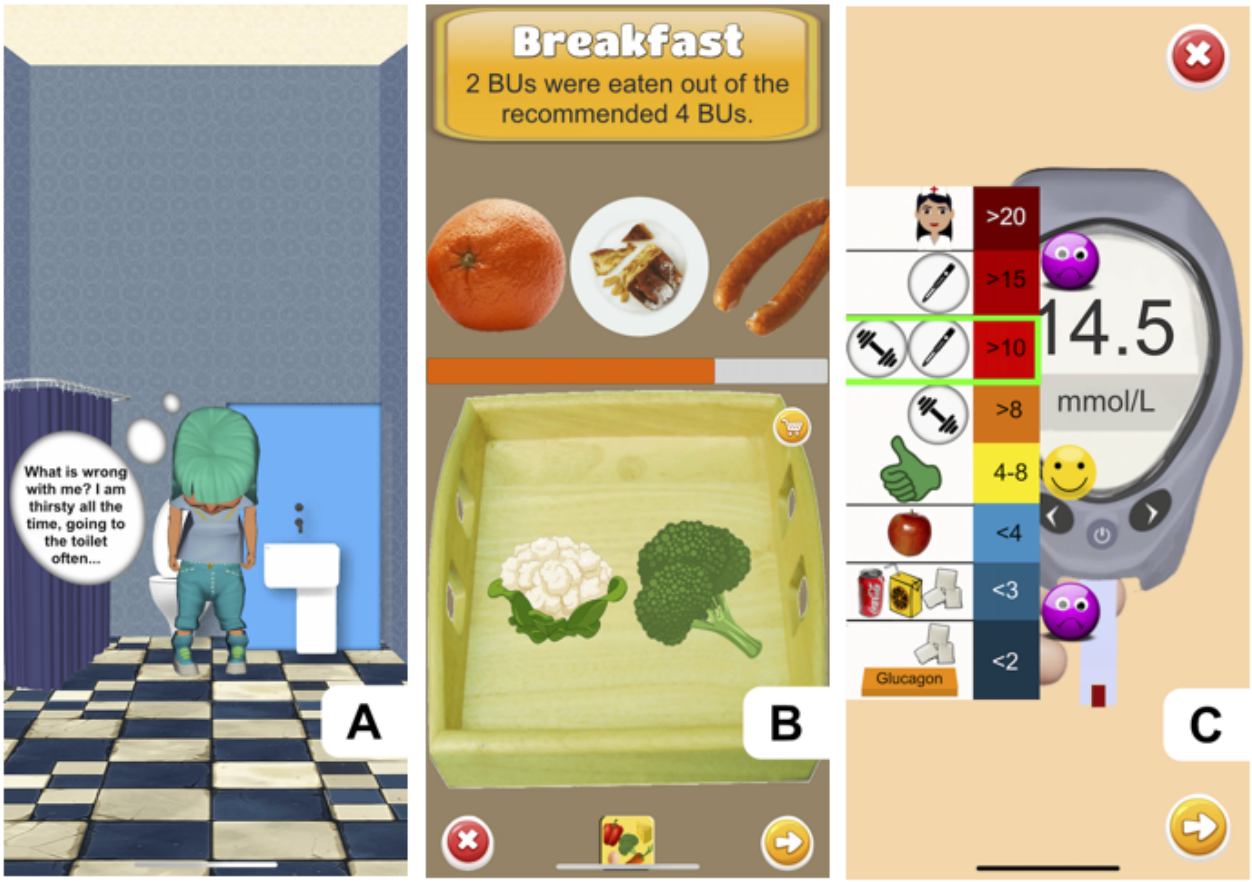
When designing the game, the choice was driven by the experience of children from quantitative research (refer to Table S3 in Multimedia Appendix 2): the most played game was Pou, which involves caring for a simulated creature, which is a proven gameplay principle of other successful games such as Moy, My Talking Tom, My Talking Angela, The Sims, and the older Tamagotchi. These games are based on the player taking care of a pet. Games of this type have had great success in the past and in recent times [34,41].

The primary design concept of the game divides the avatar's day into 6 parts, representing 6 meals, similar to the routine of a person with diabetes. The player's tasks include measuring the avatar's blood glucose level, administering insulin, and feeding the avatar. For completing these tasks, the player is rewarded with virtual coins, which can be used to enhance the avatar as well as buy new furniture, food, and other items. Neglecting the avatar's care can result in the avatar experiencing hypoglycemia or hyperglycemia, which the player can identify based on the virtual glucometer reading and the avatar's symptoms.

Onboarding and Tutorial

The game includes an introduction in which the avatar experiences the initial symptoms of diabetes and is transferred to the hospital in an ambulance, where it is diagnosed by a physician (Figure 2A).

Figure 2. (A) Onboarding, including the first symptoms and diagnosis. (B) Carbohydrate counting. (C) Measuring blood glucose level using a glucometer. BU: bread unit.



Control Elements

Herein, the control elements of the game are described using the example of a kitchen scene (Figure 3). The different rooms are represented by an icon in the bottom panel. Each icon serves not only as a switch to access that room but also to indicate whether one of the avatar's basic needs, such as sleep or food, is met. In the upper left corner, the player is reminded of the level the avatar is currently in. The key is to follow the daily routine, which can be seen on the timeline. The timeline is the same every day. During the repetition of basic actions, the player learns about the problem.

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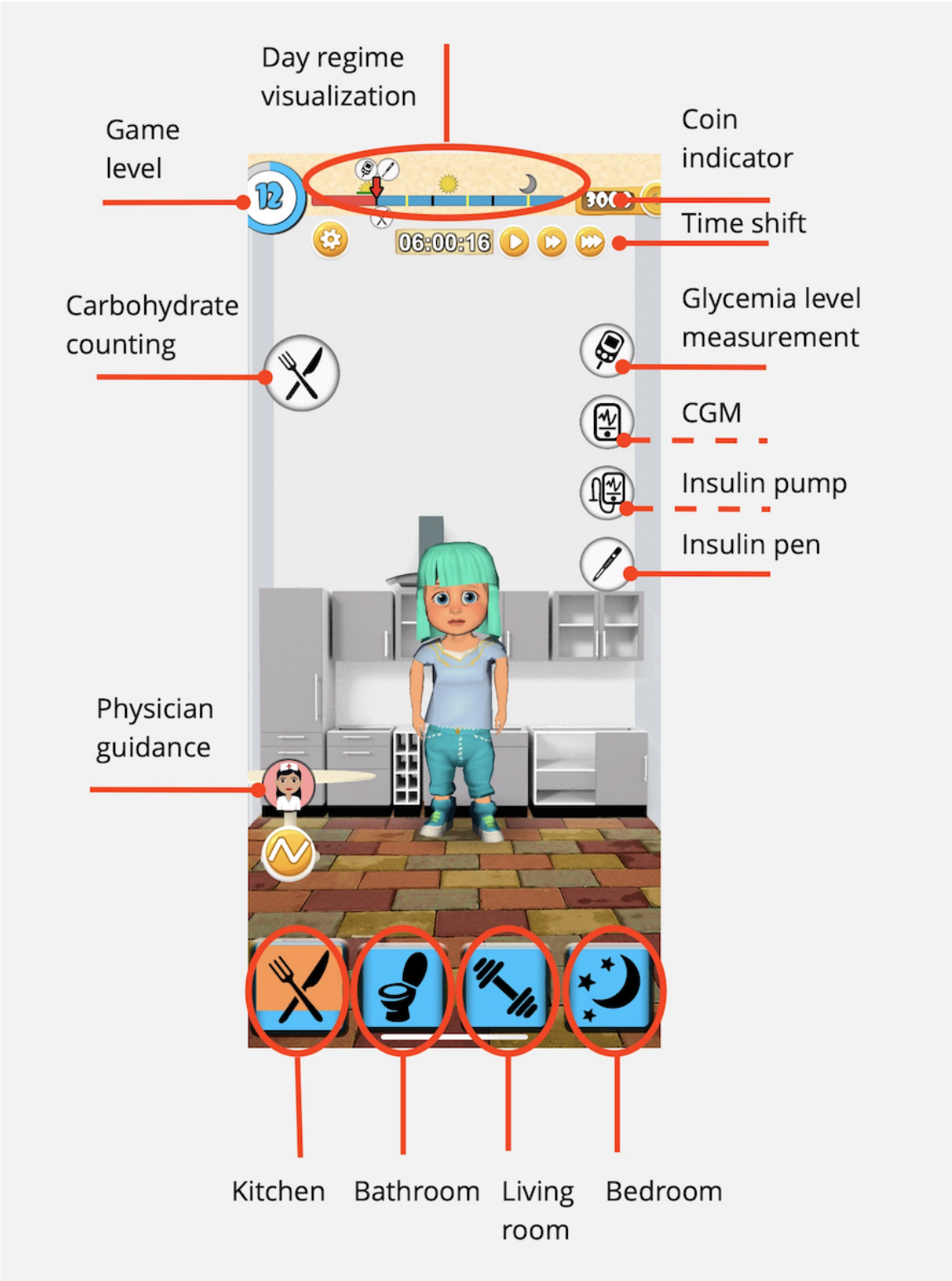
Figure 3. Description of the control elements. Continuous glucose monitoring (CGM) and insulin pen features were added in the final iteration (iteration 3) and appear in level 5.



If needed, time can be accelerated using the designated button. The amount of coins currently available in the avatar's cashbox is displayed on the right side.

To remind players of basic tasks such as measuring blood glucose levels, injecting insulin, and eating, a timeline was designed that always shows 1 task ahead, and all tasks are marked on the timeline so that the player knows approximately when the next task will occur (Figure 4).

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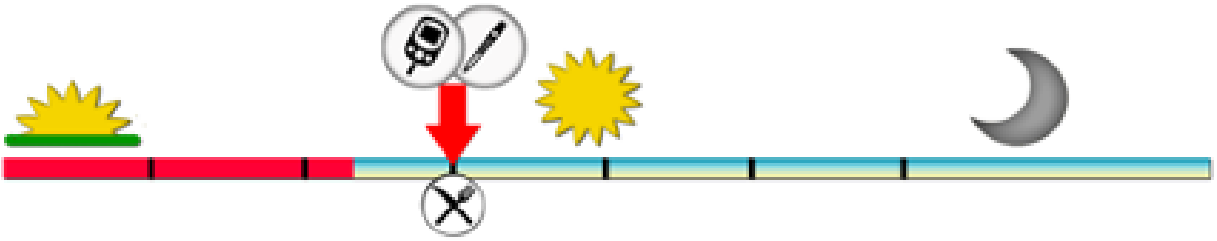
Figure 4. Illustration of the timeline for the day regime of a person with diabetes.



Carbohydrate Counting

The player must choose the proper combination from the offered food items to achieve the specified number of BUs as closely as possible. The offered food items will be selected randomly from the purchased food so that the player cannot cheat (eg, by learning the BU component of only 1 food item and repeatedly giving it to the avatar). The player can see food items as a picture of food on a plate to estimate the amount of food based on the plate size (Figure 2B).

Glycemia-Level Measurement

There is no blood glucose–level indicator in the game. The player determines the exact blood glucose level by measuring it, for which they receive a reward. The virtual measurement mimics the real measurement (Figure 2C). The needle of the lancet becomes dull over time and needs to be replaced. A limited number of test strips are inserted into the pen and run out over time. The player must buy new needles and test strips in the virtual store with the collected coins. Estimating the blood glucose level based on the avatar's current mood is possible; for example, in the case of hypoglycemia or hyperglycemia, the avatar appears sick and in a bad mood (Figure 5C).

Figure 5. (A) Performing exercise. (B) Administration of insulin with an insulin pen. (C) Visualization of the symptoms of acute hyperglycemia.

Administration of Insulin

Insulin administration too mimics real-world settings. The player learns certain habits, such as pointing the needle skyward, giving the pen a little flick or tap to loosen any bubbles to the top, and performing an *airshot* (expelling air, thus priming the needle for injecting and avoiding possible air bubbles in the cartridge). The user is first required to assemble an insulin pen by removing

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the cap from the pen, taking a new needle, removing it from the sterile packaging, inserting it in the pen, and removing the needle cap and needle shield (Figure 5B). The game only allows the user to inject insulin once the needle has been primed for injecting. The game advises the user on the appropriate dose of insulin, as well as the type of insulin to administer to the avatar. The user administers short-acting insulin before main meals and long-acting insulin at night. Changing the needle and changing the insulin cartridge (the amount of insulin in it gradually decreases) are also incorporated.

Performing Exercise

The avatar requires regular exercise; otherwise, the avatar will be in a bad mood. The player determines the duration of the exercise (Figure 5A). If the exercise is too long, the avatar goes into hypoglycemia. The muscles tend to be more insulin sensitive for 1 to 2 days after exercise, leading to an increased risk of hypoglycemia, but this is not implemented in the game. To motivate the player to be active, the game offers them bonus coins for performing physical activity. If the player owns a Fitbit fitness bracelet, it is possible to connect it to the game and receive a virtual coin for every 2 steps taken in real life.

Alpha Usability Testing

The main aim of alpha usability testing was to determine users' experience and assess their understanding of the main game concept. In total, 12 children participated in alpha testing (refer to Table S4 in Multimedia Appendix 2): 7 (58%) with diabetes (n=5, 71% boys and n=2, 29% girls; aged between 6 and 13 years) and 5 (42%) without diabetes (n=2, 40% boys and n=3, 60% girls; aged between 6 and 13 years). The involvement of children without diabetes is important to address the reduction of stigma and to provide education to friends and schoolmates. The recruitment was performed through the Association of Parents and Friends of Diabetic Children. The testing was organized at participants' premises and consisted of completing the pretesting screener (refer to the Screener subsection under Alpha Release in Multimedia Appendix 1) and testing (onboarding and going through all 4 basic screens). One observer was always present to take notes.

Regarding user experience and game mechanics, all participants were satisfied; they liked the design and were able to find their way around in all scenes, although only after several attempts. Most users asked for help, both written and audio. Some users were looking for basic educational information about diabetes. The majority of users mentioned the issue of long-term motivation to use the game regularly. The main feedback is summarized in the Feedback Summary subsection under Alpha Release in Multimedia Appendix 1. Most shortcomings were addressed in future development in iterations 2 or 3.

Iteration 2: Educational and Gamification Features

Overview

On the basis of the outcomes of the usability alpha testing and continual feedback from the clinical team (nurses and physicians), in the next iteration phase, the focus of the main design effort was on increasing adherence, game experience, and educational impact by incorporating (1) game level design (Figure S2B in Multimedia Appendix 1); (2) minigames concept and storyline (Figures S3A, S8A, and S8B in Multimedia Appendix 1); (3) virtual guidance; and (4) an educational library, including the simulation of glycemia [42] (refer to the Theoretical Background and Game Design section in Multimedia Appendix 1 for a description of the new add-ons). Incorporating the audio guidance helps preschool children who cannot usually read yet to better orient themselves within the game. The main aim of the feasibility follow-up testing was the determination of educational and adherence effects.

Beta Usability Testing

The recruitment was organized via Facebook groups and targeted children aged 5 to 15 years willing to play the game for at least 1 week. Children without diabetes were not included because this feasibility test aimed to determine the educational and adherence effects in children with T1DM. In addition, adherence was tested by inspecting game statistics implemented by applying the Google Analytics framework.

Individual Interviews

The interviews were conducted in person with the participant and their parents. The first questionnaire was the screener (refer to the Screener subsection under Beta Release in Multimedia Appendix 1), which helped to place the children in the correct category corresponding to the desired target group of the participants. This was followed by a general questionnaire (refer to the General Questionnaire subsection under Beta Release in Multimedia Appendix 1) to estimate the participant's interest in games. Furthermore, the participant was asked questions regarding their management of their diabetes (refer to the Diabetes Management subsection under Beta Release in Multimedia Appendix 1). The user was also presented with a questionnaire on diabetes education (refer to the Pretesting Knowledge of Diabetes subsection under Beta Release in Multimedia Appendix 1). Subsequently, the game was installed on their mobile device. This was followed by observation of the participant and their behavior as they undertook the first steps in the game. The participant was required to go through the whole game tutorial and later try to find their way around the game for a few minutes. The gameplay was then interrupted, and the participant was asked about first impressions (refer to the First Impression of the Game subsection under Beta Release in Multimedia Appendix 1). The participant's parents were then interviewed (refer to the Questionnaire With Parents subsection under Beta Release in Multimedia Appendix 1). The main findings of the interviews are summarized in Table S5 in Multimedia Appendix 2. Seven participants took part in the study, of whom 1 (14%) did not complete the usability testing and was excluded. Of the remaining 6 participants, 1 (17%) was a boy and 5 (83%) were girls, and they were aged 5 to 15 years. The average duration of diabetes was 4.8 (SD 2.9) years; 4 (67%) of the 6 participants were using an insulin pump.

Beta Usability Testing

The participant was asked to play the game for at least 1 week, after which they were contacted by telephone, and the second part of the test questionnaire was discussed. First, the participant was asked about their impressions of the app after the 1-week testing (refer to the Beta usability testing subsection under Beta

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Release in Multimedia Appendix 1), followed by a knowledge questionnaire on diabetes (refer to the Posttesting Knowledge of Diabetes subsection under Beta Release in Multimedia Appendix 1). The educational effect of the game is outlined in the next subsection. Regarding the usability testing results, the main findings are summarized in Table S6 in Multimedia Appendix 2.

In summary, the participant group consisted of children in different age ranges. Of the 7 participants, 2 (29%) were aged <7 years and could not read; 1 participant (14%) could not complete the usability testing because he required hospitalization. Of the 4 participants aged 8 to 12 years, 3 (75%) expressed high levels of enjoyment and found the game entertaining. Evidently, all children in this category understood the game well, confirming the study hypothesis that this age group should be the primary focus. Of the 6 participants who completed the testing, the remaining 2 (33%), aged 13 to 15 years, also understood the game well, although they commented that the entertainment aspect could have been more engaging. They highly recommended the game to younger audiences and stated that they wished such an educational tool had been available when they had been first diagnosed with diabetes. In general, the girls particularly enjoyed shopping, while the boy was more interested in minigames.

Educational Effect

Table 2 summarizes the educational impact based on the answers to the questionnaires, showing the level of education before and after the testing. The specific percentage response rates are given in Tables S7 and S8 in Multimedia Appendix 2. This score is expressed as a percentage depending on the quality of the correctly answered questions and the degree of confidence in answering them (assessed subjectively). If the answer is accurate and complete (correct), then 100% is given for this question. If the answer is partially correct or incorrect, a percentage measure of accuracy is estimated, where 0% is given for an outright nonsensical answer or if the participant does not know the answer.

Table 2. Effect of education.

	Educational score before testing (%)[a]	Educational score after testing (%)[b]	Difference (%)[c]
Participant 1	39	44	5
Participant 2	96	98	2
Participant 3	27	55	28
Participant 5	80	93	13
Participant 6	84	95	11
Participant 7	89	94	5

[a]Average 69.2.

[b]Average 79.8.

[c]Average 10.7.

Table 2 depicts the results of the educational effect after 1 week of usability testing. On average, the increase in education knowledge was approximately 10%; in the particular case of participant 3, the gain was considerably high: 28%.

Statistics Summary

Regarding game analytics, a significant improvement in skills was observed throughout the gameplay, specifically in the time taken to perform certain procedures. The time taken for glycemia-level measurement decreased by 42%, and the time taken for insulin administration decreased by 45% from the first interaction (day 1) to the last interaction (day 7).

Analyzing the purchase behavior of players, the most frequently bought food items were the large basket (46%), followed by the medium-sized basket (26%), and the small basket (28%). As for medical supplies, the majority of purchases consisted of glucometer strips (59%), followed by lancet packs (18%), injectable lancets (12%), and insulin (11%).

Examining the distribution of glycemia statistics, glucose measurements were most commonly applied on the middle finger (50%), followed by the index finger (22%), ring finger (19%), little finger (6%), and thumb (3%). Short-term insulin injections were most frequently applied to the abdomen (29%), left biceps (12%), and left thigh (7%). Long-lasting insulin injections were predominantly applied to the left and right thighs (11% and 12%, respectively) and to the chest (6%). The less frequent injection site was the right thigh 0.78%, of the 129 injections recorded.

During the gameplay, the avatar was hospitalized 31 times, with 15 (48%) of the cases involving hypoglycemia and 16 (52%) involving hyperglycemia. The average blood glucose level during these hospitalizations was 15.7 mmol/L. In addition, the avatar engaged in exercise 72 times, with 36 (50%) of the sessions lasting for 30 minutes, 19 (26%) for 90 minutes, and 17 (24%) for 60 minutes. However, the exercise was completed in only 32 (45%) of the cases, with early terminations occurring in the remaining 40 instances (55%).

The final phase of the usability testing focused on measuring adherence. At the beginning of the game, the day and time were recorded to mark the initial interaction. Subsequently, for each following day, whether the player returned to the game was noted. The retention rate, depicting the percentage of players who continued playing the game over time, is illustrated in Figure 6.

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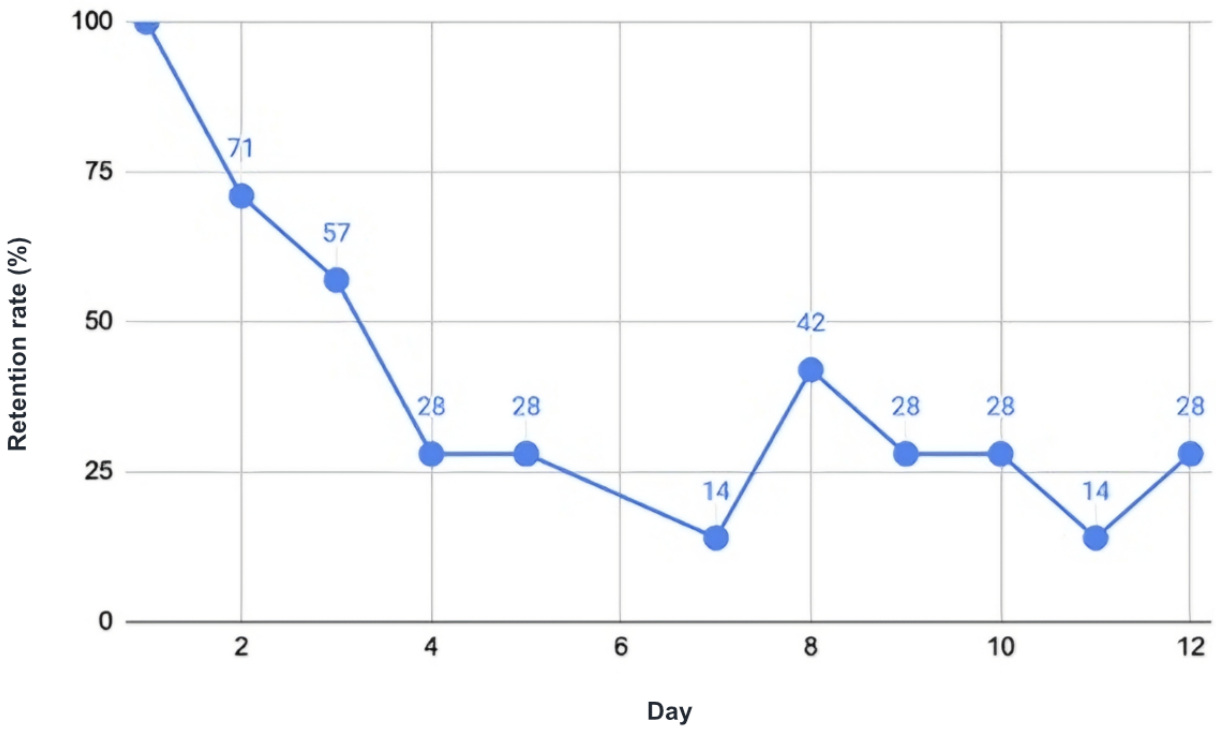
In the first week, the participants tested the game without any intervention. The telephone interview was performed on day 7. As shown in Figure 6, the adherence rate was >14%, and on the following day, day 8, the rate increased to 42% after the interview. The time spent playing the game on day 1 was approximately 39 minutes per user; on day 7, it was approximately 25 minutes. Some participants even played the game for 1.5 hours on 1 day. The daily average time for all participants was approximately 17 minutes.

Figure 6. Retention rate of participants.



Participant Feedback

Given the high number of participants (70%) using insulin pumps, it was unsurprising that there were requests to add insulin pump functionality and CGM in the game. Some users also expressed a desire for more advanced tools, such as the ability to administer glucagon and measure ketoacidosis. In response to this feedback, these features were included in iteration 3 of the game.

Of the 6 participants, 2 (33%) indicated that the game became routine after a certain period and that they desired some variation. Of these 2 participants, 1 (50%) suggested that a solution could be to introduce complications related to diabetes, such as cardiovascular issues, neuropathy, or retinopathy, which the player would need to manage.

In the real world, various types of insulin are available, each designed with different properties regarding onset, peak, and duration. Participants expressed the desire to be able to purchase and use the specific insulin types that they are familiar with and to understand their characteristics within the game.

Iteration 3: Advanced Technological Components

On the basis of the feedback received from the beta usability testing, in this iteration, more advanced tools for diabetes management were implemented. Subsequently, the final usability study briefly evaluated the new modules.

CGM and Insulin Pump Implementation

This module illustrates the use of the application of the CGM sensor (Figure S4 in Multimedia Appendix 1) and tethered insulin pump (Figures S5 and S6 in Multimedia Appendix 1). When the player's blood glucose levels reach a certain threshold (>5mmol/L), the advanced technology of using a CGM sensor and an insulin pump becomes available, unlocking new features and options in the game (see insulin pen and insulin pump icons in Figure 4).

Glucagon Administration

Glucagon administration is an essential treatment for severe hypoglycemia, particularly when a person with diabetes cannot consume food or fluids because they are in a hypoglycemic coma [12]. Another individual must administer the glucagon injection in such cases. The selected design closely resembles the real-life GlucaGen HypoKit (Novo Nordisk A/S) and visually represents the glucagon injection process (Figure S7B in Multimedia Appendix 1). The glucagon administration icon will be displayed when the avatar experiences hypoglycemia, indicating the appropriate action to take.

Measuring Ketoacidosis

Specifically, patients treated with continuous subcutaneous insulin infusion have a greater risk of developing diabetic ketoacidosis because there is no subcutaneous depot of insulin, and therefore ketoacidosis can occur much faster [1]. As the

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measurement of ketone bodies from urine using diagnostic strips is the most common and most accessible method in the home environment, the focus is on designing the scene using the home kit (Figure S7C in Multimedia Appendix 1). To simulate the level of ketoacidosis, the simplify model from the work by Fabietti et al [43] was applied (refer to the Ketoacidosis Module Implementation section in Multimedia Appendix 1).

Gold Usability Testing

The primary objective of the usability testing was to evaluate the technical feasibility of the advanced modules. Participants were recruited from a summer camp for children with diabetes. In the first phase, a general questionnaire was administered to assess the participants' knowledge about diabetes compensation. A total of 30 participants (n=12, 40% boys and n=18, 60% girls) aged between 7 and 15 years completed the questionnaire (refer to Table S9 in Multimedia Appendix 2). In the second phase, the 24 participants completed the tutorial (refer to the Onboarding and Tutorial subsection) together. Finally, the participants were divided into 3 groups to test the insulin pump and CGM sensor module (9/24, 37%), the ketoacidosis measurement module (7/24, 30%), and the glucagon administration module (8/24, 33%). Before testing, a pretesting questionnaire (refer to the Pretesting Questionnaire subsection under Gold Release in Multimedia Appendix 1) was administered. The usability testing session was conducted by a researcher, who explained the main goals to be achieved in each group in several steps.

A cohort of 9 participants (n=2, 22% boys and n=7, 78% girls) were enrolled to test the insulin pump and CGM sensor module. The study required the participants to complete several tasks, including applying the glucose sensor and insulin pump infusion set, calibrating the sensor, and spending a portion of the day using the sensor and the pump. The summary of the testing is provided in Table S10 in Multimedia Appendix 2. Overall, the insulin pump and CGM sensor module were rated positively for their realism; however, participants reported that certain complications were not accounted for in the game, such as disconnecting the infusion set from the reservoir, the possibility of the pump tubing becoming kinked and clogged, and adding insulin to the reservoir. During the pump assembly (refer to step 2 in Table S11 in Multimedia Appendix 2), participants had difficulty connecting the reservoir to the infusion set using tubing and squeezing the air out of the tubing by long pressing the button on the tank. In addition, confusion arose during the insulin infusion scene because participants needed clarification on how many units of insulin they should inject. Improvements in this scene could help better convey the necessary information to the player.

Eight participants were involved (n=4, 50% boys and n=4, 50% girls) in the testing of the glucagon administration module (refer to Table S12 in Multimedia Appendix 2). All participants were able to administer glucagon; however, sometimes the game took longer than expected due to minor bugs or nonintuitiveness, such as using a click gesture instead of a drag-and-drop gesture, which caused problems in cases of drawing the solution back into the syringe and then removing the syringe from the vial or removing the protective cover of the syringe. All participants praised the realistic handling of the game.

The ketoacidosis measurement module was successfully tested by all 7 participants (n=2, 28% boys and n=5, 72% girls), who found the scene good and did not suggest any improvements (refer to Table S13 in Multimedia Appendix 2). Only 1 (14%) of the 7 testers did not observe an increase in ketone bodies when insulin was not administered to the avatar. When asked about alternative methods of measuring ketones, most participants expressed openness to new options beyond diagnostic strips, especially for children accustomed to different measurement methods.

Discussion

Principal Findings

The main objective of this paper was to provide education mainly to children newly diagnosed with T1DM by using mobile technologies and gamification theory for educational purposes. The inclusion of gamification in diabetes management offers additional benefits compared to current methods, particularly in terms of improving patient motivation [4,5]. Given the widespread use of mobile technologies among young children, a mobile app is an ideal platform for introducing this serious topic to them entertainingly and engagingly. This approach involves combining various techniques, such as gamification theory [24] as well as topics from behavioral theory, such as tailoring [11], observational learning [29], decision-making practice [13], social and family support [30,31], and reward systems [32], to support patient motivation and compliance.

The game provides comprehensive education for children on various aspects of diabetes, including technical skills such as measuring blood glucose levels and administering insulin, as well as explanations of the nature of the disease. As a result, the game should be considered an additional resource for children newly diagnosed with T1DM to learn about the disease, along with books and brochures. The game's virtual avatar can also serve as a supportive friend for children unable to attend diabetes camps.

In addition, the game has the potential to raise awareness of diabetes among children without diabetes as well as parents [1]. By increasing knowledge of the disease and its symptoms, the game can aid in earlier diagnosis and treatment of diabetes. Initial feedback from children with T1DM and their parents on the game has been positive, with many expressing enjoyment and a willingness to participate in further testing.

Concerning the educational effect of the game, after a week of testing, there was a noticeable improvement in the educational outcomes (refer to Table 2). When compared to a previous study [16], it can be inferred that the improvement rate in educational outcomes is similar (33%). However, it is important to consider that the game in that study was tested for a year, while in this study, testing only lasted a week. In comparison, another study [18] reported an improvement rate in educational outcomes of 7% only. MyDiabetic aims to enhance traditional patient education formats (such as patient information booklets [44]) rather than replace them.

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Recent literature reviews on gameful eHealth and mobile health tools have indicated that the most commonly used game elements are externally oriented, such as points and rewards [45,46]. The concept of avoiding excessive use of externally oriented motivational features has also been explored in theoretical works on designing engaging and gameful experiences [47]. Nevertheless, in a review of similar apps targeting gaming in T1DM (refer to Table S14 in Multimedia Appendix 2), authors found that the archetypal game elements of points, badges, and competitions were the primary approaches used [48]. MyDiabetic involves using rewards to purchase food, goods, and healthy supplements, which appeal to most children. The shopping aspect serves as an educational tool that prepares young children to increase self-efficacy in managing their T1DM, consequently reducing their dependence on their parents [5,17].

One of the most effective aspects of the co-design process in achieving design goals was the participation of clinicians, patients, family caregivers, developers, and game designers. Participants brought their unique expertise to the table and contributed to the design process; for example, health care researchers provided knowledge and feedback on diabetes compensation, while the developers and designers worked on making the tool user-friendly, and the external game designer suggested more interactive and immersive solutions. Research indicates that collaborative, team-based approaches are recommended for developing mobile health interventions [49]. The strategic coordination of stakeholder involvement at each stage of development was a key benefit of this design approach.

Although there is still no consensus on the optimal combination of game mechanics for serious games [34], it is acknowledged that MyDiabetic currently leans too heavily toward education, leading to lower retention rates than anticipated. Drawing from the insights gained during the second and third rounds of the iterative usability studies, it is proposed to redesign the game by incorporating multiple storylines, such as school experiences, dating, and career development, to enhance the entertainment factor and introduce new topics as the avatar ages. The existing educational components will be seamlessly integrated into the game mechanics to improve overall gameplay and increase engagement. This new direction should also provide an easier transfer of knowledge and skills from this serious game to real-world situations [34].

Limitations

Initially, all participants involved in the study voluntarily opted to participate or were contacted by the project team or collaborating institutions. Consequently, the participating groups may have had higher motivation, resourcefulness, and better chronic illness management, thus creating a potential bias that may only represent a portion of the user group. Nonetheless, this is a common limitation in this type of research.

While the sample sizes were indeed modest in the alpha, beta, and gold testing phases (12, 6, and 24 participants, respectively), the significance of the results lies in the qualitative insights and detailed observations that were gathered through iterative usability testing. This process enabled deep delving into the experiences and perceptions of each participant, yielding rich and meaningful data on the game's usability and educational impact. Furthermore, the results that were obtained from the limited numbers of participants were consistent and provided actionable insights for further refinement and development of this serious game.

The design outcomes were influenced by the stakeholders involved in the project, who had the potential to both positively impact and limit the final design. One example is the nutrition nurse who facilitated the design activities but had limited design experience and had to learn co-design processes as the project progressed.

The MyDiabetic app was developed and evaluated solely by Czech users, although an English version is now accessible. There may still be cultural discrepancies that have not been fully addressed. The project team constantly receives feedback and makes necessary adjustments to improve the app's usability and relevance.

It is important to note that this paper focuses solely on the technical development of the game and user acceptance testing. The clinical validation of the game, using metabolic control markers such as mean glycated hemoglobin levels, is beyond the scope of this paper. While it is important to evaluate the effectiveness of the game in improving diabetes management, this will be the subject of future research.

Comparison With Prior Work

After examining the survey presented in Table S14 in Multimedia Appendix 2 [13,16,18,19,21,24-31,33,42,43,50-65], it was observed that all games, except Packy & Marlon [16], lacked clinical validation. Furthermore, assessing adherence was not a focus in any of the games. In addition, of the 18 games, 3 (17%) were previously available on Nintendo or mobile game stores, but currently only 2 (11%; MyDiabetic and Jerry the Bear) are available for download on mobile game stores. Most games were developed as prototypes or concept studies as part of academic projects, with only a few aimed at preschool children [50-52]. Only 1 (6%) of the 18 games addresses both basic (carbohydrate counting, blood glucose–level measurement, and insulin administration) and advanced (CGM and insulin pump) educational self-management skills [50]. Nevertheless, no game tackles the complexity of diabetes management from such a wide perspective as MyDiabetic, in which unique features such as glucagon administration and ketoacidosis modules are included.

One of the challenges that serious game designers face is the *uncanny principle*, also known as the *uncanny valley*. This phenomenon occurs when a representation of a human or an animal looks and behaves almost but not exactly like the real thing [66]. The result is a feeling of eeriness, discomfort, or even revulsion in the observer. The *uncanny principle* can affect the learner's immersion, engagement, and emotional connection with the serious game. The *uncanny valley* can be useful for creating more effective and engaging serious games. By carefully navigating the *valley* and finding the right balance between realism and abstraction, game designers can create experiences that are both educational and emotionally compelling [67]. MyDiabetic aimed to strike this balance by

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using cartoonish avatar designs and environments, while carefully incorporating technology features that closely resemble real-world settings, setting it apart from most other games [16,50].

Future Directions

To enhance the game's realism, it would be beneficial to incorporate real-time elements. This would involve the avatar aging as time passes In addition to managing diabetes symptoms, the avatar would also engage in typical daily activities such as attending school/work, participating in outdoor sports, visiting friends, and partaking in entertainment (Figures S8A and S8B in Multimedia Appendix 1). In addition, chronic retinopathy or diabetes foot problems would also be demonstrated (Figure S8C in Multimedia Appendix 1). By including these elements, the game could provide a more comprehensive experience for users and better prepare them for managing their diabetes in real-life situations.

Including social support in the app could be an additional valuable feature [68]. Games that allow users to connect with others in a community-type setting or through social networks could be particularly beneficial because research suggests that increased social support is linked to improved self-efficacy practices and better clinical outcomes in children with diabetes. A review of studies also found that social media were commonly used to facilitate self-care in patients and caregivers, with 77.1% of the identified studies reporting such use [69].

Conclusions

This paper has shown how participants involved in co-design activities played a creative and productive role in shaping the content and design of the MyDiabetic app.

The main objective of creating a serious educational game was to captivate children with T1DM and also make it accessible to those who are interested in learning about the disease. On the basis of the testing described earlier, the educational goal was achieved because significant enhancements in children's understanding were evident after a mere week of gameplay. The game was well-received by the participants, who expressed a willingness to recommend it to their friends or siblings who are not affected by diabetes but are curious about the disease and would like to understand it better.

To summarize, this research suggests that the target audience for this game is children aged between 5 and 12 years, with those in the 8- to 12-year range being able to fully engage with and benefit from all the features the game offers.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Additional theory background, questionnaires, and details of implementation.
[PDF File (Adobe PDF File), 12529 KB - games_v12i1e49478_app1.pdf]

Multimedia Appendix 2
Results of the feasibility testing.
[XLSX File (Microsoft Excel File), 154 KB - games_v12i1e49478_app2.xlsx]

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Multimedia Appendix 3
PowerPoint (Microsoft Corp) presentation showing key aspects of MyDiabetic and related material.
[PDF File (Adobe PDF File), 14994 KB - games_v12i1e49478_app3.pdf]

Multimedia Appendix 4
MyDiabetic video.
[MP4 File (MP4 Video), 19844 KB - games_v12i1e49478_app4.mp4]

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Abbreviations

BU: bread unit
CGM: continuous glucose monitoring
T1DM: type 1 diabetes mellitus

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Review

Virtual Reality Applications for the Implementation of Domestic Respiratory Rehabilitation Programs for Patients With Long COVID and Post-COVID Condition: Scoping Review

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Abstract

Background: Due to a high number of patients affected by long COVID or post-COVID condition, an essential step to address the long-term effects of COVID-19 lies in the development and implementation of flexible and accessible rehabilitation programs. Virtual reality (VR) technologies offer the potential to support traditional therapies with individualized at-home programs.

Objective: This study aims to provide an overview of existing scientific evidence on the development and implementation of VR-assisted respiratory rehabilitation programs for patients with long COVID and post-COVID condition and to synthesize the results.

Methods: We conducted a scoping review of studies from 6 databases. PubMed, CINAHL, Cochrane, ScienceDirect, Web of Science Social Sciences Citation Index, and PEDro were searched using an exploratory search strategy. The search, which was last updated in February 2024, included peer-reviewed studies on immersive VR applications providing respiratory rehabilitation programs for patients with chronic obstructive pulmonary disease and long COVID or post-COVID condition. Exclusion criteria were studies in clinical or inpatient settings, telemedicine, nonimmersive VR applications, and gray literature. Nine publications were included in this review. Findings were extracted and summarized from the studies according to the JBI (Joanna Briggs Institute) method and thematically categorized. Topics covered were study characteristics, physiotherapeutic concept, clinical parameters, as well as usability and acceptability.

Results: The 9 publications included in the qualitative analysis were published in 2019-2023. Eight empirical studies were included: 4 followed a mixed methods design, 3 were qualitative studies, and 1 followed a quantitative method. One scoping review was included in the data analyses. Four of the included studies were on patients with chronic obstructive pulmonary disease. The 9 studies demonstrated that VR-supported respiratory rehabilitation programs result in positive initial outcomes in terms of physical as well as psychological parameters. Particularly noteworthy was the increased motivation and compliance of patients. However, adverse effects and lack of usability are the barriers to the implementation of this innovative approach.

Conclusions: Overall, VR is a promising technology for the implementation of individualized and flexible respiratory rehabilitation programs for patients with long COVID and post-COVID condition. Nevertheless, corresponding approaches are still under development and need to be more closely adapted to the needs of users. Further, the evidence was limited to pilot studies or a

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small number of patients, and no randomized controlled trials or long-term studies were part of the study selection. The included studies were performed by 4 groups of researchers: 3 from Europe and 1 from the United States.

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KEYWORDS

long COVID; post-COVID; rehabilitation; virtual reality; implementation; respiratory; respiratory rehabilitation; scoping review; development; accessibility; support; physical; psychological; motivation; compliance; usability; COVID-19; COVID

Introduction

Background

In the wake of the COVID-19 pandemic, the rehabilitation of patients in the postacute phase of this disease is an important measure to address the long-term effects since a significant number of patients experience the condition commonly known as long or post-COVID [1]. This condition is characterized by symptoms that persist or develop after the acute phase of infection—starting from the fourth week after infection—and that cannot be explained by an alternative diagnosis [2,3]. The number of affected patients varied in the studies depending on the methodology, symptoms, as well as the population included in the analysis. Although studies provide heterogeneous results and case numbers, they show that a significant number of patients are affected by persistent symptoms after a COVID-19 infection. Patients who report an impact on everyday functioning up to 3 months after testing negative account for 10%-50% of the study participants [4]. According to a study by Peter et al [5] conducted in 2020 and 2021, including 11,710 patients from Germany, 28.5% of the patients reported persistent symptoms for 6-12 months after infection with COVID-19. That study further estimated that at least 6.5% of the adult patients in the general population who had recovered from COVID-19 infection were affected by long-term symptoms such as fatigue, dyspnea, neurocognitive impairments, and chest pain [5]. As per the World Health Organization, in the European region approximately 20% of the patients developed symptoms mentioned above continuing for at least 3 months after recovery according to a meta-analysis [6]. In addition, psychological symptoms such as anxiety and stress can have a negative impact on the quality of life caused by the abovementioned long-term effects [4,7].

After the treatment of acute symptoms is completed, patients need postacute rehabilitation, where physical therapy plays an important role in the treatment of lung-specific symptoms. For the best treatment possible, outpatient programs as well as solutions for the implementation of therapy programs in the home environment have to be established [8,9]. Pulmonary therapy approaches for chronic diseases such as chronic obstructive pulmonary disease (COPD) designed to normalize respiratory function have been well-established and are guiding the development of therapies for patients with long COVID or post-COVID condition. Therapy approaches include mobilization exercises, endurance, as well as strength training [10-14]. Since many patients experience psychological symptoms from the effects of impaired respiratory function, it is necessary to guide, counsel, and train patients in the use of appropriate strategies and coping skills when acute respiratory distress occurs [11].

Although the number of people affected by long and post-COVID symptoms remains high even as the pandemic situation continues to ease, there is still insufficient knowledge about the disease and a shortage of specialists and therapy programs [4,15]. In addition, the physical limitations of patients further impact their access to traditional physical therapy services. One way to address the shortage of adequate programs is to develop digital therapy solutions and assistive devices that are applicable in a home setting and can be individually applied without the constant supervision of specialist staff.

Initial findings suggest that digital approaches enable a more accessible implementation of therapies in the home environment and, at the same time, can contribute to increased motivation and adherence to therapy on the part of patients [16]. Previously established digital applications, for example, for patients with COPD have led to an increase in the quality of life, particularly with regard to emotional control and reduction in fatigue and dyspnea [17]. Virtual reality (VR) technologies are a solution to implement individual and flexible physical therapies in virtual space through the virtual representation of therapeutic measures and therapy situations. Approaches to integrate immersive VR applications already exist in various areas of rehabilitation as well as in psychotherapy, for example, to alleviate respiratory symptoms [18,19] and reduce anxiety and stress [20]. However, the implementation of respiratory therapy approaches for the home environment and especially programs for the target group of patients with long COVID/post-COVID condition are still under development. Further, a comprehensive review of the initial evidence on the development and implementation of appropriate VR applications does not yet exist.

Objectives

The aim of our literature review was to (1) obtain an overview of the findings in international research regarding VR-based respiratory rehabilitation programs for patients with long COVID/post-COVID condition and (2) obtain criteria for the development and implementation of respective VR applications for the home environment. Our scoping review addresses the research question: what scientific evidence exists on the development and implementation of VR-assisted rehabilitation programs for patients with long COVID/post-COVID condition that are implementable in a home setting? The selection and analysis of the studies were based on the following subquestions:

1. Which guidelines exist for the design of VR respiratory rehabilitation programs?
2. What are the enabling aspects? What are the barriers to implementation?

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3. What clinical outcomes have been reported?

Methods

Study Design

The methodological approach of the JBI (Joanna Briggs Institute) method according to von Elm et al [21] was adopted as the basis of this scoping review to give a broad overview on the existing findings and identify established criteria in international research for the implementation of VR-assisted rehabilitation programs for patients with long COVID/post-COVID condition. Since only a small number of studies was expected regarding the patient group and the focus was on respiratory rehabilitation programs, conditions with a comparable symptomatic spectrum—such as patients with COPD—were also included. Results will be reported using the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines (Multimedia Appendix 1). In preparation for this, a review protocol was developed but not published or registered.

Search Strategy

A sensitive database search was conducted using the databases PubMed, CINAHL, Cochrane, ScienceDirect, Web of Science Social Sciences Citation Index, and PEDro. The search was last updated in February 2024 in order to incorporate newly released studies. According to the search components—population, concept, and context—search terms were applied using Boolean operators, truncations, and proximity operators (see Textbox 1 and Multimedia Appendix 2).

Textbox 1. Search string using the example of the search in PubMed.

(((covid-19[MeSH Terms]) OR (respiratory*[Title/Abstract])) OR (pulmonary*[Title/Abstract])) AND (Rehabilitation[Title/Abstract]) AND (VR[Title/Abstract] OR virtual reality[Title/Abstract])

The identified studies were merged in the web-based tool “rayyan” [22] and screened by titles, abstracts, and full texts in regard to the research question, which was conducted independently by 3 researchers. Additionally, the reference lists of all the publications included in the full text screening were searched for further evidence. The inclusion and exclusion criteria for the studies were decided by team consensus (KD, IK, and HAE).

Study Selection

All types of studies published in the period between 2012 and 2023 that were available in English or German and provided with an abstract were included. The following inclusion and exclusion criteria were applied (see Textbox 2).

Textbox 2. Inclusion and exclusion criteria for the studies in this review.

Inclusion criteria

- Studies on immersive virtual reality applications providing respiratory rehabilitation programs, including breathing exercises, physical training, education, and programs introducing psychological counseling such as stress reduction for the home environment
- Studies including patients with long COVID, post-COVID condition, or chronic obstructive pulmonary disease
- Peer-reviewed empirical studies
- Mixed methods, qualitative, and quantitative studies

Exclusion criteria

- Clinical inpatient setting
- Telemedicine
- Virtual reality applications that are nonimmersive (applications for personal computers, augmented reality, etc)
- Gray literature (conference papers, opinion papers, study protocols)

Data Extraction and Synthesis

The characteristics of the identified studies were mapped in a preconsented data form (KD) and summarized narratively. Three researchers (KD, IK, and HAE) derived evidence on the development and implementation as well as the clinical outcomes of the studies concerning VR-based rehabilitation programs from the literature included in this analysis. The aspects identified were then categorized thematically, while study results covered the areas of study characteristics, physiotherapeutic concept, and outcomes in terms of clinical parameters as well as usability and acceptability aspects and were clustered and summarized according to the JBI method [21]. The categorization was then discussed within the research team.

Results

Overview

After duplicates were removed, 128 identified abstracts according to the above listed criteria were independently reviewed by 3 authors (KD, IK, and HAE). A full-text screening of the resulting 36 publications led to 9 studies, which were included in our review. Figure 1 shows the process of study selection in a PRISMA flowchart.

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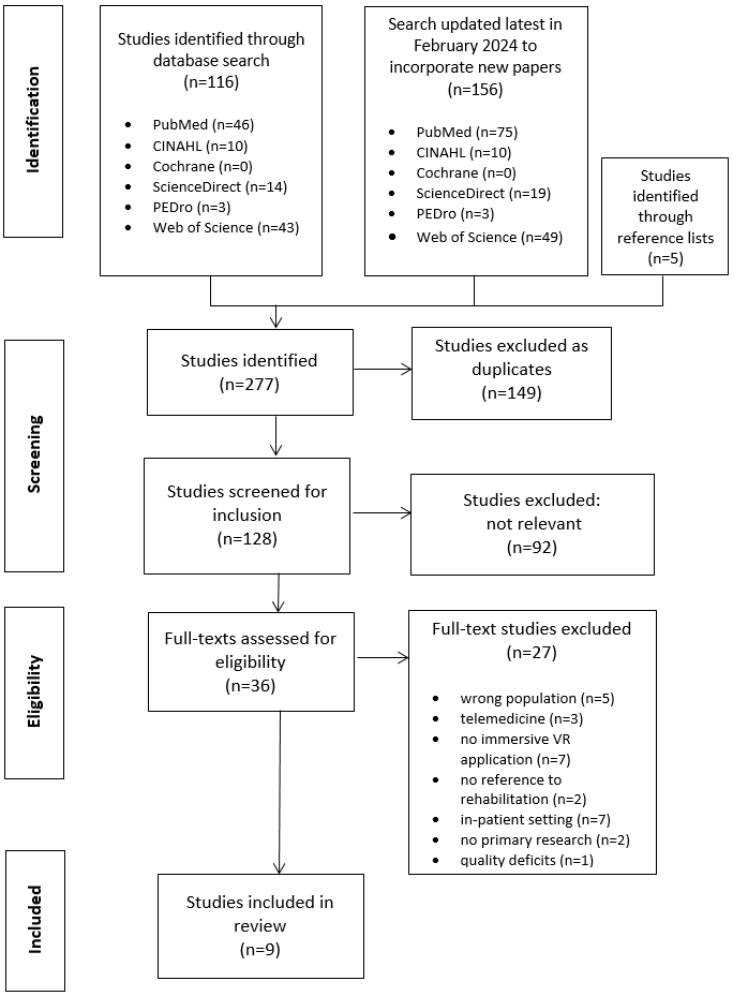
Figure 1. PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) flowchart of the study selection process.



Characteristics of the Included Studies

The included studies were published between 2019 and 2023. The majority of the studies [23-28] were published since 2022. Six empirical studies were conducted in Europe and were limited to the Netherlands, United Kingdom, and Slovakia [19,25-29]. Further, 2 publications that refer to the same study conducted in the United States were included [23,24]. Four studies followed a mixed methods design [19,23,25,27], 3 studies were qualitative studies [24,28,29], and 1 study applied only quantitative methods [26] (Table 1). The data analyses included 1 coping review: in 2020, Colombo et al [30] reported VR applications and exergaming for pulmonary rehabilitation of patients with COPD. Both immersive and nonimmersive approaches were included. However, an assessment of the results with regard to the quality of the included studies was not performed. There was no systematic review on immersive VR rehabilitation programs for home settings and targeting patients with long COVID/post-COVID condition.

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Table 1. Full list of the publications included in this scoping review.

Study, year	Objective	Study design	Population type	Sample size, n
Colombo et al [30], 2020	Literature review exploring findings on virtual reality and exergaming applications for pulmonary rehabilitation with focus	Scoping review	Patients with COPD[a]	N/A[b]
Gabriel et al [23], 2023	Qualitative evaluation of the feasibility of a pulmonary rehabilitation program, including educational content for patients with COPD	Mixed methods study	Patients with COPD	18
Gabriel et al [24], 2023	Qualitative evaluation of a pulmonary rehabilitation program for patients with COPD	Qualitative study	Patients with COPD	9
Groenveld et al [25], 2022	Evaluating self-administered virtual reality exercises at home for post–COVID-19 condition	Mixed methods study	Patients with post-COVID	48
Jung et al [19], 2020	Investigating whether virtual reality provides a credible alternative to traditional pulmonary rehabilitation programs and improves compliance among patients with COPD	Mixed methods study	Patients with COPD (Medical Research Council Dyspnea scale 4-5)	10
Lacko and Ruzický [26], 2022	Analyzing the use of virtual reality devices to rehabilitate patients in a controlled outpatient environment as well as in the home environment	Quantitative study	Patients with long-term COVID or post-COVID syndrome	16
Moorhouse et al [29], 2019	Evaluating a virtual reality pulmonary rehabilitation for patients with COPD	Qualitative study	Patients with COPD (Medical Research Council Dyspnea scale 4-5)	10
Ruzicky et al [27], 2022	Investigating the prevention, diagnosis, and treatment of patients after COVID-19 while using artificial intelligence and virtual reality in combination with traditional approaches to patient rehabilitation	Mixed methods study	Patients with post-COVID	10
Smits et al [28], 2022	Developing an evidence-based "Guidance ethics in context" for virtual reality development	Qualitative study	Patients with long COVID (n=20), physical therapists (n=15)	35

[a]COPD: chronic obstructive pulmonary disease.

[b]N/A: not applicable.

Synthesis of Results

The following section presents a synthesis of evidence from the included studies as the result of the qualitative analysis. The narrative description is based on the aspects of study characteristics, rehabilitation program, technical implementation, and evaluative and clinical outcomes.

Study Characteristics

The studies were first divided into 2 groups. The English research group led by Jung et al [19] and Moorhouse et al [29] and a US-American research group [23,24] tested VR applications designed for patients with COPD. They refer to the significance of continuous pulmonary rehabilitation, education of patients regarding the characteristics of their disease, and useful behavioral interventions. They also reported low compliance due to depression related to the condition, low awareness of the potential therapeutic approaches among patients, and lack of knowledge about the benefits of continuous therapy for chronic conditions. Immersive VR applications are intended to create an innovative motivating rehabilitation approach in this context [19,23,24,29]. The other publications refer to the development or evaluation of immersive digital rehabilitation programs for patients with long COVID or post-COVID condition [25-28]. Although the post-COVID condition, as already described in the introduction, refers to persistent symptoms from 4 weeks after a COVID-19 infection [26,27], other studies do not distinguish between long COVID and post-COVID condition at all [25]. Long COVID is usually described as a long-term consequence of infection with SARS-CoV-2 with various physical, psychological, and cognitive symptoms [25-28].

Ruzicky et al [27] collected data on symptoms and severity of the disease during COVID-19 infection and after recovery among a group of students and professors via a questionnaire. Based on the results, which included fatigue, fever, shortness of breath, and depression as common post-COVID symptoms, 2 groups of patients were included in the study. Ten patients had mild muscle pain and shortness of breath after mild exertion and another 6 patients were included who reported severe muscle pain along with shortness of breath [27]. None of the studies

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required a medical diagnosis or the submission of test results to verify if participants were actually infected with COVID-19; instead, studies relied solely on patient reports. Moreover, none of the studies provided further information regarding the characteristics of participants apart from gender and age or the cultural diversity of populations included. Studies have characterized VR as a way of facilitating access to therapeutic measures in the context of the pandemic [25,27]. In addition, 2 studies implemented individualized and multimodal therapy programs, which address both physical and psychological factors such as stress and anxiety [25,28]. Gabriel et al [23,24] further implemented educational content regarding pulmonary rehabilitation as part of the VR program [23,24].

Collection of Evaluative Data and Assessment

All the studies mentioned dealt with the evaluation of pulmonary VR rehabilitation applications by patients with regard to technology acceptance, usability, and criteria for implementation [19,23-29]. Only 1 publication also included the viewpoint of physical therapists in the assessment [28]. The majority of the studies used interview procedures as the qualitative data collection method [19,24,27-29]. Focus groups in which those affected by COPD were able to discuss their experiences in using the VR application were also used in this context [19,29]. The quantitative survey instruments used in the studies by Jung et al [19] and Groenveld et al [25] included both standardized questionnaires and assessments of physical performance. The questionnaires included the Chronic Respiratory Disease Questionnaire, Patient Health Questionnaire-9 [19], and the 11-point Borg Scale [25], as well as questionnaires regarding psychological and cognitive factors such as Generalized Anxiety Disorder-7 items [19], Hospital Anxiety and Depression Score, and Cognitive Failure Questionnaire [25]. Gabriel et al [23] further applied questionnaires to assess the usability of the application such as the System Usability Scale [23]. Notably, Groenveld et al [25] collected physical performance parameters. These include the 6-Minute Walk Test, Timed Up and Go Test, or 30-Second Chair to Stand Test. In addition, sensors such as smart bracelets (heart rate, pedometer, hand movements, sleep cycles) and pulse oximeters were used to measure the progress of therapy in the studies [27]. Overall, clinical outcomes (physical as well as psychological) and the evaluation of the application used in terms of acceptance and usability were analyzed in the studies.

Rehabilitation Program

The physiotherapy programs in the studies described in Table 2 primarily involve respiratory physiotherapy aimed at improving patients' functional ability [19,23-26,28,29].

Table 2. Characteristics of the rehabilitation programs evaluated in the studies included in this review.

Study, year	Type of training	Length of training	Setting of training	Virtual scenario
Gabriel et al [23], 2023	Physical training (pulmonary rehabilitation), educational content	Not reported	Home setting	Custom-made minigames and multiple choice
Gabriel et al [24], 2023	Physical training (pulmonary rehabilitation)	Not reported	Home setting	Custom-made minigames
Groenveld et al [25], 2022	Physical training, cognitive training, psychological exercises (meditation), independent training: self-management by patients	6-week trial	Home setting	Custom-made applications (minigames) for different exercises
Jung et al [19], 2020	Educational material, physical training (traditional pulmonary rehabilitation + focus on lower extremity), independent training: self-management by patients	8-week trial	Home setting, remotely supervised by health practitioners	Digital avatar
Lacko and Ruzický [26], 2022	Breathing exercises, physical training (upper limb), cognitive training	6-10 weeks	Diverse, remotely supervised by health practitioners	Digital avatar, photorealistic environments
Moorhouse et al [29], 2019	Physical training (pulmonary rehabilitation), educational material, independent training: self-management by patients	8-week trial	Home setting	Digital avatar
Ruzicky et al [27], 2022	Breathing exercises, physical training (upper limb)	Minimum of 3-4 weeks trial up to more than 5 months	Diverse, remotely supervised by health practitioners	Digital avatar, photorealistic environments
Smits et al [28], 2022	Physical training, cognitive training, psychological exercises (meditation), independent training: self-management by patients	6-week trial	Diverse	Custom-made applications (minigames) for different exercises

The focus of the studies was on various aspects such as relief of respiratory distress [19,23,24], rehabilitation of the upper limbs [26,27], and strengthening of the respiratory support muscles [19,29]. For this purpose, physiotherapeutic programs consisting of endurance, strength, and respiratory training were implemented. In addition, mental rehabilitation in light of the impact of the disease [28] as well as long-term goals such as feeling confident leaving the house [19] and quality of life [29] are addressed. Three studies also included exercises to improve cognitive skills [25,26,28]. Ruzicky et al [27] claimed that they addressed prevention, diagnosis, and treatment after COVID-19 but did not provide any further details on that. The length of

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the therapy programs ranged from 6 to 10 weeks [19,25,26,28,29]. Only in the study of Ruzicky et al [27], a minimum duration of 3-4 weeks was indicated, while in individual cases, the rehabilitation may last several months. In each case, the training program was designed for implementation in the home setting [19,23-29], but half of the publications also reported hybrid use cases within the study. For example, patients were able to try out the VR application in a therapy practice.

Moorhouse et al [29] as well as Jung et al [19], Smits et al [28], and Groenveld et al [25] implemented respiratory rehabilitation measures that were applied fully independently by patients. However, Ruzicky et al [27], Lacko and Ruzický [26], and Jung et al [19] implemented measures to monitor exercise progress. Patients were remotely assisted in setting up the program, for example, via telerehabilitation methods, while the exercises themselves were then performed independently [26,27]. Jung et al [19] focused on ensuring patient safety in their study on patients with COPD. For this reason, data such as heart rate and oxygen saturation were continuously measured in order to be able to intervene in the event of respiratory distress [19]. The selection of exercises was either defined by the patients themselves [29] or discussed with the therapist and adjusted to the requirements of the patients [26-28]. Ruzicky et al [27] and Lacko and Ruzický [26] specified that they included age, gender, and personality type in the selection process but did not specify what the criteria for the personality type is referring to and how age and gender influence the selection of the program.

The interdisciplinary research team consisting of researchers, medical doctors, physical therapists, designers, and VR developers as part of the study by Smits et al [28] developed a toolkit with resources and games. The program consisted mainly of pre-existing games and apps for physical, mental, and cognitive rehabilitation [28]. Three studies stated that a 3D avatar guides the exercises in the immersive VR environment [19,26,29]. Thereby, only 2 studies (from the same research team in Slovakia) chose a realistic representation of the avatar and environment [26,27]. Most commonly used VR headsets were Oculus Quest 2 [23,24,26,27] and Oculus Quest [25,28]. Other headsets used were Pico Interactive Goblin [19] and HTC VIVE Pro EYE [26]. Only Moorhouse et al [29] did not specify the headset used in their research.

Usability and Acceptance

VR-assisted digital respiratory rehabilitation was found to be generally acceptable and feasible in the reviewed studies. In this context, both the enabling factors and barriers for the development and implementation of corresponding applications could be derived from these studies. The benefits of virtual therapy include the aspects of immersion, motivation, as well as autonomy, flexibility, and the possibility of monitoring by therapists. In contrast, barriers include the initial adverse effects related to VR technology and the technical problems and lack of accessibility or usability of the VR applications.

Enabling Factors

In general, study participants described the tested applications as easy to use and enjoyable [19,23-25,28-30]. Studies in the context of respiratory rehabilitation of patients with COPD, in particular, also addressed the immersion in a virtual world, which among other things represents a distraction from the disease. In addition, the avatar guiding the exercises was considered as a social element to a certain extent [19,30]. VR is also considered easier to apply compared to traditional options such as instructions from printed material and booklets for the home environment [29]. Patients with COPD as well as patients with long COVID described the VR application as engaging and pleasurable [23,24,29]. They emphasized experiencing increased motivation to engage in therapeutic measures due to the stimulating or even calming nature of the virtual world, depending on the exercise [19,23-26,29,30]. The increased motivation leads to an increased frequency in usage [19,26,27]. Additionally, Smits et al [28] concluded that the gamification of exercises, in particular, contributes to the motivation of patients. Gamification refers to design elements that reproduce game elements and logics. This includes, for example, the integration of exercises into a game environment, earning scores through correct performance, and competitive approaches such as playing against each other.

Groenveld et al [25] distinguished between users according to their age and found that the duration of VR application increases with age. A possible explanation could be older persons' lesser familiarity with VR technologies because of which they are slower in navigating through the application and they lose interest in the interactive environment and the immersion less quickly [25]. Other studies reported patient groups without any previous experience with VR technology showing difficulties at the beginning of the program [26,27]. Lacko and Ruzický [26] and Ruzicky et al [27] also address the so-called "WOW-effect" in their study, describing first-time users' initial curiosity and great interest in VR [26,27]. However, according to this logic, boredom could also set in after a certain time of using the rehabilitation measure. In 2 studies, comments from study participants, including those who dropped out early, also indicated this same issue [25,26]. The digital program was described as boring, and doubts were expressed about the usefulness of the therapy [25].

Finally, the flexibility and autonomy in the implementation of VR therapy measures is emphasized in the reviewed studies [19,23,24,28,29]. This includes the feasibility of rehabilitation independent of time or location restrictions [23,24,28]. Jung et al [19] concluded that VR reduces the barriers for compliance by increasing the accessibility of rehabilitation programs, which are applicable in the home environment [19]. Patients mentioned that implementation in the home environment, in particular, can contribute to a feeling of comfort and security. In addition, patients reported that monitoring by therapists also gave them confidence [19,23,24]. Nevertheless, VR is perceived as a way to complement traditional therapies offering the advantage of social contact, which VR applications cannot fully compensate for [29].

All rehabilitation programs were customized for the patients in question. However, a distinction was made whether the program was determined by the therapist [19,26,27,29] or by the patients themselves [28]. Smits et al [28] also found that the ability to adapt the therapy to one's own level of rehabilitation and to select exercises individually offered a high added value and

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contributed to patients' autonomy. Likewise, Jung et al [19] and Moorhouse et al [29] corroborated the same findings in their evaluations.

Barriers

In addition to the benefits of VR-assisted respiratory therapy, barriers to VR implementation were described in these studies. First, the potential adverse effects of VR therapy are motion sickness or overextension due to immersion in an interactive virtual environment [25,28]. Motion sickness is a condition characterized by symptoms of nausea, vomiting, and dizziness caused by conflicting sensations related to motion. Motion sickness is commonly experienced when using VR devices, as the immersive nature of VR can create a sensory conflict between the visual input of a virtual environment and the lack of corresponding physical movement [31]. Further, dizziness, headache, or neck pain were among the most frequent reasons for patients to discontinue the studies [25,28]. Second, immersion can also cause anxiety through a realistic representation of an environment that does not match one's own setting. For example, some patients were afraid of falling while performing the exercises [28]. Third, the VR application was sometimes perceived as overwhelming [25,28]. Smits et al [28] stated the assumption that cognitive impairment as part of long/post-COVID condition may also make the use of VR difficult or impossible for certain patients. This also means that VR-assisted therapy programs should be used individually depending on the condition of each patient. Smits et al [28] therefore recommend a close physiotherapeutic supervision, tracking of training sessions, as well as the monitoring of vital signs. Furthermore, the headset was felt to be too heavy [19,23,29,30].

Studies with a focus on the technical user-friendliness of the application provided information on how to improve the tested applications [26,27,29]. These included, in particular, information on the navigation of the programs (ie, pause or fast forward button [29], one-click solution to start program [26,27]), which states that the technical accessibility and intuitive environment that allows handling even by less technically experienced people, are of great importance. In addition, some studies recommend providing the virtual environment with a simple graphical user interface [26,27] and using clear instructions [30] to facilitate use. Smits et al [28] point out that lack of usability can not only prevent usage and acceptance but also influence the results of studies aiming toward the evaluation of efficacy of programs. An appropriate design could also reduce the abovementioned adverse effects. Therefore, an interdisciplinary design process is recommended to ensure usability [28]. Furthermore, therapists will need proper training and logistical support in regard to the use and implementation of respective VR technology to adequately supervise the training of patients [28].

Clinical Outcomes

In addition to usability and acceptance assessments, all studies listed here also collected clinical parameters for the evaluation of respiratory rehabilitation. These included both physical and psychological outcomes. In regard to the respiratory function and fatigue, an overall improvement was reported in 3 studies [19,25,27]. Jung et al [19] reported that outcomes of female participants with regard to dyspnea and fatigue were even better than the results from male participants. In addition, a significant increase in patients' physical abilities such as strength and mobility was also observed [19,27-29]. Groenveld et al [25] found significant improvements in the 6-Minute Walk Test, grip strength, and 30-Second Chair to Stand Test. Ruzicky et al [27] mentioned that the program focused on developing upper limb mobility and cognitive skills through interactive tasks in the VR environment. However, information on the exact content of the tasks is lacking.

Surveys of the health-related quality of life and the Positive Health questionnaire and 12-Item Short Form Survey showed significant improvement in the quality of life in patients with COPD and patients with long COVID [19,25,29]. Patients felt fitter and were more likely to participate in social activities [19,29]. In the study of Groenveld et al [25], the improvement occurred already after 6 weeks. Further, stress and anxiety were reduced during the rehabilitation [19,25,29]. However, this was partly only true for patients who used specific mental health applications [25]. Participants also felt more confident in dealing with their own disease and in everyday tasks [19,28,29]. Some patients said that they were more mindful of their own health as a result of the program, making time for meditation on their own and setting preventive boundaries in their daily lives [28]. These experienced benefits of VR therapy as well as increased patient motivation also led to improved compliance [19,26-29].

Discussion

Principal Findings

The results of the reviewed studies show internationally available and initial evidence with regard to the development as well as the feasibility of respiratory VR rehabilitation for patients with long COVID in particular. The topic addressed in this review is a very new field of research. Approaches to VR therapy for other therapeutic needs such as for patients who had a stroke or Parkinson disease have already been implemented in the past 15 years [25,26,29]. However, lung-specific virtual physiotherapy appears to be still under development even in regard to the condition of COPD, which is already well-studied. The reported results are promising for VR applications, as the tested applications were described as enjoyable, pleasurable, and motivating when correctly introduced [19,23-27,29]. Furthermore, they can offer a more flexible rehabilitation program without restrictions of time and location [19,23,24,28,29]. Nevertheless, the studies also showed that the implementation of VR therapy interventions cannot generally be considered appropriate for every patient or in every setting because some patients could not complete the training due to motion sickness [25,28], and VR poses various hurdles in terms of the digital literacy of patients and therapists [23,24,28].

Comparison With Prior Work

A previous study that is the most similar to ours is the comprehensive review of VR for pulmonary rehabilitation by Pittara et al [32] in 2023. They offer a broader overview of VR applications in pulmonary rehabilitation by including all types of VR experiences, ranging from nonimmersive to fully

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immersive, and various populations, including healthy individuals as well as patients with COPD and asthma. In comparison to Pittara et al [32], our review takes a more focused approach by specifically filtering publications to include only immersive VR experiences within pulmonary rehabilitation programs for outpatients. The main strength of our review therefore lies in its clearly defined goals to provide an overview of immersive VR experiences for outpatients experiencing long COVID and COPD. Our review highlights the findings and shortcomings of existing research specifically in relation to the implementation of home-based rehabilitation programs for the target group. In particular, the hurdles of digital literacy identified for implementation at home and the need for training to ensure adequate use and guidance can be highlighted in this regard [27-29].

Our study findings also show the necessity to include the needs and prior knowledge of the target groups in the development of appropriate therapies. Only when appropriate programs achieve added value (eg, through individualized programs, monitoring) and are at the same time easily implemented, they can be applied in practice. The approaches adopted to involve patients in the evaluation of the applications, in terms of usability and acceptance, have shown that patients can provide important information for the development and implementation of VR-supported therapies [19,28,29].

Participatory approaches to technology development, which involve patients already during the development of applications and therapy programs, could help to adapt the applications even more precisely to the needs and requirements of users. The World Health Organization, for instance, recommends a patient-centered development of rehabilitation measures, digital services, and devices in order to support the self-care competence, especially of patients with long/post-COVID condition [4]. Regarding the novelty of the postacute condition, the involvement of patients seems even more crucial because researchers, practitioners, and patients are still undergoing a learning process on how to address and manage the symptoms reported [15]. Therapists, who are to integrate the applications into their therapy services and train the patients in their use, can also provide concrete information on their feasibility in practice. Of the studies analyzed in this review, however, only 1 study design included therapists [28].

Limitations

Although this scoping review was supported by steps, including refinement of the protocol through team discussion, blinded searching, and selection of papers by 3 researchers, several limitations have to be mentioned. First of all, limitations in the scope of the reported study results must be explained, as only 4 groups of researchers (from Slovakia, the Netherlands, United States, and United Kingdom) were involved in the studies analyzed, which represents quite a Eurocentric perspective. This scoping review was limited to studies published in English and German—the spoken languages of the researchers in this scoping review. However, the scoping review method and the explorative search strategy were deliberately chosen in order to be able to explore an overview of the topic while maintaining the focus of the research, and a critical evaluation of the studies was not intended. The second important aspect to note is that study designs implemented by the included studies and the quality in regard to scientific standards were very heterogeneous. Due to the diverse applied assessments and questionnaires, the comparability remains limited. Furthermore, evidence is still limited to pilot studies or a small number of patients, and no long-term studies or randomized controlled studies could be integrated—only cross-sectional surveys.

Conclusion

The results of this scoping review show that VR applications are well accepted by users, especially due to their flexible and individual applicability. Particularly mentioned by patients was the possibility of individualizing training plans and schedules as well as monitoring functions for remote monitoring by therapists. The implementation of rehabilitation measures in a playful, immersive setting contributed to motivating patients and increasing their compliance in respective studies. Initial feasibility studies also show an improvement in physical performance as well as psychological parameters such as confidence in managing the disease and quality of life. At the same time, hurdles arise with regard to the technical feasibility of VR therapies. Virtual applications must be as accessible and easy to use as possible so that patients without prior knowledge can also benefit from the therapy options. Furthermore, scientific research has to further develop empirical reliable findings for the sustainable long-term implementation of support programs for patients with long/post-COVID condition in the years ahead. In particular, the question on how to implement these findings into practice with regard to financing, further education of therapists, technical support, and the alignment of traditional and innovative autonomous approaches to therapy have to be a priority.

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Authors' Contributions

KD contributed to conceptualization, methodology, data collection/analysis, and writing the original draft. HAE and IK contributed to data collection/analysis and writing the original draft. SH contributed to funding acquisition, reviewing, and editing. DS contributed to supervision, project administration, funding acquisition, and reviewing. DP contributed to methodology,

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conceptualization, reviewing, and editing. PJ and MZ contributed to methodology, reviewing, and editing. All authors have read and agreed to the published version of this manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist.
[PDF File (Adobe PDF File), 157 KB - games_v12i1e52309_app1.pdf]

Multimedia Appendix 2
Search strategy.
[DOCX File , 14 KB - games_v12i1e52309_app2.docx]

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Abbreviations

COPD: chronic obstructive pulmonary disease
JBI: Joanna Briggs Institute
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews
VR: virtual reality

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An Augmented Reality Serious Game for Children's Optical Science Education: Randomized Controlled Trial

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Abstract

Background: Knowledge construction in the context of children's science education is an important part of fostering the development of early scientific literacy. Nevertheless, children sometimes struggle to comprehend scientific knowledge due to the presence of abstract notions.

Objective: This study aimed to evaluate the efficacy of augmented reality (AR) games as a teaching tool for enhancing children's understanding of optical science education.

Methods: A total of 36 healthy Chinese children aged 6-8 years were included in this study. The children were randomly divided into an intervention group (n=18, 50%) and a control group (n=18, 50%). The intervention group received 20 minutes of AR science education using 3 game-based learning modules, whereas the control group was asked to learn the same knowledge for 20 minutes with a non-AR science learning app. Predict observe explain tests for 3 topics (animal vision, light transmission, and color-light mixing) were conducted for all participants before and after the experiment. Additionally, the Intrinsic Motivation Inventory, which measures levels of interest-enjoyment, perceived competence, effort-importance, and tension-pressure, was conducted for children after the experiment.

Results: There was a statistically significant difference in light transmission (z=−2.696; P=.008), color-light mixing (z=−2.508; P=.01), and total predict observe explain test scores (z=2.458; P=.01) between the 2 groups. There were also variations between the groups in terms of levels of interest-enjoyment (z=−2.440; P=.02) and perceived competence (z=−2.170; P=.03) as measured by the Intrinsic Motivation Inventory.

Conclusions: The randomized controlled trial confirmed that the AR-based science education game we designed can correct children's misconceptions about science and enhance the effectiveness of science education.

Trial Registration: ClinicalTrials.gov NCT06184022; https://classic.clinicaltrials.gov/ct2/show/NCT06184022

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KEYWORDS

augmented reality; serious game; science education; childhood education; cognition; children; scientific cognition; cognitive process; effectiveness

Introduction

Children's level of scientific concept generation is representative of their inquiry, comprehension, and application of natural events and phenomena and reveals their cognitive capacities and developmental stages [1]. Knowledge construction in children's science education contributes to early scientific literacy development, which improves children's cognitive level by enhancing thinking skills, and is being emphasized by scholars and parents [2]. Traditionally, children build domain knowledge in science through films, literature, and lectures in science education [3]. Although some forms of educational learning are accessible, they often uses a monotonous instructional format, and confusing content hinders the transmission of scientific knowledge [4].

Serious games provide a more engaging interactive environment and an accessible cognitive framework to facilitate effective learning [5]. Studies have shown that serious games have more effective learning outcomes than traditional methods of science education (eg, face-to-face lectures and book-based knowledge transfer) [6,7]. It is suitable for children's investigation of natural phenomena because the game's visual design simulates paranormal phenomena that cannot be produced in real life. Lester et al [8] constructed virtual environments that generate natural phenomena, allowing children to assume roles in open-world environments and to freely rely on their knowledge of the geography and biology of natural environments. Laine et al [9] permitted children to interact with hosts in virtual narrative game scenarios and to investigate the geometry of the virtual environment with the protagonist. The concept of light, a prevalent natural phenomenon, was selected as the subject of this research to explore its design for enhancing children's

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cognitive abilities. Optical science education programs are still presented in a 2D format, which has been demonstrated to be ineffective [10].

Due to the spatial complexity and abstract nature of optics, it is challenging to accurately convey knowledge through flat visual representations [11]. Therefore, it is necessary to blur the boundaries between the 3D real world and the 2D digital world to reduce the distance between children's learning of science concepts and their learning environments [12]. 3D representations and interactions in augmented reality (AR) games have the potential to enhance spatial cognition, thereby facilitating children's comprehension of spatially abstract scientific concepts [13], such as simulating the movement of the sun in a classroom environment [14]. Sahin and Yilmaz [15] demonstrated that students who used AR technology to improve their science literacy performed better on tests than those who learned using traditional methods. This is as a result of AR technology's ability to enhance the dynamic potential of human consciousness to comprehend the science learning process [16]. In addition, motivational improvement was mentioned as one of the frequently observed AR outcomes [17]. Using AR apps increased student motivation relative to other instructional aids [18]. Our study investigated whether designing optical science education with more comprehensible 3D interactions for children can enhance science education and promote children's motivation.

The study designed the "AR Serious Game for Optical Science" and conducted a randomized controlled trial to determine the efficacy of this AR game product in enhancing children's science education. The primary objective of this study was to validate the efficacy of AR science education games for children; the secondary objective was to investigate the intrinsic motivation of children toward them.

Methods

Study Design

Guardians of children with independent mobility provided informed written consent for their participation in the study. Participants were randomly assigned to the intervention and control groups using a randomization list, which was maintained by members of the study group uninvolved in any other aspect of the study. Participants' guardians received and opened opaque, sealed envelopes containing group assignments following the initial evaluation. The evaluator in charge of assessing the results of the AR science education course had no access to participant information or group assignment.

Sample size calculations were performed using PASS software (NCSS LLC) based on the predict observe explain (POE) test scores from the preintervention questions. Group sample sizes of 18 and 18 achieve 90.118% power to reject the null hypothesis of equal means, when the population mean difference is $\mu 1 - \mu 2 = 3.2 - 1.0 = 2.2$, with SDs of 2.0 and 1.9 for the 2 groups and with a significance level (α) of .05 using a bilateral, 2-sample, equal-variance, 2-tailed *t* test.

Participants

A total of 36 Chinese children (aged 6-8 y) were recruited from Jiangyin Children's Education Center and Jiangyin Wuxi Community in Jiangsu Province and divided into the intervention (n=18, 50%) and control (n=18, 50%) groups.

AR Science Education Game Design

During the learning phase, children are required to engage in physical activities, such as walking around with a handheld device, to interact with the AR scene's content to discover what is unique about the light phenomenon. When children touch the interactive points, the content is explained by animation and voice-overs. This study developed several interactive approaches for children within AR games, such as through in-game visual representations, speech, and interactive methods, which permit children to connect game content to unfamiliar information as they explore. The advantages are as follows: (1) children can use more familiar physical activities with light concepts to establish metaphorical mappings related to orientation, not just gestural touch; (2) rendering light with 3D attributes in the real world reduces the cognitive load generated by children's linkage of abstract knowledge and the real phenomena; and (3) adding various kinds of digital augmentation effects in the AR scene helps children understand the concepts. The project created 3 games based on the characteristics of scientific understanding (Multimedia Appendix 1 and Figure S1 in Multimedia Appendix 2 [9,14,19-28]).

Game 1 introduces children to the fundamentals of animal vision (Figure 1). Animal vision concepts are investigated through AR scenes. By clicking on the icons in the lower-left corner, the game transforms to an animal simulation. In each scenario, a voice-over narration instructs children to identify the visual differences between the animal and the human. When the handheld device is trained on a specific target, a voice-over narration and feedback animation will play.

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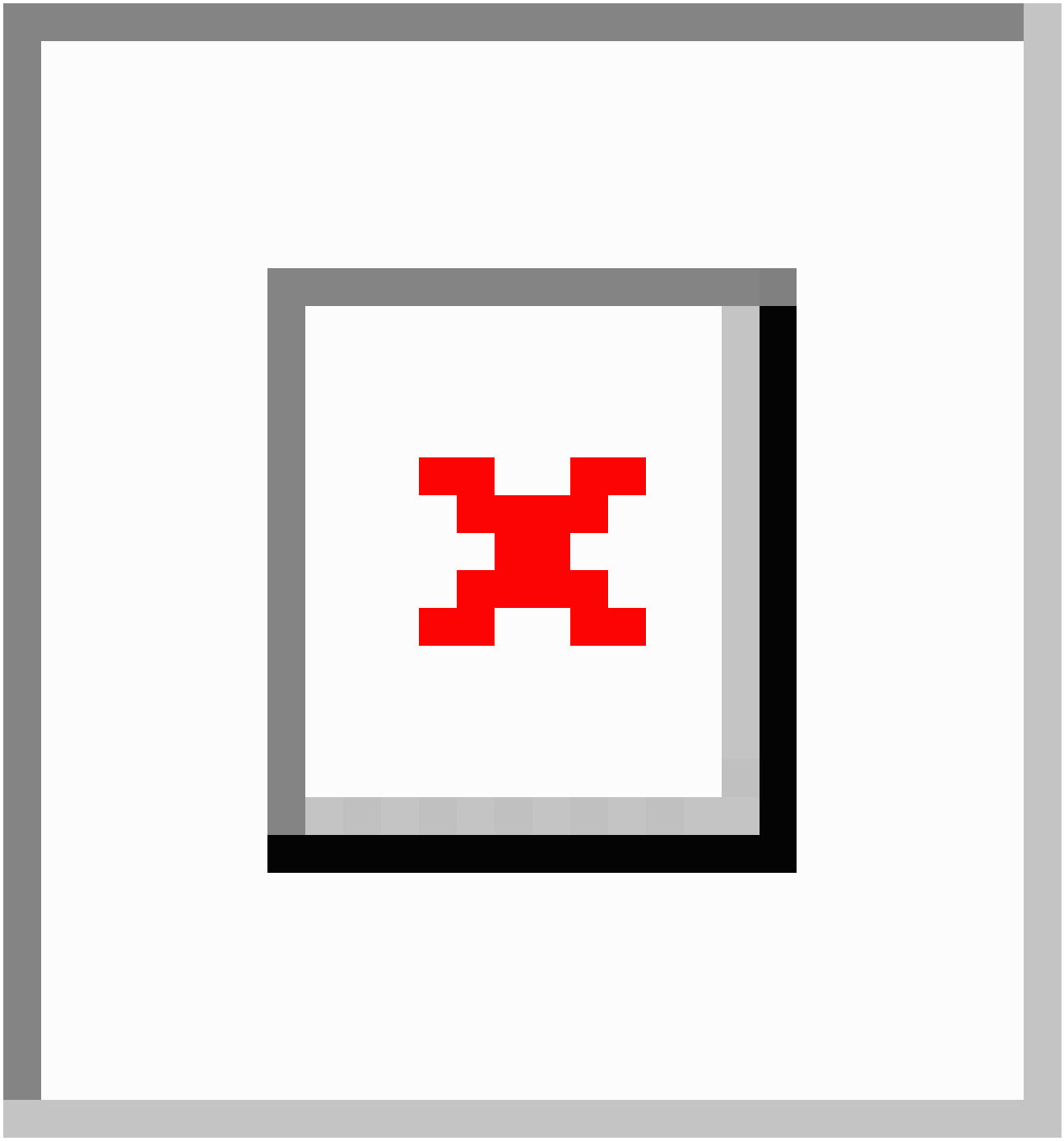
Figure 1. Animal vision augmented reality (AR) game introduction.



In the design of the interaction mode, 3 display modes were established for the game's interactive elements: far, medium, and near (hybrid camera mode). The concept of invisible light is introduced to children in greater detail based on the ray distance between the device's camera and the target element. The far view provides children with an intuitive impression of the invisible light's overall effect; the medium view uses transition animation to illustrate the invisible light's characteristics; and the near view uses special effect particles to illustrate the invisible light's trajectory.

Game 2 introduces children to light transmission–related concepts (Figure 2). In the AR scenario, children navigate the environment with a handheld device and activate energy panels by interacting with flat mirrors and optics. By targeting AR-enhanced prop objects and manipulating the angle of light emission to investigate how light propagates, voice-over explanations and feedback animations are activated.

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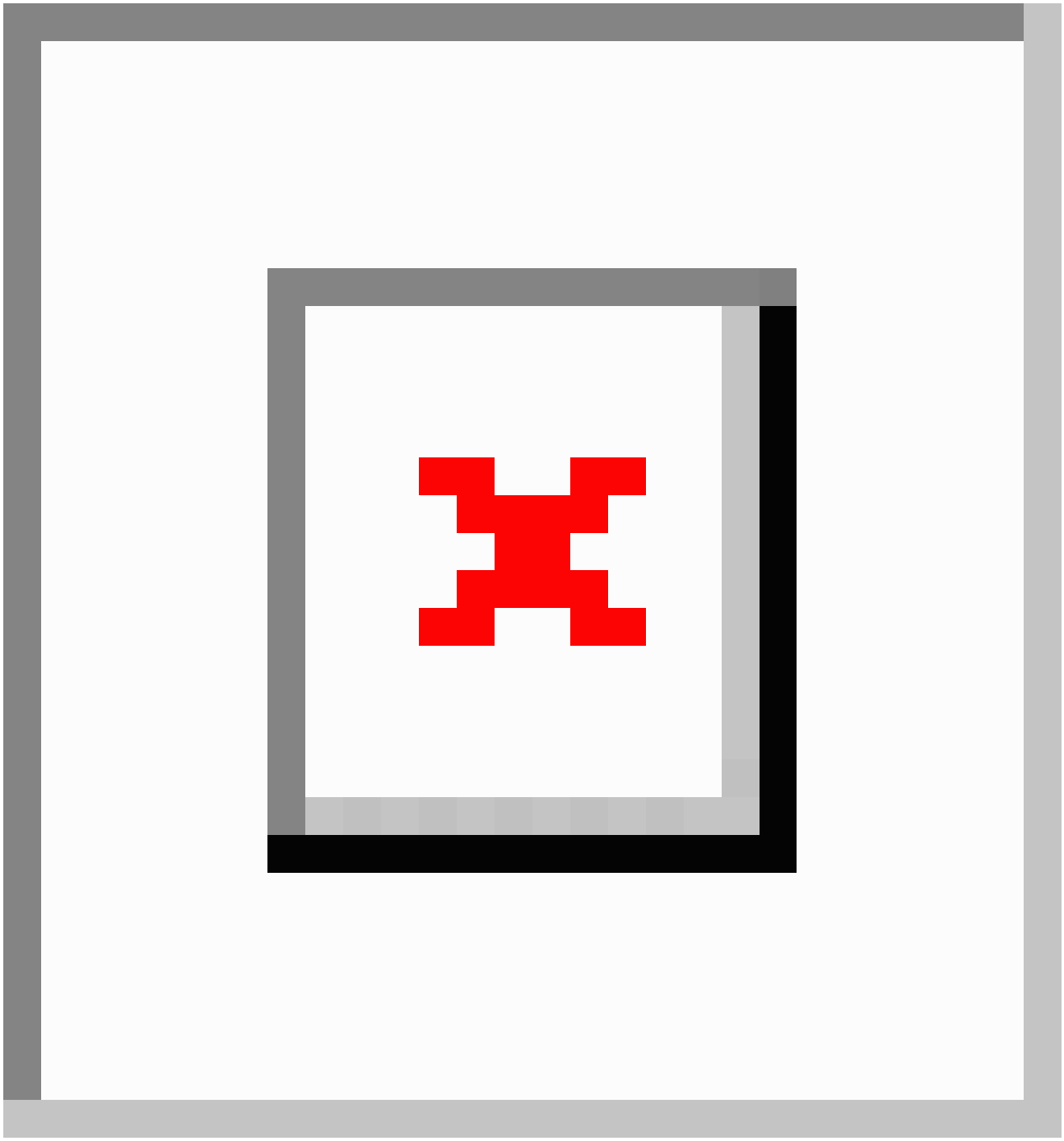
Figure 2. Light transmission augmented reality (AR) game introduction.



According to the voice-over prompts, children can hold the device and manipulate the flashlight from a first-person perspective (spatial exploration mode) as part of the interactive design. They then complete 3 steps: locating the interactive elements (mirrors, ice crystals, etc), adjusting the flashlight's tilt angle, and using the flashlight to complete the light-up task. The progression encourages children to investigate the principles of light transmission through the game.

Game 3 introduces children to color-light mixing concepts (Figure 3). Children were instructed to walk around with the device in hand and explore the color changes of props such as AR-enhanced birds, which are illuminated with various colors of lights. Collecting the target color's shadow initiates a voice-over explanation and feedback animation.

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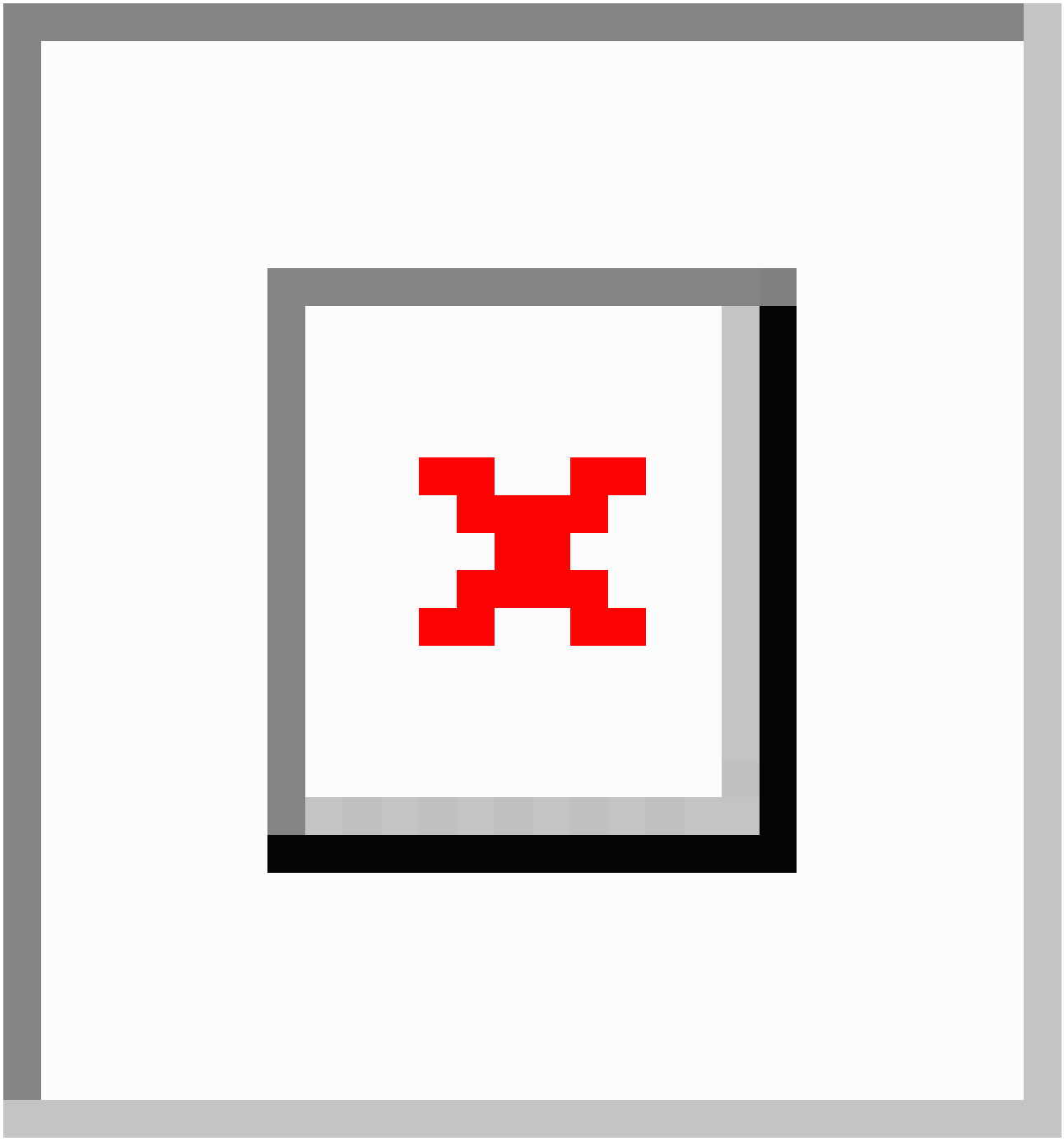
Figure 3. Color-light mixing augmented reality (AR) game introduction.



Regarding the interactive design, children need to hold the device to illuminate the creatures and cast shadows on the present wall, and then they need to press the button to turn the light on and off (projection irradiation mode). The objective of the game required children to perform single-color illumination, 2-color mixing, and 3-color mixing to achieve the desired hue. In another vibrant nursery game, children were instructed to move plants to receive various colors of light and to observe the plants' root elongation and leaf dispersal.

This game design used Unity 3D (Unity Technologies) as the development engine, and the app was installed on an Apple iPad (2018) with a screen resolution of 2048×1536 (264 pixels per inch). The AR component made use of the Vuforia AR SDK (Parametric Technology Corporation) to accomplish the fundamental duties of plane identification and virtual object generation. The interaction section used lens focus to determine the interactions; when the device camera's output rays collide with the target virtual object and the distance is close, it is deemed to have located the target effectively. To imitate the illusion of invisible light, Unity's *Post Processing* module was applied to the camera filter. The principle entailed presenting the camera screen into the buffer of Unity and applying filters and effects prior to displaying it; it can be applied to both the camera screen and the virtual item.

Procedure

This experiment was a randomized controlled trial, and the participants were randomly separated into the intervention group

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and the control group. The random numbers were generated by applying the SAS software analysis system (SAS Institute) on a computer simulation, and no experimental group was allowed to be selected at random. Every child was tested in the company of a guardian and 2 researchers.

The independent variable was the type of game (an optical science education app called "Light and Color" or the AR game we designed; see Figure S2 in Multimedia Appendix 2 for a comparison of the differences between the 2 games). The dependent variables for both intervention and control group participants were the differences between the pre- and posttest results of the POE tests and the children's motivation to play the game. To create control variables for the experiment, both games included the topics of animal vision, light transmission, and color-light mixing, and neither game involved a human teacher. In addition, there were no significant sex (P=.49) or age (P=.67) differences between the 2 groups.

Intervention Group

Before the test started, the researcher provided the basic information of the experiment to the participants, including the test topic, test technique, test time, and other information. The participants were asked to complete a cognitive exam on the notion of light and perform a POE test for each topic to find out how well they comprehend the content, without being told whether their answers were correct.

After completing the pretest, intervention group participants were instructed to complete the 3 game-based learning modules of the AR science education app on the iPad regarding animal vision, light transmission, and color-light mixing. On their initial encounter with the game, respondents were given around 10 minutes to comprehend its mechanics. The intervention group's total learning time was limited to 20 minutes, the testing process was completed under the supervision of the instructor and the experimenter, and the children's behavioral characteristics were recorded. During the experiment, the participants were not disturbed in any way; researchers only intervened when they faced difficulties or requested assistance. The participants were given a 15-minute respite at the conclusion of the trial to take another POE test. Before and after the experiment, each participant's performance on the game was recorded. The researcher then read aloud and described the items on the intrinsic motivation and cognitive load scales to the participants, who scored the scale items using a 5-point "smiley face" scale.

Control Group

The control group was also introduced to the experiment and given a preintervention POE test to assess their prior knowledge of the learning material. The control group completed the same 3 game courses for a maximum of 20 minutes using the non-AR app "Light and Color" after completing the pretest. The participants took a 15-minute break at the conclusion of the trial to complete another POE test and the Intrinsic Motivation Inventory (IMI) scale (Figure 4).

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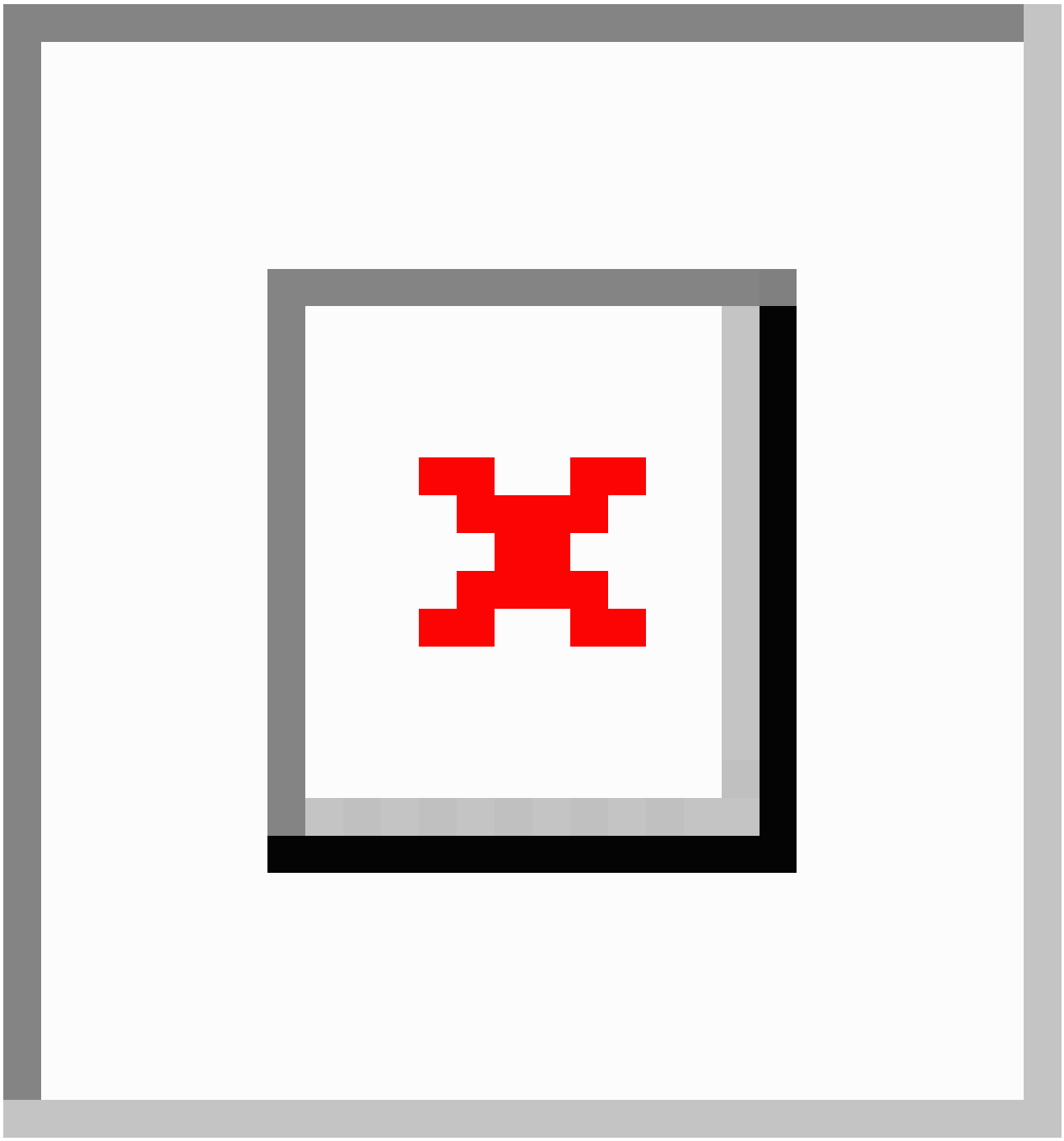
Figure 4. Photos of the experimental process: (A) the process of using the augmented reality (AR) game for participants in the intervention group; (B) the process of using the "Light and Color" app game for participants in the control group, and (C) the process of filling out the questionnaire by the participants.



Evaluation Metrics

The study was validated based on several experiments.

The POE test is commonly used in science classes and tries to expose students' expectations about certain events and the rationale for these predictions [29]. It is used to demonstrate scientific experiments to pupils and is advantageous for fostering children's critical thinking and assessing students' grasp of scientific topics. The investigator then displays the relevant physical events to the students using basic prop materials after requiring the students to independently determine the correct answers to the questionnaire along with their justifications. Finally, students are instructed to alter or supplement their explanations in light of the observations. Since children may appear to be able to answer the question properly but not comprehend the reasoning behind it, for each topic, it is possible that they do not comprehend the underlying concept. In this study, individuals' accurate answers and explanations were recorded, and different situations were rated differently based on a 2-tier test [30] (Table 1). This scoring method is frequently used to evaluate students' conceptual understanding [31]. The outcomes were categorized as correct answer+correct explanation, correct answer+incorrect explanation, incorrect answer+correct explanation, and incorrect answer+incorrect explanation. Each topic's overall score was included in the

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subsequent analysis. To avoid disruptions caused by children's memorization of answers, the experimental posttest questionnaire in this study was different from the pretest questionnaire but was founded on the same scientific concepts. The examination topics are provided in Table S1 in Multimedia Appendix 2.

Table . Two-tier test assessment criteria.

Level of conceptual understanding	Score
Correct answer+correct explanation	2
Correct answer+incorrect explanation	1
Incorrect answer+correct explanation	1
Incorrect answer+incorrect explanation	0

Due to the young age of the study participants, the simplified version of the IMI adapted by Vos et al [32] was selected for this research. It was developed under game conditions with 3 subscales: interest-enjoyment, perceived competence, and effort-importance, to assess the perceived levels of motivation, enjoyment, and perceived difficulty of the participants. To investigate the negative emotions of children using the AR game, the study inserted questions from the original scale's tension-stress section [33] (Table S2 in Multimedia Appendix 2). Participants were asked to rate the extent to which they concurred with the statement using a 5-point Likert scale depicting 5 smiling faces. A score of 5 indicated that the child participant strongly agreed with the statement. To minimize the effect of differences in reading ability, the researcher read the questionnaire audibly to the child participants, who then completed the questionnaire independently.

Ethical Considerations

The study was approved by the Human Research Ethics Committee of Shanghai Jiao Tong University (H2022041I) in China. Informed consent was signed by guardians and the data were deidentified. A toy with a value of CNY ¥50 (US $7.01) was provided as compensation.

Results

A total of 36 healthy Chinese children aged 6-8 years were recruited in May 2022, including 22 male and 14 female children, all of whom participated in the experiment with the consent of their guardians and of their own volition. The 36 participants were randomly assigned to the intervention group (n=18, 50%) and the control group (n=18, 50%), with the mean age of the intervention group being 7.16 (SD 0.76) years and that of the control group being 7.06 (SD 0.78) years. Baseline demographic data and POE test scores for the intervention and control groups are shown in Table 2. The statistical analysis revealed that there was no statistically significant distinction observed between the 2 groups across all variables (all $P>.05$). This suggests that the intervention and control groups exhibited a similar overall comprehension level prior to the commencement of the trial. The experimental procedure is provided in Figure 5.

Table . Baseline data for the intervention and control groups.

Variable	Intervention group[a] (n=18)	Control group[b] (n=18)	*z* score or chi-square (*df*)	*P* value[c]
Male sex, n (%)	10 (56)	12 (67)	0.467 (1)[d]	.49
Age (y), mean (SD)	7.17 (0.76)	7.06 (0.78)	−0.421[e]	.67
POE[f] test score for animal vision, mean (SD)	1.83 (1.10)	1.94 (1.21)	−0.296[e]	.77
POE test score for light transmission, mean (SD)	2.83 (1.72)	2.67 (2.20)	−0.437[e]	.66
POE test score for color-light mixing, mean (SD)	1.50 (1.09)	1.94 (1.16)	−1.031[e]	.30
Total POE test score, mean (SD)	6.17 (2.28)	6.56 (2.12)	−0.273[e]	.78

[a]Augmented reality game.

[b]Non–augmented reality game.

[c]Mann-Whitney *U* test and χ^2.

[d]Chi-square value.

[e]*z* score.

[f]POE: predict observe explain.

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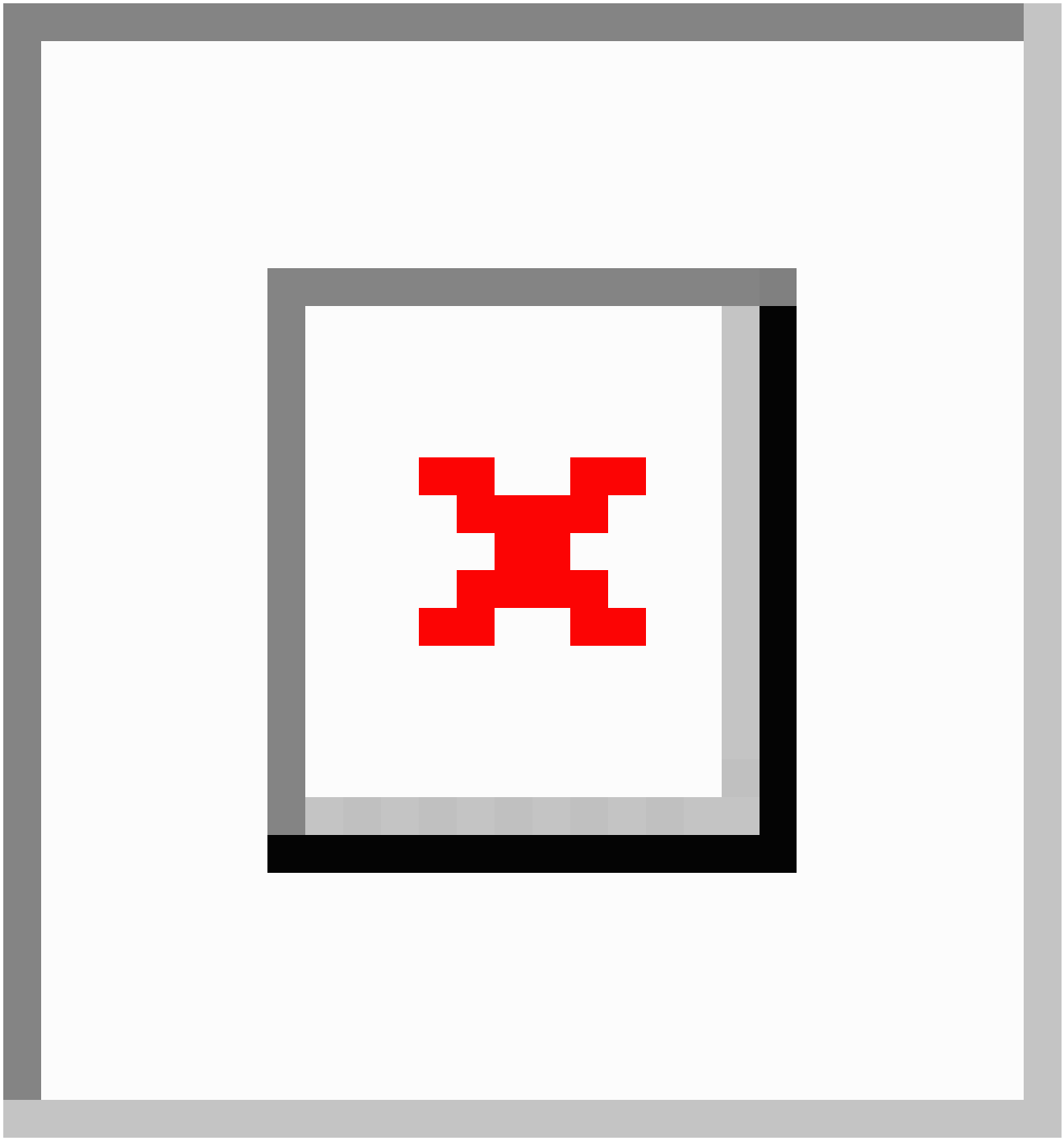
Figure 5. CONSORT (Consolidated Standards of Reporting Trials) flow diagram. AR: augmented reality; IMI: Intrinsic Motivation Inventory; POE: predict observe explain.



The results of the normality test revealed a nonnormal distribution of the data (Table S3 in Multimedia Appendix 2). Consequently, the researchers conducted a paired-sample Wilcoxon rank sum test to compare the pre- and posttest findings of the intervention and control groups to assess any differences between the 2 groups. The results shown in Table 3 demonstrate notable fluctuations in both light transmission (z=−2.696; P=.008) and total POE test scores (z=−2.458; P=.01). Nevertheless, the results of the study indicate that there was no statistically significant advantage observed in animal vision (z=−0.847; P=.42) and color-light mixing POE test scores (z=−0.782; P=.46) as a result of the AR game intervention. It should be noted, however, that there was an improvement in scores following the intervention.

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Table . Between-group differences between the intervention and control groups on each of predict-observe-explain (POE) test (pre- and posttests).

POE test score		Intervention group[a] (n=18), mean (SD)	Control group[b] (n=18), mean (SD)	Difference, mean (95% CI)	*z* score	*P* value[c]
Animal vision				0.36 (−0.71 to 1.43)	−.847	.42
	Pretest	1.83 (1.10)	1.94 (1.21)			
	Posttest	2.33 (1.14)	2.17 (0.99)			
Light transmission				0.97 (−0.37 to 2.31)	−2.696	.008
	Pretest	2.83 (1.72)	2.67 (2.2)			
	Posttest	4.44 (1.76)	3.00 (1.88)			
Color-light mixing				0.72 (−0.44 to 1.88)	−0.782	.46
	Pretest	1.50 (1.09)	1.94 (1.16)			
	Posttest	2.39 (1.24)	2.50 (1.04)			
Total				2.06 (−0.1 to 4.22)	−2.458	.01
	Pretest	6.17 (2.28)	6.56 (2.12)			
	Posttest	9.17 (2.48)	7.67 (1.71)			

[a]Augmented reality game.

[b]Non–augmented reality game.

[c]Mann-Whitney *U* test.

In this study, subjective IMI scale values acquired during the trial were statistically analyzed. It was observed that the different groups showed significant variability in levels of interest-enjoyment (z=−2.440; P=.02) and perceived competence (z=−2.170; P=.03; Table 4), whereas significant differences were not observed in levels of effort-importance (z=−1.310; P=.20) and tension-pressure (z=−0.733; P=.48).

Table . Comparison of Intrinsic Motivation Inventory (IMI) variability between the intervention and control groups.

IMI subscale	Intervention group[a] (n=18), mean (SD)	Control group[b] (n=18), mean (SD)	*z* score	*P* value[c]
Interest-enjoyment	20.28 (2.72)	18.00 (2.57)	−2.440	.02
Perceived competence	18.83 (3.05)	16.33 (3.34)	−2.170	.03
Effort-importance	12.89 (1.97)	11.83 (2.57)	−1.310	.20
Tension-pressure	10.44 (2.33)	9.77 (2.90)	−0.733	.48

[a]Augmented reality game.

[b]Non–augmented reality game.

[c]Mann-Whitney *U* test.

Discussion

Principal Findings

The integration of science education into the foundational education of children aims to systematically cultivate their abilities in inductive and deductive thinking [34]. Serious games have demonstrated efficacy in enhancing teaching and learning outcomes within the contemporary domain of children's science education [7]. AR technology has garnered growing interest in the realm of serious game design in recent times due to its ability to visually represent scientific processes that are not easily observable in real-life situations [35]. Further, the incorporation of AR technology into mobile devices has resulted in widespread adoption, facilitating the implementation of many apps [17]. Nevertheless, there is a lack of comprehensive study and experimentation to substantiate the efficacy of AR design in the realm of children's science education. Consequently, a series of AR science instructional games were developed, focusing on the comprehension of light principles. The objective was to assess the efficacy of the games and the degree of intrinsic motivation of the students. The results showed that children who participated in the AR science game had substantially higher POE test scores and conceptual understanding of light propagation than the control group.

The study revealed that children exhibited varying levels of comprehension in relation to light concepts across diverse themes. Reliable between-group differences were detected among the topics of light propagation. The rationale behind the use of AR lies in its inherent benefits, which include the ability for children to engage in physical activity while delving into a more comprehensive exploration as compared to 2D games. Additionally, AR technology facilitates the rendering of real-world light phenomena, as supported by previous studies [36,37]. Our game was developed with the purpose of creating

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a metaphorical representation of concepts connected to light orientation using gesture-touch interactions. It aims to alleviate the cognitive burden experienced by children when trying to connect abstract information about light with real-world light occurrences. This is achieved by incorporating 3D properties of lighting effects into the game. Furthermore, a notable increase in the game scores of the intervention group was noticed across all topics. This observation serves as evidence for the beneficial influence of AR games on children's conceptual transformation during the process of acquiring scientific knowledge. Our game also serves as a means of scientific investigation, necessitating active engagement from the children. Certain children had not before contemplated the underlying mechanisms responsible for commonplace visual occurrences. The stimulation of their drive to study and their high curiosity played a significant role in facilitating their conceptual shift and fostering the development of scientific thinking [38]. Nevertheless, the intervention group did not exhibit any noteworthy disparity compared to the control group in relation to the topics of animal vision and color-light mixing. The limited influence of the different interactive designs, specifically mixed camera mode and projected lighting mode, on children's cognition may account for this disparity when compared to the visual representation format in the 2D game.

Intrinsic motivation is a potent factor that influences performance, learning persistence, and productivity [39]. Children in the intervention group demonstrated greater interest and enjoyment in intrinsic motivation than those in the control group, and they demonstrated an ability to embrace and comprehend the causes of certain light phenomena.

AR imparts scientific information that challenges children's prior knowledge and stimulates their interest. Consequently, it can arouse interest in the principles and stimulate active thought [35]. During the test, we observed that participants had a keen interest in the game and avidly explored the interface's interactive elements. Moreover, there was a significant difference in perceptual ability between the intervention and control groups. We believe that this difference stems from the fact that AR games, created by adding 3D virtual objects to real-world images, can better facilitate children's understanding of complex concepts [15]. However, we also found that the intervention group showed some stress toward AR games. Children have a period of adjustment for things to which they are not accustomed to, as evidenced by their inattention and attempts to communicate with the observer when they encounter difficulties in the game [17]. Future research can therefore concentrate on how to provide prompts even when encountering difficulties.

The researchers observed that the children's engagement in gameplay facilitated their conscious observation of light occurrences in their daily lives, resulting in a modest improvement in their comprehension during the final phase of the tests. Furthermore, when the optical principles pertaining to linear propagation, reflection, and refraction became increasingly complex, it became more challenging for the children to comprehend, leading to confusion in certain preintervention participants regarding the distinctions between these concepts. It is important to acknowledge that when a child misinterprets the dynamic effects, animation, or creative expression of a game feature, the game can potentially facilitate the development of novel alternative understanding. Fortunately, the occurrence of this scenario was limited in the 2 assessment tests conducted during the formal experiment.

The strengths and weaknesses of our study in comparison with other studies is shown in Table S4 in Multimedia Appendix 2.

In summary, the integration of AR into educational games has the potential to enhance children's science education by offering a more immersive and engaging learning experience. This approach also may address the challenges associated with inadequate education and the lack of motivation among children to explore scientific subjects.

Conclusions and Limitations

The results suggest that the use of AR serious games can effectively motivate children to undergo conceptual shifts during the initial phases of science education. This, in turn, leads to an improved level of comprehension of scientific material. Furthermore, it is expected that these positive outcomes can be replicated in future preschool science education settings. This randomized controlled trial provides confirmation that the science education game we developed, using AR technology, has the potential to rectify children's misconceptions regarding scientific concepts and improve the overall efficacy of science teaching.

However, there are also some limitations. First, the sample size used in the study was limited, and the sample population was mainly from the more resource-rich region of Jiangsu Province, China. Consequently, it is challenging to ascertain the presence of regional variations in other geographical areas. Prospective studies with large samples are needed to further confirm the results, and the results can be improved by considering gender, family upbringing, and children's interest preferences in subsequent studies. Second, AR apps require a lot of attention and can be a distraction. It can cause students to ignore instructions or important stages of the experience. In addition, as the situation appeared in the pre-experiment, the game as a teaching tool may generate new misconceptions if the child misinterprets the content of the game. Finally, the existing game conveys scientific concepts mostly through voice-over prompts, which are insufficient to grab the children's attention, and children may be distracted and lose essential information during the voice-over prompts.

Editorial Notice

This randomized study was only retrospectively registered, as the authors had not considered it necessary to register prospectively. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials, because the risk of bias appears to be low. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims

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related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The designed augmented reality game.
[MP4 File, 18278 KB - games_v12i1e47807_app1.mp4]

Multimedia Appendix 2
Supplementary tables and figures.
[DOCX File, 7270 KB - games_v12i1e47807_app2.docx]

Checklist 1
CONSORT eHEALTH Checklist.
[PDF File, 1214 KB - games_v12i1e47807_app3.pdf]

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Abbreviations

AR: augmented reality
IMI: Intrinsic Motivation Inventory
POE: predict observe explain

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Original Paper

Effects of a Serious Smartphone Game on Nursing Students' Theoretical Knowledge and Practical Skills in Adult Basic Life Support: Randomized Wait List–Controlled Trial

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Abstract

Background: Retention of adult basic life support (BLS) knowledge and skills after professional training declines over time. To combat this, the European Resuscitation Council and the American Heart Association recommend shorter, more frequent BLS sessions. Emphasizing technology-enhanced learning, such as mobile learning, aims to increase out-of-hospital cardiac arrest (OHCA) survival and is becoming more integral in nursing education.

Objective: The aim of this study was to investigate whether playing a serious smartphone game called MOBICPR at home can improve and retain nursing students' theoretical knowledge of and practical skills in adult BLS.

Methods: This study used a randomized wait list–controlled design. Nursing students were randomly assigned in a 1:1 ratio to either a MOBICPR intervention group (MOBICPR-IG) or a wait-list control group (WL-CG), where the latter received the MOBICPR game 2 weeks after the MOBICPR-IG. The aim of the MOBICPR game is to engage participants in using smartphone gestures (eg, tapping) and actions (eg, talking) to perform evidence-based adult BLS on a virtual patient with OHCA. The participants' theoretical knowledge of adult BLS was assessed using a questionnaire, while their practical skills were evaluated on cardiopulmonary resuscitation quality parameters using a manikin and a checklist.

Results: In total, 43 nursing students participated in the study, 22 (51%) in MOBICPR-IG and 21 (49%) in WL-CG. There were differences between the MOBICPR-IG and the WL-CG in theoretical knowledge (P=.04) but not in practical skills (P=.45) after MOBICPR game playing at home. No difference was noted in the retention of participants' theoretical knowledge and practical skills of adult BLS after a 2-week break from playing the MOBICPR game (P=.13). Key observations included challenges in response checks with a face-down manikin and a general neglect of safety protocols when using an automated external defibrillator.

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Conclusions: Playing the MOBICPR game at home has the greatest impact on improving the theoretical knowledge of adult BLS in nursing students but not their practical skills. Our findings underscore the importance of integrating diverse scenarios into adult BLS training.

Trial Registration: ClinicalTrials.gov (NCT05784675); https://clinicaltrials.gov/study/NCT05784675

(JMIR Serious Games 2024;12:e56037) doi:10.2196/56037

KEYWORDS

serious smartphone game; adult basic life support; teaching; game; games; gaming; education; nurse; nursing; nurses; educational; mHealth; mobile health; app; apps; application; applications; smartphone; smartphones; RCT; randomized controlled trial; controlled trial; technology-enhanced learning; TEL; life support; knowledge retention; theoretical knowledge; practice; practical; resuscitation

Introduction

Sudden cardiac arrest is one of the leading causes of death in adults worldwide. It is responsible for over a million deaths annually [1]. Most deaths occur in the out-of-hospital setting, and the outcome possibly can be improved with proper adult basic life support (BLS) [2]. Effective implementation of adult BLS can double the chances of survival after a sudden cardiac arrest [3,4]. Reviews report poor cardiopulmonary resuscitation (CPR) by nursing students, despite the completion of adult BLS certification [5]. BLS knowledge and skills decline significantly within months of initial training [5,6]. For this reason, the European Resuscitation Council (ERC) and American Heart Association guidelines recommend shorter and more frequent adult BLS training as it helps retain adult BLS content longer and maintain competency levels [7,8]. Currently, adult BLS education in higher nursing education institutions traditionally imparts theoretical knowledge through a frontal approach and teaches practical skills using manikins and automated external defibrillators (AEDs), although the approach can vary significantly from one university to another [5,9].

A noticeable generational shift is evident in health care systems, both in Europe and abroad, characterized by the increasingly common employment of younger individuals. These younger future health care employees bring a higher proficiency in technology and information literacy [10,11], attributes cultivated from growing up in an era dominated by modern technology [12]. Technology-enhanced learning (TEL) approaches, developed to improve adult BLS knowledge and skill retention, ultimately aim to increase out-of-hospital cardiac arrest (OHCA) survival [8]. The most recent adult BLS guidelines highlight the integration of TEL into adult BLS courses [8,13,14]. This includes not only immersive technologies, such as extended reality [15], but also mobile learning (m-learning), which has increased dramatically in nursing education in recent years [16]. A recent meta-analysis indicates that serious smartphone games are a promising and effective tool for adult BLS education [17].

M-learning, by its definition, encompasses the use of mobile technology [18], with mobile apps on smartphones often serving as the educational platform [19]. Research has demonstrated m-learning's beneficial effects on fostering a variety of learning outcomes and competencies in the field of nursing [20,21]. Smartphone-based m-learning [21] seamlessly complements education through serious games and gamification [15]. Gamification involves applying game design elements to nongame contexts [22], such as educational content in higher education [23]. Conversely, serious games are crafted to use a specific type of game (eg, computer or mobile games) for the purpose of learning about significant subjects, such as adult BLS content education at the higher education level [24].

To the best of our knowledge, only a limited number of studies have explored the use of serious smartphone games for teaching adult BLS to health care students [25-29]. Among these, only 1 study demonstrated an improvement in both the theoretical knowledge and practical skills associated with adult BLS [28]. Other studies have reported enhancements in either theoretical knowledge [29] or practical skills related to adult BLS. The positive effects of a serious smartphone game can be seen as early as 2 weeks [25,26], as well as 1 month after the intervention [27-29]. Studies have compared different teaching methods, where the use of serious smartphone games seems to have better results than simulation-based learning but is less effective than virtual reality–based game learning [26,30]. Some studies have also shown improvements in practical skills, such as compression rate accuracy [27,28], although this tends to be inferior when compared to simulation-based methods [30]. In contrast, in 2 studies, serious smartphone games did not provide notable benefits and led to worse performance in theoretical and practical areas, although students showed a clear preference in favor of serious smartphone games [27,28].

The aim of the study was to evaluate whether playing a serious smartphone game called MOBICPR [31] at home can enhance nursing students' theoretical knowledge of and practical skills in adult BLS.

Methods

Study Protocol

The study was conducted at the Faculty of Health Sciences, University of Maribor (Maribor, Slovenia) between March and May 2023. The study was registered in ClinicalTrials.gov (NCT05784675). The study protocol was written in accordance with the Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth (Multimedia Appendix 1) [32].

Ethical Considerations

Ethical approval was obtained from the Slovenian National Medical Ethics Committee (0120-157/2018), and permission to conduct the study on the faculty premises was obtained from

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the Faculty of Health Sciences, University of Maribor. During an oral presentation of the study, nursing students were informed about the research protocol, and written consent was obtained afterward. Data confidentiality and anonymity were maintained throughout the study. Participants were rewarded for their participation in the study with a free beverage from a vending machine and a copy of the *Game Changer* painting by street artist Banksy [33].

Participants

All nursing students enrolled in the first-degree nursing program at the Faculty of Health Sciences, University of Maribor, during the 2022-2023 academic year were invited to participate in the study. Inclusion criteria to participate in the study were written informed consent, an age of at least 18 years, and ability to perform adult BLS on a manikin (eg, without injury). Our study had no exclusion criteria.

Study Design and Randomization

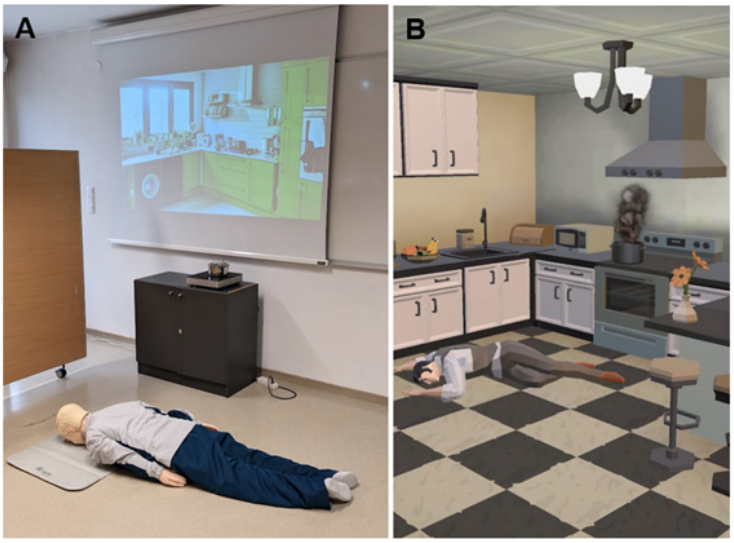
This study had a randomized wait list–controlled design, where nursing students were randomly assigned in a 1:1 ratio using a computer-generated list (Microsoft 365 Excel Enterprise) to either a MOBICPR intervention group (MOBICPR-IG) or a wait-list control group (WL-CG). The WL-CG was a group of nursing students who were assigned to a wait list and received the intervention (MOBICPR game for playing at home) 2 weeks after the MOBICPR-IG.

Interventions

All assessments of the participants' theoretical knowledge of and practical skills in adult BLS were conducted 3 time points: baseline, 2-week follow-up, and 4-week follow-up. At the baseline assessment, the investigators first collected demographic data from the participants. Additionally, the participants were questioned about their willingness to assist both family members and strangers during OHCA with CPR. Prior to practical skills in adult BLS, participants' the theoretical knowledge of adult BLS was assessed using a questionnaire with 33 single- and multiple-choice questions [25,34-36] on an open source online survey app called 1ka (Ljubljana, Slovenia); see Multimedia Appendix 2. A back-translation approach was used for translating the questionnaire into the Slovenian language.

Prior to the assessment of adult BLS practical skills, each participant was given a scenario based on OHCA to read (Multimedia Appendix 3). After reading the scenario, the participants were given a smartphone for calling emergency services at the time of performing adult BLS. Instead of dialing the actual emergency number, the participants used the contact stored on the smartphone as 112 (ie, the Slovenian emergency number). After the call was placed by each participant, the investigator answered the phone and conducted a simulated dispatcher conversation [37]. The investigator was a registered nurse working at the local medical dispatch center. Each participant performed 2-minute adult BLS without any help in a staged kitchen on a manikin (Resusci Anne Quality Cardiopulmonary Resuscitation [QCPR], Laerdal Medical) using an AED (Defibtech, Trainer AED). The staged kitchen was a space surrounded by mobile walls in the hospital's simulated room. A photo of a kitchen was projected onto the wall, and below it was an electric stove with a pot full of water (Figure 1). In each adult BLS scenario, the investigators turned on the electric stove, and the scenario began when the water started to boil, simulating a hazard. The kitchen was chosen because the majority of OHCAs occur there [38].

Figure 1. Staged kitchen with the Resusci Anne QCPR in the middle (A) and a cartoon person in the MOBICPR game lying on the floor in a kitchen (B). QCPR: Quality Cardiopulmonary Resuscitation.



After 2 minutes of performing adult BLS, each participant received assistance from an outside person bringing in an AED and taking over CPR. The adult BLS practical skills of each participant were recorded using a Sony Handycam 4K AX53 camera and an Apple iPad Pro 3rd generation tablet. Two investigators with a background in emergency medicine and teaching laypersons adult BLS assessed the participants' practical skills in adult BLS using a modified checklist [25,36,39] according to the ERC BLS guidelines of 2015 [40] and 2021 [34], with a total of 34 items (Multimedia Appendix 4). A back-translation approach was used for translating the checklist into the Slovenian language. Numerical data from the

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SkillReporter for Tablet version 1.4.1 (Laerdal Medical) app installed on a Samsung Galaxy Tab S6 Lite tablet was also included in the evaluation of the participants' practical skills in adult BLS. Investigator debriefing was not conducted following the assessment of the participants' adult BLS theoretical knowledge and practical skills. Instead, each participant (from MOBICPR-IG at baseline and from WL-CG 2 weeks after baseline) first played the MOBICPR game [31] on a Samsung Galaxy A13 smartphone in front of the investigator and then received the same smartphone to play at home. The objective of the MOBICPR game is for participants to interact with a smartphone using gestures (eg, tapping) and actions (eg, talking) to help save the life of a virtual patient with OHCA by performing evidence-based adult BLS. The MOBICPR game is based on the 2021 ERC BLS guidelines [34], and the BLS content was developed using the Delphi process. The patient's chance of survival in the MOBICPR game reduced with each incorrect interaction by the participants. At the end of the MOBICPR game, each participant received a total score in the form of a gamification feature that corresponded to the risk of survival (score>50% meant the patient survived) [41]. Gamification, defined as "using game design elements in non-game contexts," has been introduced into nursing education to promote engagement using features such as leaderboards, rewards, badges, and avatars [22]. After playing the MOBICPR game as much as they wanted for 2 weeks, participants in the MOBICPR-IG returned the smartphones. Participants in the W-CG then received the smartphones and followed the same protocol as participants in the MOBICPR-IG, that is, they played the MOBICPR game in front of the investigator before taking the smartphone home. Participants in the W-CG also returned the smartphones after playing the MOBICPR game at home for 2 weeks. Additionally, at the study's conclusion, each participant was asked an open-ended question regarding the number of family members or friends with whom they shared the MOBICPR game for playing.

Outcome Measures

The primary outcomes were (1) assessment of the participants' theoretical knowledge of adult BLS using a questionnaire with a total maximum score of 33 points, where each correct answer was awarded 1 point (Multimedia Appendix 2), and (2) assessment of the participants' practical skills in adult BLS using a checklist with a total maximum score of 39 points (Multimedia Appendix 4).

The secondary outcome was a summary score of high-quality CPR components: (1) a chest compression (CC) rate of 100-120 beats per minute (bpm), (2) a CC depth of 50-60 mm, (3) CC fraction>80%, and (4) a rescue breath volume of 500-600 mL (Multimedia Appendix 4). All measures were taken as mentioned earlier [16,23,27,28]. A total QCPR score was also included, ranging from 0% to 100%. More detailed information about software scoring is available on the Laerdal Medical website [42]. Both primary and secondary outcomes were measured at 3 time points: baseline, 2-week follow-up, and 4-week follow-up.

Statistical Analysis

Statistical analyses were conducted in October and November 2023. Data were analyzed using the R statistical programming language (R Foundation for Statistical Computing). The data presented in the summary table were prepared using frequency analysis, which also included a chi-square test to assess the similarity of the distribution between the intervention and control groups. Theoretical knowledge and practical skill assessments were averaged at the item level and subsequently analyzed using nonparametric statistical tests (Wilcoxon paired-sample test and Mann-Whitney *U* test) as the normality of the distribution was violated. As nonnormal distribution might represent a problem when calculating mean values, violin plots were also used for the purpose of visualizing aggregated scores due to their ability to visualize the distribution of the data. $P<.05$ was considered statistically significant. Effect size (η^2) values >0.1 represented a small effect; 0.3, a moderate effect; and ≥0.5, a large effect. Continuous variables were analyzed according to the Gaussian distribution and reported as the mean (SD) or the median (IQR), whichever was appropriate.

Results

Participant Details

Of 124 nursing students, 80 (64.5%) declined to participate in the study and 44 (35.5%) were enrolled into the study. At follow-up, 1 (5%) of the 22 participants in the WL-CG dropped out. In the end, 43 (98%) of 44 participants were included in the final analysis (Figure 2).

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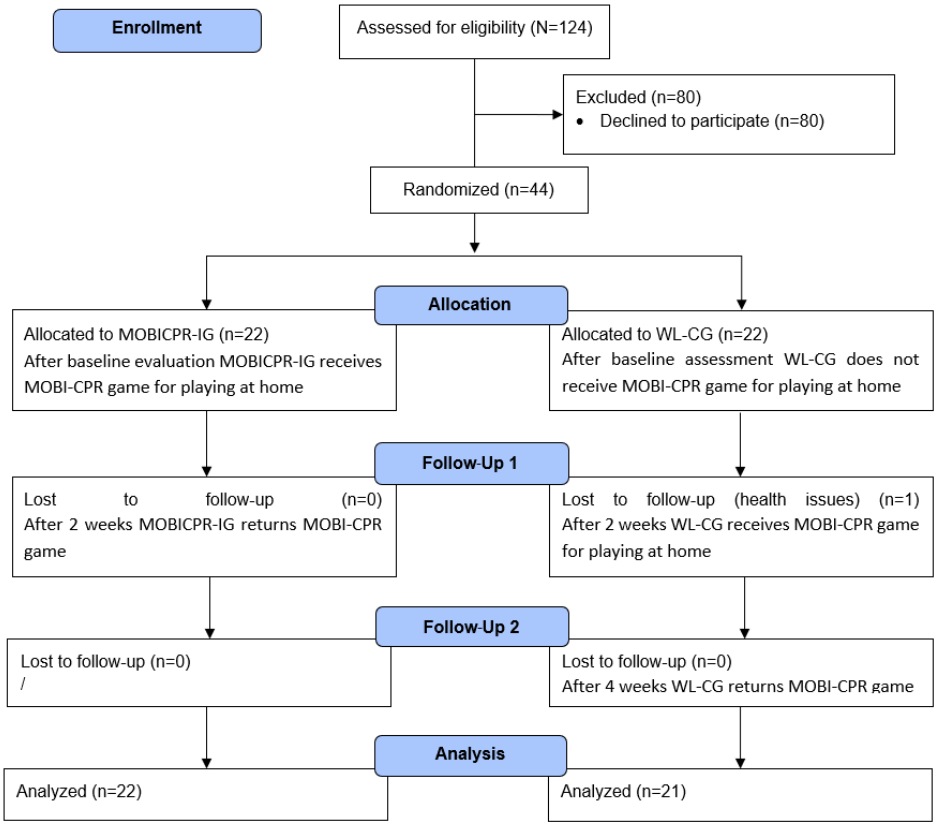
Figure 2. Flow diagram of study participants. MOBICPR-IG: MOBICPR intervention group; WL-CG: wait-list control group.



The mean age of the participants was 19 (SD 0.6) years, 38 (88%) were female, 35 (81%) had a background in health care and nursing education, 32 (74%) had an iOS smartphone, and the self-reported mean daily time spent on the smartphone was 3.8 (SD 1.2) hours (Table 1).

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Table 1. Baseline demographic characteristics.[a]

Characteristics	Total participants (N=43), n (%)	MOBICPR-IG[b] (n=22), n (%)	WL-CG[c] (n=21), n (%)	*P* value
Gender				.67
Male	5 (12)	3 (14)	2 (10)	—[d]
Female	38 (88)	19 (86)	19 (90)	—
Age (years)				.90
19	30 (70)	16 (73)	14 (67)	—
20	11 (26)	5 (23)	6 (29)	—
21	2 (5)	1 (5)	1 (5)	—
Education				.19
Health care and nursing	35 (81)	18 (82)	17 (81)	—
High school/gymnasium	5 (12)	4 (18)	1 (5)	—
Pharmacy	2 (5)	0	2 (10)	—
Economy	1 (2)	0	1 (5)	—
Operating system on smartphone				.001
Apple iOS	32 (74)	11 (50)	21 (100)	—
Android	11 (26)	11 (50)	0	—

[a]The percentages may exceed 100 because of rounding.

[b]MOBICPR-IG: MOBICPR intervention group.

[c]WL-CG: wait-list control group.

[d]Not applicable.

All participants had received some previous adult BLS training. However, only 2 (5%) had witnessed a cardiac arrest. Most of them (n=38, 88%) had already performed CCs on manikins, but only a few had also been giving rescue breaths (n=12, 28%) and used any kind of AED (n=13, 30%). All participants (n=43, 100%) expressed a willingness to assist a patient with OCHA and perform adult BLS. In addition, they all expressed a willingness to perform mouth-to-mouth resuscitation on a family member or acquaintance. However, only about half of them (n=19, 44%) were willing to do the same for a stranger. The predominant concern for not administering rescue breaths to unknown individuals was the uncertainty regarding the patient's medical history and the risk for infectious diseases, as cited by 22 (92%) of the 24 (56%) participants who expressed reluctance. On average, each participant introduced and shared the MOBICPR game with 3 (SD 2) family members or friends for trial and play.

Primary Outcomes

To assess the differences between the 2 groups at all 3 observed time points, we calculated the cumulative scores of adult BLS theoretical knowledge and practical skills for both groups.

Figure 3 shows that playing the MOBICPR game at home for 2 weeks improved the overall adult BLS theoretical knowledge (median gain of 4 points, IQR 3, η^2=0.113, *P*=.005) and practical skills (median gain of 4 points, IQR 7, η^2=0.05, *P*=.04). However, in the WL-CG, which waited for 2 weeks to play the MOBICPR game at home, the theoretical knowledge of adult BLS improved by 2 points (IQR 4, η^2=0.302, *P*=.001), whereas the practical skills in adult BLS increased by 3 points (IQR 3, η^2=0.018, *P*=.14). In the MOBICPR-IG, after 2 weeks of not playing the MOBICPR game at home, the retention of theoretical knowledge gained an additional 2 points (IQR 2, η^2=0.019, *P*=.13) and practical skills gained 3 points (IQR 3.75, η^2=0.122, *P*=.003) compared to the 2-week follow-up.

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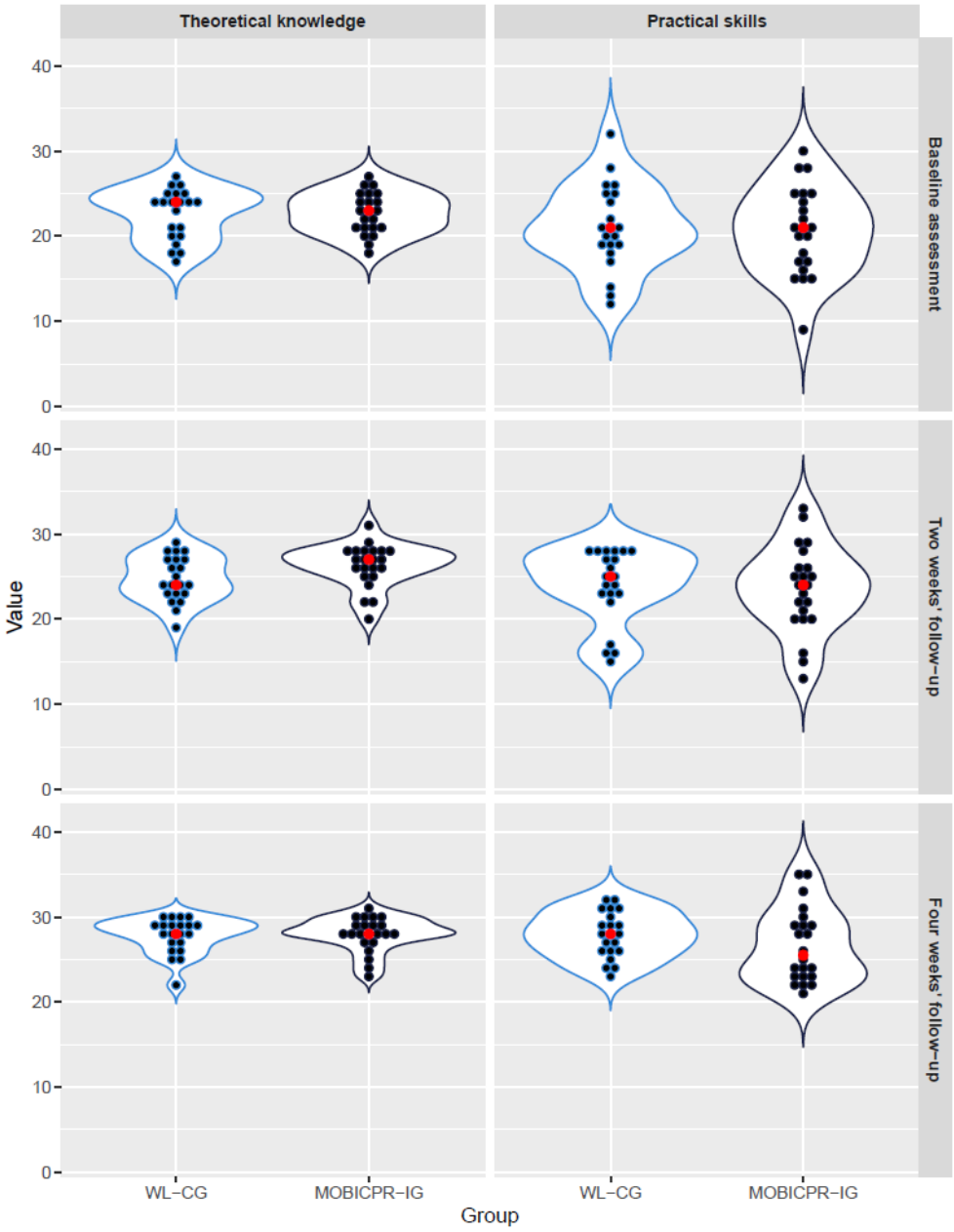
Figure 3. Comparison of theoretical knowledge and practical skill scores for all study participants at baseline, 2-week follow-up, and 4-week follow-up measurements. MOBICPR-IG: MOBICPR intervention group; WL-CG: wait-list control group.



To focus on the impact of playing the MOBICPR game on adult BLS theoretical knowledge and practical skills, we observed participants in both groups and calculated the difference in the cumulative points for both groups after they played the MOBICPR game at home for 2 weeks.

As demonstrated in Figure 4, in the WL-CG, only 3 (14%) participants improved their theoretical knowledge by ≥5 points and only 6 (29%) study participants who achieved this kind of improvement in the adult BLS practical skill score. In contrast, in the MOBICPR-IG, 9 (41%) participants improved their score by at least 5 points in both adult BLS theoretical knowledge and practical skills. The difference in improvement between the MOBICPR-IG and the WL-CG was not significant in practical skills (η^2=0.021, *P*=.45), while in theoretical knowledge, we observed a statistically significant difference (η^2=0.268, *P*=.04).

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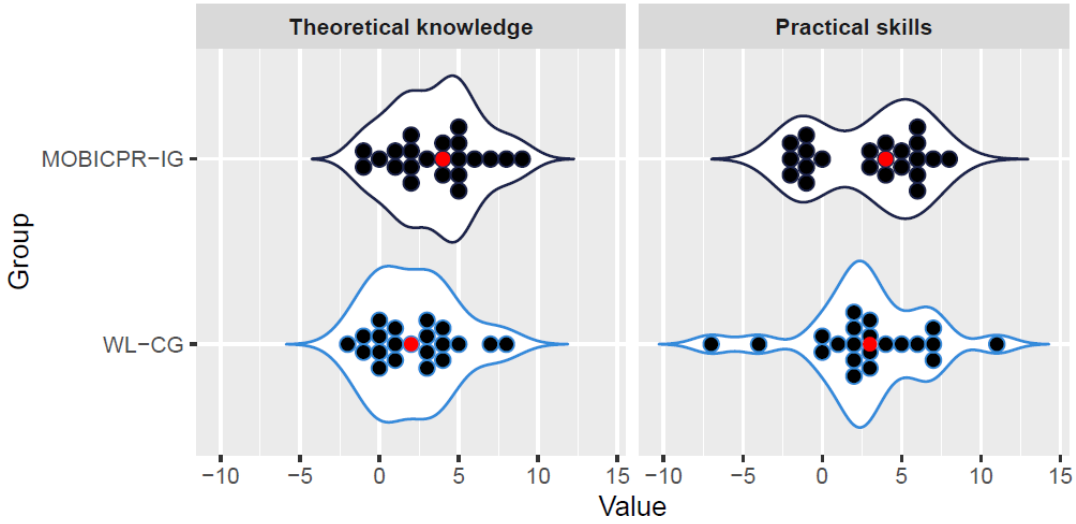
Figure 4. Difference in theoretical knowledge and practical skills score before and after playing the MOBICPR game. MOBICPR-IG: MOBICPR intervention group; WL-CG: wait-list control group.



To obtain more detailed insight into the improvements due to playing the MOBICPR game, we observed the differences in item-level scores before and after playing. Table 2 compares the participants' scores on questions used to test their theoretical knowledge. It is evident that there were notable differences in most items following engagement with the MOBICPR game. Of 33 scores, 13 (39%) decreased during MOBICPR game playing. For example, the score on question 3 (What is the second thing we check in a patient with cardiac arrest?) improved notably after MOBICPR game playing at home (P=.001). In contrast, the score on question 16 (You are alone. Will you go for the AED if it is 100 m away?) did not improve after MOBICPR game playing at home (P=.103).

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Table 2. Question-level comparison of the mean scores for adult BLS[a] theoretical knowledge evaluation for MOBICPR-IG[b] and WL-CG[c] before and after MOBICPR game playing at home for 2 weeks (N=43).

Questions for evaluation of adult BLS theoretical knowledge	Score before playing the MOBICPR game at home, mean (SD)	Score after playing the MOBICPR game at home, mean (SD)	Difference (after – before)	*P* value
1. What is the first thing we check when we approach the patient?	2.51 (0.86)	1.72 (0.43)	–0.79	.04
2. On what kind of surface do we perform adult BLS?	2.88 (0.45)	2.09 (0.34)	–0.79	.001
3. What is the second thing we check in a patient with cardiac arrest?	2.14 (0.74)	2.93 (0.58)	0.79	.001
4. How many seconds do we need to assess consciousness?	1.74 (0.54)	1.95 (0.43)	0.21	.05
5. Before we assess breathing or perform CC[d], do we remove the patient's clothes?	1.26 (0.44)	1.77 (0.21)	0.51	.001
6. How do we open the airway?	2.95 (0.21)	1.05 (0.15)	–1.91	.001
7. What maneuver do we use to open the airway?	1.02 (0.15)	2.98 (0)	1.95	.001
8. How do we assess breathing?	2.95 (0.3)	1.00 (0)	–1.95	.001
9. How many seconds do we need to assess breathing?	1.51 (0.86)	3.00 (0)	1.49	.001
10. What is the most common breathing in a patient with cardiac arrest?	2.47 (0.83)	1.00 (0.63)	–1.47	.001
11. Who are you calling on the 112 number?	3.16 (0.37)	2.12 (0.32)	–1.05	.001
12. Will calling 911 in Slovenia or Europe reach emergency services?	1.72 (0.45)	3.12 (0.5)	1.40	.001
13. Who dials 112 in the case of cardiac arrest?	2.81 (0.55)	1.58 (0.3)	–1.23	.001
14. What do we need to tell the emergency medical dispatcher?	2.51 (0.51)	2.95 (0.51)	0.44	.001
15. What do you do with the phone after providing all the data?	1.91 (0.29)	2.70 (0.15)	0.79	.001
16. You are alone. Will you go for the AED[e] if it is 100 m away?	1.88 (0.32)	1.98 (0.35)	0.09	.10
17. You have help. Will you send it for the AED if it is 2 minutes away?	1.02 (0.15)	1.86 (0.15)	0.84	.001
18. Is this the sign for an AED?	2.00 (0)	1.02 (0)	–0.98	.001
19. Which picture shows the correct hand grip for CPR[f]?	2.00 (0)	2.00 (0.15)	0	.99
20. What is the right depth for CCs?	2.44 (0.77)	2.02 (0.35)	–0.42	.001
21. What is the correct body position for CCs?	1.98 (0.15)	2.86 (0)	0.88	.001
22. Where is the right place for CCs?	1.19 (0.59)	2.00 (0.78)	0.81	.001
23. What is the right frequency for CCs?	2.65 (1.41)	1.23 (0.48)	–1.42	.001
24. What is the CC-to-breath ratio for an adult?	1.98 (0.15)	1.09 (0.46)	–0.88	.001
25. How long can you interrupt CCs for rescue breaths?	1.30 (0.6)	1.93 (0.51)	0.63	.001
26. What is the volume of a rescue breath?	1.88 (0.59)	1.30 (0.26)	–0.58	.02
27. What do you do first if you have an AED?	2.58 (0.91)	2.93 (0.82)	0.35	.002
28. What do we do during AED rhythm analysis?	2.19 (0.59)	2.42 (0.46)	0.23	.17
29. What do we do during AED defibrillation?	1.00 (0)	2.07 (0)	1.07	.001

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Questions for evaluation of adult BLS theoretical knowledge	Score before playing the MOBICPR game at home, mean (SD)	Score after playing the MOBICPR game at home, mean (SD)	Difference (after – before)	*P* value
30. Which of the following statements about the use of AEDs is false?	3.02 (1.3)	1.00 (1.05)	–2.02	.001
31. What do we do after the AED delivers an electric shock?	2.63 (0.69)	3.47 (0.65)	0.84	.001
32. When do we stop CPR?	1.74 (0.44)	2.91 (0.39)	1.16	.001
33. When is it recommended to replace someone during CPR?	1.72 (2.20)	1.81 (0.52)	0.09	.80
Cumulative score	2.08 (0.44)	2.06 (0.26)	0.03	.89

[a]BLS: basic life support.

[b]MOBICPR-IG: MOBICPR intervention group.

[c]WL-CG: wait-list control group.

[d]CC: chest compression.

[e]AED: automated external defibrillator.

[f]CPR: cardiopulmonary resuscitation.

Similarly, in the item-level score differences for practical skills, in 7 (21%) of 34 items, a significant increase was calculated (Table 3). For example, the score on item 1 (Approaches the patient safely) improved after MOBICPR game playing at home (*P*=.001). In contrast, the score on item 2 (Checks responsiveness: shouts and shakes the patient) did not improve after MOBICPR game playing at home (*P*=.81).

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Table 3. Item-level comparison of the mean scores for adult BLS[a] practical skill evaluation for MOBICPR-IG[b] and WL-CG[c] before and after MOBICPR game playing at home for 2 weeks (N=43).

Items for evaluation of adult BLS practical skills	Score before playing the MOBICPR game at home, mean (SD)	Score after playing the MOBICPR game at home, mean (SD)	Difference (after – before)	*P* value
1. Approaches the patient safely	0.09 (0.29)	0.95 (0.46)	0.86	.001
2. Checks responsiveness: shouts and shakes the patient	0.67 (0.47)	0.70 (0.32)	0.02	.81
3. Opens the airway: head tilt–chin lift	0.40 (0.49)	0.88 (0.46)	0.49	.001
4. Performs look, listen, feel	0.74 (0.44)	0.70 (0.15)	–0.05	.62
5. Looks, listens, feels: time	0.53 (0.74)	0.98 (0.78)	0.44	.001
6. Calls 112 in the first minute	0.65 (0.48)	1.35 (0.26)	0.70	.001
7. Calls 112 at the right time	0.65 (0.48)	0.93 (0.29)	0.28	.003
8. Turns on the phone speaker and immediately starts CPR[d]	0.33 (0.47)	0.91 (0.49)	0.58	.001
9. Provides correct information to the dispatcher	0.33 (0.47)	0.37 (0.5)	0.05	.62
10. Provides information about the location	0.21 (0.41)	0.42 (0.5)	0.21	.05
11. Time to the first CCs[e]	0.51 (0.51)	0.56 (0.5)	0.05	.68
12. Corrects the body position for CCs	0.72 (0.45)	0.53 (0.32)	–0.19	.07
13. Corrects the CC location	0.88 (0.32)	0.88 (0.35)	0.00	.99
14. Corrects hand CCs	0.72 (0.45)	0.86 (0.41)	0.14	.11
15. Corrects the CC depth	1.49 (0.8)	0.79 (0.9)	–0.70	.001
16. Recoil of the chest	0.79 (0.41)	1.26 (0.21)	0.47	.002
17. Corrects the CC rate	1.42 (0.7)	0.95 (0.76)	–0.47	.001
18. Ratios CCs	0.91 (0.68)	1.37 (0.53)	0.47	.004
19. CC fraction	0.84 (0.43)	0.95 (0.38)	0.12	.17
20. Opens the airway: head tilt–chin lift	0.44 (0.5)	0.95 (0.45)	0.51	.001
21. Closes the nose and fits lips around the patient's mouth	0.63 (0.49)	0.72 (0.37)	0.09	.32
22. Average pause of ventilation	0.70 (0.46)	0.84 (0.43)	0.14	.08
23. Opens the nose	0.02 (0.15)	0.77 (0.32)	0.74	.001
24. Looks for the chest to rise between 2 rescue breaths	0.37 (0.49)	0.12 (0.51)	–0.26	.003
25. Two rescue breaths	0.84 (0.37)	0.51 (0)	–0.33	.001
26. Volume of rescue breaths	0.53 (0.7)	1.00 (0.65)	0.47	.001
27. Switches on the AED[f] first at the right time	0.49 (0.51)	0.65 (0.46)	0.16	.20
28. Removes clothing	0.98 (0.15)	0.70 (0)	–0.28	.001
29. Position of the right AED pad	0.28 (0.45)	1.00 (0.45)	0.72	.001
30. Position of the left AED pad	0.47 (0.5)	0.28 (0.5)	–0.19	.103
31. Ensures nobody is touching the patient: analyzing	0.51 (0.51)	0.44 (0.5)	–0.07	.58
32. Ensures nobody is touching the patient: shock	0.09 (0.29)	0.58 (0.26)	0.49	.001
33. Presses the shock button at the right time	0.67 (0.47)	0.07 (0.44)	–0.60	.001
34. Immediately restarts CCs	0.95 (0.21)	0.74 (0.29)	–0.21	.002
Cumulative score	0.613 (0.14)	0.76 (0.17)	0.14	.04

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[a]BLS: basic life support.
[b]MOBICPR-IG: MOBICPR intervention group.
[c]WL-CG: wait-list control group.
[d]CPR: cardiopulmonary resuscitation.
[e]CC: chest compression.
[f]AED: automated external defibrillator.

Secondary Outcomes

Table 4 shows a comparison of the high-quality CPR components between participants before and after MOBICPR game playing at home for 2 weeks. There were notable differences in the median (IQR) of the total QCPR score for MOBICPR game playing at home for 2 weeks for the MOBICPR-IG (before: median 41 (IQR 54); after: median 70 (IQR 41); *P*=.011). There was no difference for the MOBICPR-IG after not playing the MOBICPR game at home for 2 weeks.

Table 4. Results for high-quality CPR[a] components for the MOBICPR-IG[b] and the WL-CG[c].

High-quality CPR components	Baseline assessment[d], median (IQR)	Score after 2 weeks of playing the MOBICPR game at home[e], median (IQR)	*P* value[d,e]	Score after 2 weeks of not playing the MOBICPR game at home[c], median (IQR)	*P* value[e,f]
CC[g] rate (bpm[h])					
MOBICPR-IG	108 (18)	112 (18)	.24	112 (18)	.12
WL-CG	103 (22)	110 (10)	.38	__[i]	—
P value	.78	—	—	—	—
CC depth (mm)					
MOBICPR-IG	57 (7)	56 (7)	.56	57 (4)	.25
WL-CG	58 (6)	59 (2)	.27	—	—
P value	.16	—	—	—	—
CC fraction (%)					
MOBICPR-IG	70 (6)	72 (6)	.26	68 (9)	.15
WL-CG	68 (13)	70 (8)	.63	—	—
P value	.88	—	—	—	—
Volume of rescue breaths (mL)					
MOBICPR-IG	496 (369)	600 (463)	.54	473 (204)	.66
WL-CG	356 (147)	567 (270)	.45	—	—
P value	.64	—	—	—	—
Total QCPR[j] score (%)					
MOBICPR-IG	41 (54)	70 (41)	.01	77 (38)	.54
WL-CG	43 (42)	72 (46)	.24	—	—
P value	.62	—	—	—	—

[a]CPR: cardiopulmonary resuscitation.
[b]MOBICPR-IG: MOBICPR intervention group.
[c]WL-CG: wait-list control group.
[d]Measurement at baseline.
[e]Measurement after 2 weeks of playing the MOBICPR game at home.
[f]Measurement after 2 weeks of not playing the MOBICPR game at home.
[g]CC: chest compression.
[h]bpm: beats per minute.
[i]Not applicable.
[j]QCPR: Quality Cardiopulmonary Resuscitation.

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Discussion

Principal Findings

In this study, playing the MOBICPR game at home for 2 weeks improved the theoretical knowledge of adult BLS in the participants but little their practical skills. These outcomes were expected, considering that the MOBICPR game was designed primarily to impart theoretical knowledge of adult BLS, rather than providing hands-on practice with an actual BLS manikin. To the best of our knowledge, only 2 studies have used data collected from manikin software to evaluate the practical parts of adult BLS as we did [27,28]. We observed in our study population that both the CC rate and the CC depth remain within the margins of the current ERC recommendation [34]; in comparison to our results, in the 2 studies [27,28], both the CC rate and the CC depth dropped below the margins after serious smartphone game playing. These 2 studies [27,28] also presented the total QCPR scores, and where our scores improved compared to theirs. Consequently, we recommend considering the MOBICPR game as a supplementary educational tool in future BLS course formats that incorporate immersive technologies [43,44] for retention of adult BLS knowledge.

In evaluating study participants performing adult BLS on a manikin, we observed 5 learning points (all reported in Tables 2 and 3), which could be useful for debriefing topics after BLS courses. Initially, a large number of participants struggled with checking the manikin's response as it lay face down. Some checked the response without turning the manikin onto its back, while others did so with the manikin still face down. After playing the MOBICPR game at home, only a minority checked the response after turning the manikin onto its back. Studies show that two-thirds of all patients are found in positions unsuitable for performing CCs, such as the recovery position [45]. The second learning point concerned the right time for chest exposure during CPR. Many participants removed the clothing before looking, listening, and feeling for signs of breathing, while others did so before applying AED electrodes to the manikin's bare chest. Studies indicate that exposing the chest during CPR can improve the rescuer's ability to locate the center of the patient's chest, leading to more effective CCs and reducing the risk of inaccurate compressions [46]. The third point was about shouting for help. A recent study revealed that almost all European BLS instructors teach laypersons to shout for help [47], even though it was removed from the ERC BLS guidelines [34,40]. Despite playing the MOBICPR game at home, the participants still tended to shout for help before calling emergency services. As a fourth point, we noticed that some participants attempted to multitask by calling the dispatcher and performing CCs simultaneously. This practice resulted in lower-quality CCs, as the focus was divided between providing information to the dispatcher and maintaining the 30:2 CC-to-rescue-breath ratio. Generation Z, like the participants in our study, tends to multitask and is more engaged in independent work [48]. Considering this insight, we are re-evaluating the recent ERC BLS guidelines, particularly their recommendation to activate the speakerphone or another hands-free feature on a mobile device before promptly initiating CPR [34]. Finally, we observed that almost all study participants failed to ensure safety before defibrillation when using an AED on the manikin. Issues arose before pressing the shock button, either because they did not check whether someone was touching the manikin or because they pressed the shock button prematurely. This highlights that using an AED is not intuitive for laypersons, as studies suggest, and special training should be considered [49].

The International Liaison Committee on Resuscitation provides a scientific statement on teaching laypersons adult BLS and suggests using TEL, such as serious smartphone games, to engage, motivate, and educate children and adolescents in saving more lives [34]. Several legitimate smartphone games have been identified as suitable for teaching adult BLS, but their content is questionable because it does not follow current BLS guidelines [50,51]. Moreover, most of them teach only hands-on CPR. Some also include ventilation and AED use [51]. However, the MOBICPR game was developed based on recent ERC BLS guidelines [34] and includes all the recommended BLS steps. In a recent MOBICPR study, students agreed that it was beneficial to play the MOBICPR game before practicing adult BLS on a manikin [41]. They also highly rated the usability of the MOBICPR game for providing adult BLS theoretical knowledge and practical skills. The results show that the MOBICPR game could be a novel, interactive, evidence-based BLS educational tool for playing at home after adult BLS training [41,52]. Moreover, our study revealed that the MOBICPR game could be an effective method for enhancing bystander willingness and awareness in performing CPR. This potential is demonstrated by the fact that all study participants introduced the MOBICPR game to their family members, relatives, or friends, as seen in similar studies where enhanced technology was used teaching adult BLS [53].

This gamified learning approach fits well with the educational theory heutagogy, also known as self-determined learning, where learners determine what they want to learn [8]. In the case of the MOBICPR game, learners can play it at any time to refresh their adult BLS knowledge without waiting for the next training session [54]. Moreover, the use of do-it-yourself manikins made from everyday items, such as plastic bottles, toilet paper, or even a pillow, for practicing CC techniques at home, especially in low-resource settings, coupled with the MOBICPR game, can potentially improve and solidify practical skills in adult BLS [55-58]. The MOBICPR game also includes gamification features, such as avatars, points, and various audio, textual, and graphical feedback. These gamification elements could motivate learners to engage with the game more frequently than they normally would [59]. Future educational tools, such as the MOBICPR game, should align with the 5 key messages outlined in the recent ERC BLS guidelines, ranging from recognizing cardiac arrest to learning the proper techniques for performing CPR [34]. This adherence is crucial for the effective education and retention of adult BLS skills, particularly following adult BLS courses in a home environment.

Limitations

This study has several limitations. First, because the study participants were only followed for 4 weeks, we were not able to show that the MOBICPR game improved their long-term

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retention of resuscitation knowledge and skills. Second, the sample size was small due to the lack of interest of participants in participating in the study and because only 1 generation of participants was able to be included at that time. Third, this was a single-faculty study, which limits the generalizability of the results. Fourth, in this study, participants were familiar with smartphone games. It is unclear how effective the MOBICPR game would be in children or older populations. Fifth, because this was a simulation-based study, the performance results may not be generalizable to real-life situations and could not present the impact on patient outcomes. Finaly, the content in the MOBICPR game was developed by researchers based on recent ERC BLS guidelines [34]. In the future, there are plans to introduce the MOBICPR game to the Slovenian National Resuscitation Council, with the goal of securing its certification, a process akin to that followed by the Italian Resuscitation Council for its smartphone-based serious games [60].

Conclusion

The home use of the MOBICPR game shows promise in enhancing the theoretical knowledge of adult BLS. Although there was no significant improvement in performing adult BLS or in retaining the related knowledge and skills, the study yielded important learning objectives for the enhancement of future adult BLS training. Further research is necessary to explore its lasting effects across various demographics and to determine the most effective use of the MOBICPR game in teaching adult BLS.

Acknowledgments

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Authors' Contributions

The study was carried out through collaboration among all authors. NF developed the study design and supervised the study. NF, GŠ, and ŠM drafted the manuscript. NF, GŠ, RG, and ŠM conducted data collection and analysis. NF, MS, PS, and RG interpreted results from the cardiopulmonary resuscitation point of view. RMC and RG conducted a comprehensive content review. All authors have read, revised, and approved the final manuscript.

Conflicts of Interest

NF is a member of the European Resuscitation Council (ERC) basic life support (BLS) Science and Education Committee. RG is the ERC director of guidelines and the International Liaison Committee on Resuscitation (ILCOR) and chair of the ILCOR Education, Implementation, and Teams Task Force. Other authors declare no conflicts of interest.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1235 KB - games_v12i1e56037_app1.pdf]

Multimedia Appendix 2
Adult BLS theoretical knowledge questionnaire. BLS: basic life support.
[DOCX File , 155 KB - games_v12i1e56037_app2.docx]

Multimedia Appendix 3
Out-of-hospital cardiac arrest scenario.
[DOCX File , 13 KB - games_v12i1e56037_app3.docx]

Multimedia Appendix 4
Adult BLS practical skills checklist. BLS: basic life support.
[DOCX File , 28 KB - games_v12i1e56037_app4.docx]

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Abbreviations

AED: automated external defibrillator
BLS: basic life support
bpm: beats per minute
CC: chest compression
CPR: cardiopulmonary resuscitation
ERC: European Resuscitation Council
m-learning: mobile learning
MOBICPR-IG: MOBICPR intervention group
OHCA: out-of-hospital cardiac arrest
QCPR: Quality Cardiopulmonary Resuscitation
TEL: technology-enhanced learning
WL-CG: wait-list control group

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Original Paper

Adoption of Augmented Reality in Educational Programs for Nurses in Intensive Care Units of Tertiary Academic Hospitals: Mixed Methods Study

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Abstract

Background: In the wake of challenges brought by the COVID-19 pandemic to conventional medical education, the demand for innovative teaching methods has surged. Nurse training, with its focus on hands-on practice and self-directed learning, encountered significant hurdles with conventional approaches. Augmented reality (AR) offers a potential solution to addressing this issue.

Objective: The aim of this study was to develop, introduce, and evaluate an AR-based educational program designed for nurses, focusing on its potential to facilitate hands-on practice and self-directed learning.

Methods: An AR-based educational program for nursing was developed anchored by the Kern six-step framework. First, we identified challenges in conventional teaching methods through interviews and literature reviews. Interviews highlighted the need for hands-on practice and on-site self-directed learning with feedback from a remote site. The training goals of the platform were established by expert trainers and researchers, focusing on the utilization of a ventilator and extracorporeal membrane oxygenation system. Intensive care nurses were enrolled to evaluate AR education. We then assessed usability and acceptability of the AR training using the System Usability Scale and Technology Acceptance Model with intensive care nurses who agreed to test the new platform. Additionally, selected participants provided deeper insights through semistructured interviews.

Results: This study highlights feasibility and key considerations for implementing an AR-based educational program for intensive care unit nurses, focusing on training objectives of the platform. Implemented over 2 months using Microsoft Dynamics 365 Guides and HoloLens 2, 28 participants were trained. Feedback gathered through interviews with the trainers and trainees indicated a positive reception. In particular, the trainees mentioned finding AR particularly useful for hands-on learning, appreciating its realism and the ability for repetitive practice. However, some challenges such as difficulty in adapting to the new technology were expressed. Overall, AR exhibits potential as a supplementary tool in nurse education.

Conclusions: To our knowledge, this is the first study to substitute conventional methods with AR in this specific area of critical care nursing. These results indicate the multiple principal factors to take into consideration when adopting AR education in hospitals. AR is effective in promoting self-directed learning and hands-on practice, with participants displaying active engagement and enhanced skill acquisition.

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Trial Registration: ClinicalTrials.gov NCT05629663; https://clinicaltrials.gov/study/NCT05629663.

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KEYWORDS

augmented reality; AR; clinical skills education; nurse education; technology-based education; education; nurse; nursing; allied health; technology-enhanced learning; interview; training; usability; acceptability; educational; teaching; ICU; intensive care unit; self-guided; self-directed; hands-on; adoption; TAM; Technology Acceptance Model; skill; acquisition

Introduction

In recent years, conventional education, especially in the medical field, has been challenged by the introduction of new technologies [1]. The COVID-19 pandemic further highlighted the limitations of conventional teaching methods [2]. Nurse training, with its emphasis on hands-on practice and self-directed learning, was particularly affected by the pandemic, making it evident that conventional training methods could not sustain the demands of the situation [3,4]. Given these constraints, the search for alternative, technology-driven educational methods intensified, aiming to address both physical resource and time challenges without compromising education quality [5,6]. In this context, an immersive learning environment, based on a computer-generated environment enabling real-time user interactions [7], has emerged as a promising solution.

Such an immersive platform merges augmented reality (AR) and virtual reality (VR), offering a dynamic 3D space for learners. This integration not only enhances the learning experience by providing a rich, immersive environment [8,9] but also reshapes the boundaries between reality and the virtual realm, paving the way for innovative learning avenues [10,11]. Exploring AR's potential reveals that its uses surpass merely aiding in remote education. AR also introduces real-time feedback mechanisms, empowering trainees to obtain immediate insights about their actions and performance through virtual aids [12,13]. This immediacy in feedback is invaluable, as it allows errors to be addressed promptly, fostering continuous improvement in learning [14,15].

In the field of critical care, there has been an exploration of the use of AR and VR in educational applications [16]. VR-enhanced training for tracheostomy care in the intensive care unit (ICU) setting has demonstrated the potential of education in an immersive learning environment [17,18]. Studies have been conducted for training mechanical ventilator settings and central line insertion, showing improvements in self-efficacy, increased familiarity, confidence, and reduced anxiety compared to conventional methods [13,17,19]. However, while the advantages are evident, existing research into AR and VR remains limited. These studies are usually one-time or short-term investigations, mainly focusing on the effectiveness of the immersive learning environment [20]. Moreover, integrating these technologies into a nursing curriculum represents an area yet to be fully explored [21].

In this study, we aimed to derive key considerations for each phase of implementation based on our experience of introducing an AR nursing program within an ICU in a tertiary hospital setting.

Methods

Experimental Design

Overview

Our methodology was refined based on the Kern six-step approach to transition nursing education into an immersive AR-based format [22], focusing on the following key stages: (1) problem identification, (2) needs assessment, (3) setting goals and objectives, (4) choosing educational strategies, (5) implementation, and (6) evaluation [23] (Figure 1).

Our initial steps involved conducting interviews with trainer nurses to discern existing issues and identify a procedure amenable to transition into an AR format [24]. We then developed and implemented an AR-based educational program encapsulating two distinct procedures. We surveyed and interviewed trainees, focusing on technology acceptance and usability.

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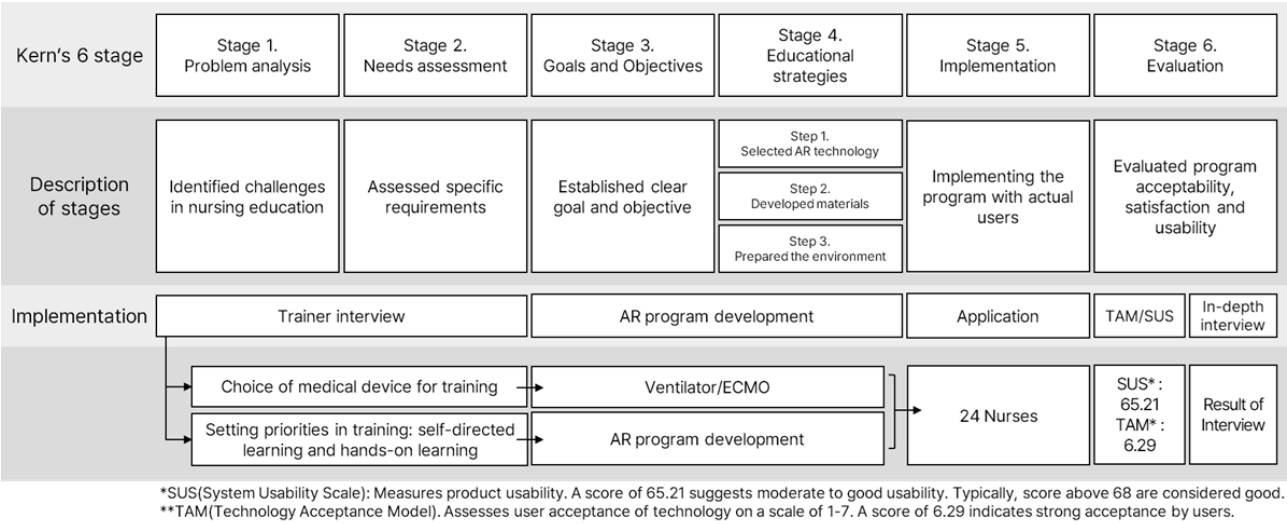
Figure 1. Overall process of the adoption of augmented reality into nursing education based on the Kern 6-step framework [22]. AR: augmented reality; ECMO: extracorporeal mechanical oxygenation.



Stage 1: Problem Identification

In this foundational stage, we endeavored to identify core problems through a general needs assessment, employing two primary approaches: engaging in interviews with training nurses and reviewing the extant literature [24-27].

The interviews, conducted with nurses from the nursing education department, were based on a semistructured format and were held online or offline depending on participant preference. Voice recordings ensured the precise capture of data shared during these interactions.

In addition to the interviews, we explored previous studies with the aim of harvesting insights and identifying common issues found within the existing research landscape, thereby anchoring our findings in a robust context of existing knowledge [28].

Stage 2: Needs Assessment

Upon conducting the interviews in stage 1, we recognized the challenges endemic to conventional educational methods as identified by educators. We investigated possible solutions to these challenges, and found the need for feedback through remote supervision, especially regarding certain devices. We further identified key elements that should be considered in the development of the educational program. This stage also served to validate our problem identification process.

Stage 3: Goals And Objectives

We defined our goals through collaboration between trainers and researchers, focusing on improving access and proficiency with complex medical equipment.

Stage 4: Educational Strategies

Step 1: Selecting Appropriate Technology

With the imperative for hands-on practice in nursing education, AR was chosen to enable nurses to interact with virtual medical devices within a realistic clinical setting [29]. AR's ability to superimpose digital models onto the physical world allows for a highly interactive and immersive learning experience without the traditional constraints of location, time, or physical resources [30]. This aligns with our goal to empower self-directed learning, permitting nurses to engage in practical education at their own pace and convenience [31].

Step 2: Developing Educational Material

Navigating through the lens of self-directed learning and hands-on practice, we considered AR options that could facilitate tangible interaction with 3D objects. The development of materials required a detailed comprehension of the unique needs of nurses and the incorporation of AR content to support self-directed learning.

Step 3: Preparation of the Educational Environment

To facilitate a high-fidelity learning experience, our AR-based educational program was set within the hospital's simulation laboratory. A designated area within the lab was prepared, encompassing a minimum of 3×3 meters to provide trainees with sufficient room to maneuver and interact with the virtual elements without spatial constraints. To ensure uninterrupted delivery of our AR-based educational program, we utilized five HoloLens 2 devices. This approach was adopted to mitigate against battery and overheating issues that could disrupt the learning process. This setup was optimized to allow multiple nurses to receive training at the same time, promoting efficient learning throughout while maintaining an individualized, hands-on experience.

Stage 5: Implementation

We recruited the participants through an advertisement posted on the hospital's internal internet network. Our goal was to enroll a minimum of 10 participants for each session to ensure a dynamic and interactive learning environment while still allowing for personalized instruction. We designed the sessions to accommodate up to five nurses at a time, which was determined as the optimal number for both effective learning and space utilization within our AR setup. This small-group approach not only facilitated focused attention from the instructors but also ensured that each participant could engage deeply with the AR modules.

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To maintain a high standard of education and safety, we appointed two experienced supervisors for each training session. These supervisors were selected based on their expertise in intensive care procedures and their familiarity with AR technology. Their role was to provide immediate assistance and feedback, ensuring that any technical issues could be addressed without disrupting the learning process. They were also tasked with observing the sessions to gather informal feedback, contributing to the continuous improvement of the program.

Stage 6: Evaluation

This study was conducted at a large academic tertiary hospital in Seoul, Korea, which accommodates more than 3100 nurses and 2000 inpatient beds. The research provided education to intensive care nurses and included a postsession survey and semistructured interview.

Ethical Considerations

The Institutional Review Board of Samsung Medical Center approved the study design (SMC-2022-08-058 and SMC-2022-08-079), and all trainers and trainees provided written informed consent before participating in the study, ensuring ethical adherence throughout the research. To protect the participants' privacy and confidentiality, all data collected during this study were anonymized or deidentified. Stringent data protection measures are in place, including the use of secure, encrypted data storage systems accessible only by authorized personnel. These precautions are designed to safeguard sensitive information and maintain the integrity of the data. Participants were compensated for their time and contribution. Each participant received 30,000 KRW (~US $22) upon completion of their involvement in the study. This compensation was intended to acknowledge their valuable time and effort and to offset any inconvenience associated with participation. The compensation structure was clearly communicated to all participants prior to their enrollment and was administered transparently to ensure fairness.

Outcome Measures of the Survey

Upon completion of the educational program, participants were asked to fill out a questionnaire evaluating their user experience. This evaluation was based on the theories of self-directed learning and hands-on practice, including questions on personal characteristics, job satisfaction, and appropriateness. To evaluate the AR program's acceptability and usability, we employed the System Usability Scale (SUS) and the Technology Acceptance Model (TAM) [20,32,33].

We chose the SUS for its proven reliability and efficiency across various technologies. The SUS is widely used across various domains, including software, websites, and medical devices, to assess overall user experience. Moreover, it has been validated in hospital environments and shown effectiveness with small sample sizes. The SUS consists of 10 simple questions presented in a 5-point Likert-scale format, assessing both positive and negative aspects of the system, with total scores ranging from 0 to 100 [34,35]. The TAM was selected for its emphasis on understanding user acceptance of information technology [16,36,37]. We adapted the TAM-based survey questions to fit the context of AR nurse education, informed by various relevant studies [24,26,27,38]. In contrast, the SUS was employed in its unmodified form. In addition, we conducted a correlation analysis between the TAM and SUS elements [37,39].

Outcome Measures of Interviews

Nurses who responded to the questionnaire were selectively screened for their willingness to participate in further interviews. These interviews were semistructured and guided by nursing education theories from previous studies. The format allowed flexibility, permitting up to two additional questions based on the responses of the interviewees.

Statistical Analysis

The statistical analysis was performed using R software (version 4.3.2). Continuous variables are expressed as either mean (SD) or median (IQR), depending on their distribution, while nominal variables are expressed as counts (n) and percentages (%). We performed a correlation analysis to examine the relationship between the TAM and SUS using survey data.

Results

Stage 1: Problem Identification

Overview

We obtained interview results from four nurses who are trainers and operators in the nursing education department. The insights garnered from the interviews are summarized below and detailed in Table 1.

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Table 1. Key considerations in augmented reality (AR) education development as expressed during trainer interviews.

Category	Key details	Core implications
Educational needs and challenges	Training requirements necessary for handling advanced medical equipment; aligning AR educational content to complement the features of specific medical devices; adapting training modules to meet the unique demands precipitated by the COVID-19 pandemic; implementing streamlined training processes for the rapid acclimatization of new nurses; addressing the limitations inherent in conventional training techniques; tackling the deficit of hands-on training equipment in nursing training	Imperative for AR solutions in bridging training disparities and responding to progressive requirements
Program development and strategies	Tailoring educational programs to align with the diverse experience levels of nursing professionals; standardizing the phases of training to ensure uniformity and consistency in educational outcomes; formulating well-structured and strategic plans for nursing training; ensuring efficient and effective distribution and management of training equipment and resources	Criticality of a holistic design and meticulous implementation in AR training for optimal efficacy
Challenges and future concerns	Addressing trainees' physical challenges, such as the necessity to wear glasses or masks, in the training environment; guaranteeing the safety and appropriateness of both the devices and venues utilized for training; modifying AR training methods to be inclusive and effective for older nursing personnel; integrating strategies within training programs to manage and reduce trainee fatigue effectively	Recognition of and addressing present and prospective hurdles for continuous advancement in AR training

Requirement of Education in Difficult-to-Use Devices

Using difficult-to-use medical devices in health care can pose a significant challenge for medical staff due to the increased risk of errors, negatively impacting patient outcomes. Proper education on these devices is essential to ensure that medical staff can use them safely and effectively.

Lack of Resources: Space, Instructor, Time, and Cost

The lack of education resources in health care can be a significant challenge for health care organizations and medical staff [15]. Education is essential to ensure that health care professionals possess the necessary knowledge, skills, and abilities to provide safe and effective care to patients. However, the interviewees mentioned that many health care organizations face barriers in providing adequate education resources to their staff, which can negatively impact patient outcomes.

Another challenge is the lack of adequate education time. Health care professionals are often required to work long hours, and finding time to attend education sessions and complete the necessary course work can be difficult. This lack of time can make it difficult for health care organizations to provide education tailored to the specific needs of their staff.

Stage 2: Needs Assessment

Following the interviews, we identified crucial factors to consider when selecting educational topics. Educators highlighted the significant challenges of limited access to educational devices and instructors. Additionally, they emphasized the necessity for education in technically demanding skills. Trainers expressed a preference for educational topics that required hands-on practice. Their reasoning is grounded in the knowledge that complex devices are frequently used in treating patients with critical illnesses. The competence of nurses in operating these devices directly impacts patient outcomes. The responses from trainers and operators related to needs are summarized in Table 1.

Stage 3: Goals and Objectives

Selected Objectives

Based on the interview results, extracorporeal membrane oxygenation (ECMO) machines and ventilators were selected as the objectives for training owing to their complexity and difficulty of use. Ventilators were selected as important yet challenging devices to master. The complexity of ventilators, compounded by the multitude of lines and connections involved, can pose challenges for nurses with limited experience.

By contrast, an ECMO machine is a high-risk medical device that is essential for patients with COVID-19. When the alarm of an ECMO machine sounds, nurses must promptly find a solution. However, given its rarity, even experienced nurses may not have encountered this situation. Nevertheless, as this could pose a risk to the patient, appropriate education was deemed necessary, and therefore use of the ECMO machine was selected as the problem scenario for this evaluation.

Selected Goals

Our aim was to develop a sustainable AR-based educational program that could offer numerous benefits to trainers and trainees. These benefits include enhanced engagement and motivation, interactive and immersive learning experiences, and the facilitation of personalized learning. Key considerations for developing such a sustainable AR-based educational program encompass designing for scalability and accessibility, and incorporating user feedback to enhance the program in its maintenance and operation over time.

Stage 4: Educational Strategies

Step 1: Development of an AR-Based Educational Program

The ECMO machine educational program comprises 45 slides divided into four parts, each detailing the operation of the machine, managing machine disruptions, responding to "low battery" alarms, and addressing the loss of flow signal ("SIG") alarm. Each part includes approximately 8-10 steps, guiding trainees on how to manage each situation effectively.

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The ventilator program is composed of three parts encompassing a total of 46 slides. Each part involves 26 steps related to ventilator settings and preuse inspections, as well as seven steps for application, alarm configuration, and educational content evaluation. The education process involves checking supplies, power sources, wall oxygen and medical gas connections, and exhalation cassette connections; powering on the device; performing preuse checks; connecting test tubes; selecting the target and application method; turning on the humidifier; configuring the mode and parameters; connecting the patient to the system; monitoring after patient application; and setting alarms.

Step 2: Adoption of Innovative Technology

The AR-based education was performed with a Maquet Servo-I mechanical ventilator and the RotaFlow II System Permanent Life Support ECMO machine from Getinge. We attempted to incorporate a 3D guide for hands-on practice and used videos to enhance understanding. The AR-based educational program was developed using the Microsoft Dynamics 365 Guides program. The program's content was delivered to users through a Microsoft HoloLens 2 device.

Step 3: Operation Plan

The previously designated simulation laboratory was successfully used during the AR-based educational program. The allocated space for the program proved sufficient, with each trainee having access to the minimum 3×3 meters space as planned [40]. This spatial arrangement allowed for unimpeded movement and interaction with the AR components, which was critical for the immersive learning experience.

In practice, the ventilator and ECMO machine simulations were conducted without any spatial constraints, enabling a total of 28 trainees to complete the training per the session schedules. The effective use of space was evidenced by the trainees' ability to perform the necessary tasks and their reported comfort level during the training sessions.

Stage 5: Implementation

The AR-based educational program platform was operational for a period of 2 months, with education sessions scheduled from 9 AM to 5 PM. This schedule allowed nurses to select their preferred date and time within this interval. To facilitate the program's implementation, we used five HoloLens 2 devices, along with two laptops for supervisor screen connections and two large screens for the research environment. Throughout the research, a total of 22 trainees actively engaged in the education sessions. The trainees' screens, as viewed through the HoloLens 2 devices, were immediately visible to the trainer, enabling real-time progress monitoring. Additionally, trainees were encouraged to request assistance if they encountered any difficulties during the session.

Stage 6: Evaluation

Participants

Training sessions were conducted by two trainers and two operators for the 28 nurses in the ICU from January 1 to February 3, 2022. Twenty-four nurses participated in the survey, 11 of whom took part in an in-depth interview. They were trained either in ventilator or ECMO machine usage with an even distribution across both groups. The participants' baseline characteristics are presented in Table 2. The median work experience was 3 (IQR 0-6.25) years with a mean of 3.75 (SD 3.90) years. There was a predominance of female participants (17/24, 71%). All participants belonged to the general nursing field with a slight majority working in the medical ICU compared to the surgical ICU (Table 2).

Additionally, all participants (24/24, 100%) owned smartphones and the majority (23/24, 95.83%) possessed either a tablet PC or laptop. Prior to the instruction, 13 (54%) nurses had previous experience with a head-mounted display.

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Table 2. Demographic and clinical characteristics of the surveyed nurse trainees (N=24).

Characteristics	Trainees, n (%)
Method trained on	
ECMO[a]	12 (50)
Ventilator	12 (50)
Sex	
Male	7 (29)
Female	17 (71)
Medicine specialty	
Internal medicine	15 (63)
Surgical department	9 (38)
Experience (years)	
<1	5 (25)
1-2	3 (15)
3-4	2 (10)
5-6	2 (10)
≥7	3 (15)

[a]ECMO: extracorporeal membrane oxygenation.

Comparison of SUS and TAM Scores

In the usability test, the items “I think that I would like to use this system frequently” and “I don’t think the system is unnecessarily complex” received the highest rating of 4.38 out of a possible 5, while the lowest-rated item, “I thought there was too much inconsistency in this system,” received an average score of 1.83. The responses concerning technology acceptance were categorized into four areas according to the TAM: perceived usefulness (PU), perceived ease of use (PEU), perceived enjoyment (PE), and intention to use (IU). The survey included 15 questions scored on a 7-point scale. The item with the highest score was “It is fun to use,” scoring 6.71, while the lowest-rated item was “It is easy to use,” scoring 5.17. In further survey results, factors such as age, sex, department of work, and years of work did not impact satisfaction with the education or usability. All response results for the survey are provided in Multimedia Appendix 1.

Correlation of Usability and Acceptance

Our correlation analysis revealed varying degrees of association between SUS and TAM factors. For instance, there was a strong correlation between PU and IU and a moderate correlation between PE and PU. However, the correlation between PEU and IU was not significant (Table 3).

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Table 3. Correlation between the Technology Acceptance Model–based survey items and System Usability Scale (SUS).

Variable	UE[a] (SUS)	PU[b]	PEU[c]	PE[d]	IU[e]
UE (SUS)					
r	1	0.2	0.34	0.15	0.22
P value	__[f]	.50	.12	.45	.30
PU					
r	0.2	1	0.2	0.69	0.76
P value	.50	—	.50	<.001	<.001
PEU					
r	0.34	0.20	1		0.31
P value	.12	.50	—	.34	.33
PE					
r	0.15	0.69	0.32	1	0.72
P value	.45	<.001	.34	—	<.001
IU					
r	0.22	0.76	0.31	0.72	1
P value	.30	<.001	0.33	<.001	—

[a]UE: user experience.
[b]PU: perceived usefulness.
[c]PEU: perceived ease of use.
[d]PE: perceived enjoyment.
[e]IU: intention to use.
[f]Not applicable.

Insights From Participant Interviews

Four participants completed interviews related to their experiences with the AR-based educational program. Key insights from these interviews have been collated and are summarized in Table 4. We present a curated selection of interview responses that most effectively capture the key insights. These selections were thoroughly chosen for their relevance and ability to represent the broader findings of the study.

Overall, the evaluation of the AR-based education was positive, with participants indicating that AR could enhance their actual clinical performance. AR technology is particularly well-suited for individuals interested in self-directed or hands-on learning theories. Nurses were found to be open to education using innovative technology. When asked if they needed assistance with the curriculum, no participant responded negatively regarding the content. However, some participants did express a need for help in adapting to new devices and technologies.

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Table 4. Trainees' feedback after augmented reality (AR) implementation in the training program.

Category and subcategory	Details
Motivation	
Intrinsic motivation	Interest in the integration of AR into educational settings; desire among learners for practical experience with medical devices; expectations that AR technology will significantly improve learning efficacy
Reasons for participation	Influence of colleague recommendations; curiosity about AR teaching methods; specific needs related to own job
Existing issues	Noticing varying standards in educational quality; underscoring the need for improvement; necessity to establish standardized training procedures and protocols; need for training programs to be customized to individual learning styles and needs
Learning preferences	
Preferred learning method	Balancing traditional (54.5%) and self-directed (45.5%) learning approaches; valuing feedback and interaction in traditional learning; preference for flexibility and pace in self-directed learning
Face-to-face versus nonface-to-face	Equilibrium between face-to-face (54.5%) and remote learning (45.5%); diverse preferences shaped by feedback, comfort, and flexibility
Feedback	
Practical use	Majority opinion holding that AR technology is beneficial for skill development; mixed opinions regarding the real-world applicability of AR in professional settings; varied levels of expectation regarding the use of AR devices in educational contexts
Training experience	Recognizing the benefits of AR in providing realistic scenarios, allowing for self-directed learning, and enabling repeated practice; challenges include unfamiliarity with AR, focus on operation over content, and limited interaction
Content and support	General satisfaction with AR content amid comparisons to traditional methods; requirement for technical support and assistance in AR training
Comparative analysis and outlook	AR's superiority in learning pace, error identification, and training repetition over conventional methods; challenges in mastering AR operation and content depth; mixed perspectives on AR replacing traditional methods (viewed as supplementary); AR's efficacy in specific scenarios; considered resource-intensive for broad implementation; potential for enhancing self-directed and iterative learning
Future considerations	
Target demographics for AR training	Target new nurses, individuals lacking device experience, and department transfers; however, limited relevance for experienced nurses
Benefits of self-learning with AR	Reduced pressure, time efficiency, review flexibility; utility in learning uncommon scenarios and repeatable sessions
Concerns with self-learning	Limitations of AR training in actual clinical settings; lack of communal learning opportunities in AR environments; concerns over system errors and device quantity limitations

Discussion

Principal Results

The principal findings of this study provide valuable insights into the strategic translation of conventional critical nursing education to AR-based education platforms in the use of difficult-to-use medical devices [41]. Through interviews conducted with trainers before program development, the study successfully identified the specific needs and requirements of trainers in critical care nursing education. The study employed AR-based educational technology to enhance self-directed learning and hands-on practice.

In the educational strategies employed, the study leveraged the unique features of AR to facilitate self-directed learning. By offering interactive and self-controlled learning experiences, AR empowered trainees to take ownership of their learning process. The program incorporated instructional materials and modules that allowed learners to explore and acquire knowledge at their own pace, fostering a sense of autonomy and self-guided learning. The use of AR also enabled real-time feedback and assessment, allowing learners to track their progress and identify areas for improvement [29].

Through the overlay of 3D objects and virtual models onto real-world settings, trainees engaged in simulated scenarios closely resembling authentic ICU environments. This hands-on component of the program enabled learners to apply their knowledge and skills in realistic contexts, promoting an understanding of the subject matter and the development of critical thinking and problem-solving abilities.

This study highlights how AR technology significantly contributes to the success of self-directed learning and hands-on practice. The utilization of AR technology facilitates active engagement, learner-centeredness, and skill development, thereby enhancing the overall effectiveness of critical care nursing education. Moreover, we provide useful insights based on the perspectives of trainers and operators of the platform. The inherent nature of education often necessitates a lower

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number of educators compared to learners. The main strength of our study thus lies in presenting an infrequent perspective of educators, a viewpoint seldom encountered within the large-scale hospital setting.

Comparison With Prior Work

AR technology has been extensively explored in areas related to nursing education [42] such as surgical simulation [43], anatomy education [20], and patient safety education [44]. However, it is worth noting that this study represents the first investigation into the use of AR for replacing a conventional educational program in the use of difficult-to-use devices such as an ECMO machine and mechanical ventilator specifically within the critical care nursing field. By incorporating AR into these fields, this study pioneers the integration of innovative approaches in nursing education.

Limitations

This study, being characteristic of a pilot study to identify and apply new educational methods, has the limitation of a restricted number of participants. In further research, a larger sample size could be recruited to identify factors influencing user acceptability and to enhance usability, leveraging insights for more effective implementation.

Implications

This study highlights the implications of AR in future research and practice. The findings suggest the need for longitudinal studies to assess AR's long-term impact on clinical performance and patient outcomes, and to explore its scalability and cost-effectiveness compared to traditional training. Practically, the results of our study indicate that institutions adopting AR should invest in technical support and training and consider integrating AR as a supplementary tool in curricula for a blended learning approach.

Conclusions

This study provides insights on the development, launch, and operation of an AR-based medical educational program. The study suggests that an AR-based educational program can be an alternative to compensate for insufficient resources for conventional critical care nursing education. Further research can be conducted to compare the effectiveness and feasibility of this program with other AR-based educational programs and traditional nursing educational programs.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
All response results for the System Usability Scale and survey based on the Technology Acceptance Model.
[DOCX File , 16 KB - games_v12i1e54188_app1.docx]

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Abbreviations

AR: augmented reality
ECMO: extracorporeal membrane oxygenation
ICU: intensive care unit
IU: intention to use
PE: perceived enjoyment
PEU: perceived ease of use
PU: perceived usefulness
SUS: System Usability Scale
TAM: Technology Acceptance Model
VR: virtual reality

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Exploring the Design of Upper Limb Strength Training Through High-Intensity Interval Training Combined With Exergaming: Usability Study

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Abstract

Background: High-intensity interval training (HIIT) has become a popular exercise strategy in modern society, with the Tabata training method being the most popular. In the past, these training methods were mostly done without equipment, but incorporating exergaming into the training may provide a new option for muscle training.

Objectives: The aim of this study was to explore the differences in upper limb muscle activation using an HIIT program combined with exergaming.

Methods: A total of 15 healthy male participants were recruited for the study, and the differences in muscle activation were compared between push-ups and exergaming (Nintendo Switch Ring Fit Adventure with the Ring-Con accessory) during HIIT. Prior to the tests, participants underwent pretests, including maximal voluntary contractions of various muscle groups, maximal push-up tests, and maximal movement tests using the exergaming device. The push-up and exergaming tests were conducted on separate days to avoid interference, with a warm-up period of 5 minutes on a treadmill before testing. Muscle activation in the lateral and anterior portions of the deltoid muscle, the sternal and clavicular heads of the pectoralis major muscle, and the latissimus dorsi muscle were measured during the maximal voluntary contractions and single-round tests for each exercise mode. A repeated measures ANOVA was used to assess the variations in muscle activation observed across the 2 distinct modes of exercise, specifically push-ups and exergaming.

Results: In exergaming, the number of repetitions for push-ups was significantly fewer than for single-site exercises across both exhaustive (mean 23.13, SD 6.36 vs mean 55.67, SD 17.83; P=.001; effect size [ES]: 2.43) and single-round (mean 21.93, SD 7.67 vs mean 92.40, SD 20.47; P=.001; ES: 4.56) training. Heart rate differences were not significant (all P>.05), yet exergaming led to better muscle activation in specific muscle groups, particularly the right anterior deltoid (mean 48.00%, SD 7.66% vs mean 32.84%, SD 10.27%; P=.001; ES: 1.67) and right pectoralis major (sternal head: mean 38.99%, SD 9.98% vs mean 26.90%, SD 12.97%; P=.001; ES: 1.04; clavicular head: mean 43.54%, SD 9.59% vs mean 30.09%, SD 11.59%; P=.002; ES: 1.26) during exhaustive training. In single-round training, similar patterns were observed with the anterior deltoid (mean 51.37%, SD 11.76% vs mean 35.47%, SD 12.72%; P=.002; ES: 1.30) and pectoralis major (sternal head: mean 53.27%, SD 10.79% vs mean 31.56%, SD 16.92%; P=.001; ES: 1.53; clavicular head: mean 53.75%, SD 13.01% vs mean 37.95%, SD 14.67%; P=.006; ES: 1.14). These results suggest that exergaming may be more effective for targeted muscle activation.

Conclusions: In conclusion, HIIT can increase muscle activation in the upper extremities and can be incorporated into exergaming strategies to provide a fun and engaging way to exercise.

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KEYWORDS

muscle; electromyography; healthy; home training; exercise

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Introduction

In recent years, motion-based video games have made substantial contributions to both medical education and sports training [1]. They have shown notable effects in the rehabilitation or training of upper limbs [2-4]. The enjoyment derived from gaming can enhance participants' motivation, and when combined with specific game design, it becomes one of the hot topics in research. Compared to longer-duration, moderate-intensity exercise, the strategy of high-intensity interval training (HIIT) [5] has become the mainstream exercise approach in modern society. The most popular approach is the Tabata training method, which involves performing 8 cycles of 20 seconds of all-out exercise, interspersed with 10 seconds of complete rest, for a total exercise time of 240 seconds [6]. Results have shown significant improvements in aerobic power [7], fat oxidation [8], and muscular endurance [9]. It can be observed that the HIIT strategy not only shortens exercise participation time but also has positive effects on the body. Tabata exercises, apart from running, also include various forms of bodyweight exercises, such as push-ups, squats, and burpees [10]. Among these, push-ups are the most used bodyweight exercise in Tabata training. In a study on muscle activation for strength training, Alizadeh et al [11] investigated the muscle activation patterns of push-ups and sit-ups, measuring the activation of the anterior and lateral portions of the deltoid muscle, as well as the sternal and clavicular heads of the pectoralis major muscle. The results showed variations in muscle activation levels despite the similarity in the exercises, highlighting differences in muscle engagement across different parts of the body. Another study by Putra et al [12] explored the muscle activation levels in the upper limbs during a boxing game while in standing and sitting positions in virtual reality gaming. The study found significant differences in the activation of the upper trapezius muscle during uppercut punches, whereas no differences were observed in straight and hook punches. Combining the findings of these 2 studies, it is evident that different exercises lead to varying levels of muscle activation in different muscle groups.

Push-ups, historically used to assess upper body strength, are frequently incorporated into HIIT sessions. This exercise primarily targets the deltoid, pectoralis major, and latissimus dorsi muscles. Similarly, virtual reality gaming offers training modes specifically designed to target these muscle groups. In summary, the research highlights the diverse muscle activation patterns associated with different exercises. Push-ups, a fundamental bodyweight exercise, have been traditionally used to assess upper body strength and are a common component of HIIT workouts, effectively engaging the deltoid, pectoralis major, and latissimus dorsi muscles. Additionally, virtual reality gaming provides tailored training modes focusing on these specific muscle groups. For individuals engaged in recreational physical activities, these conventional exercise methods might be perceived as monotonous due to their limited variation, potentially leading to reduced adherence to training. This lack of variety could negatively impact exercise adherence, as the "lack of enjoyment" is frequently cited as a common barrier to regular physical activity [13].

In studies on the application of HIIT in strength training, the focus has been on investigating the rest intervals between exercises [14] and movement speed [15]. Tomoo et al [14] examined the effects of long and short rest intervals between sets and found that shorter rest intervals led to higher muscle activation levels at the same exercise intensity. In contrast, Dora et al [15] found that faster movement speed resulted in higher muscle activation levels. Taken together, these studies suggest that shorter rest intervals and faster movement speed lead to greater muscle activation. Previous literature has also shown that shorter rest intervals can improve muscle adaptations during resistance training [16,17]. However, in upper body exercise design, push-ups are commonly included as one of the training movements and are frequently used to assess upper body muscle strength and endurance [18].

Exergaming have been used for exercise training for many years and have contributed to improving exercise participation [19]. Related exergaming devices includes Xbox 360, Nintendo Wii, Nintendo Switch, and Sony PlayStation 2. Through exergaming, aerobic capacity, agility, muscle strength, muscle endurance, and coordination can be improved [20]. Regarding muscle strength training, Willaert et al [21] showed that muscle activation can be improved by more than 40%. Although the level of activation is relatively low, this study aims to design a training program with the combination of HIIT and body-sensing video games to enhance the quality and effectiveness of the training. There are relatively few studies on the use of HIIT for muscle strength training, and the level of muscle activation using exergaming combined with HIIT has not been clarified. The aim of this study was to explore the differences in upper limb muscle activation using an HIIT program combined with exergaming.

Methods

Study Participants

In this study, we recruited 15 healthy male participants. They had an average age of 24.4 (SD 10.4) years, stood at an average height of 174 cm with a minimal variance of 0.05 cm, and weighed an average of 71.9 (SD 13) kg. Their BMI averaged at 23.5 (SD 3.57) kg/m^2. All participants maintained a regular exercise routine, engaging in physical activity 3 times per week over the past year, and had experience in performing push-ups correctly. They also completed the Physical Activity Readiness Questionnaire [22] and confirmed that they had no history of upper or lower limb skeletal muscle injury or major injury. Participants were instructed to avoid vigorous activity and the intake of caffeine or supplements that enhance muscle performance for 24 hours prior to the experiment. Before the study began, all participants provided their personal information and medical history and filled out the health questionnaires and informed consent form. Additionally, the data were proofread to ensure accuracy and readability.

Ethical Considerations

The human research ethics committee of the local university approved this study, which was also approved by the human research ethics committee of the National Cheng Kung

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University, Taiwan (approval NCKU HREC-E-112-419-2). Users volunteered for this study and agreed to participate by signing an informed consent form. The research ensures the issues of privacy and confidentiality by assigning participants with numerical identifiers during the experiment to safeguard the confidentiality of their personal information. In terms of compensation, participants were volunteers and there was no remuneration involved.

Experimental Design

Overview

This study used a randomized, crossover, and repeated measures experimental design to compare the differences in muscle activation between push-up exercise and a Nintendo Switch Ring Fit Adventure exercise. Prior to the tests, participants underwent pretests, which included maximal voluntary contractions (MVCs) for each muscle group, maximal push-up tests, and maximal exercise tests for each part of the Nintendo Switch Ring Fit Adventure exercise. The 2 types of tests were conducted with a minimum interval of 3 days to avoid interference. Prior to each test, a 5-minute warm-up on the treadmill at a speed of 2 m/s was recommended. During the tests, muscle activation in various muscle groups was observed and measured, including the lateral and anterior portions of the deltoid muscle, the sternal and clavicular heads of the pectoralis major muscle, and the latissimus dorsi muscle, which were referenced and modified from previous studies by van den Tillaar [23], Alizadeh et al [11], and Maeo et al [24] (Figure 1). The aim was to explore the differences in upper limb muscle activation using an HIIT program combined with exergaming.

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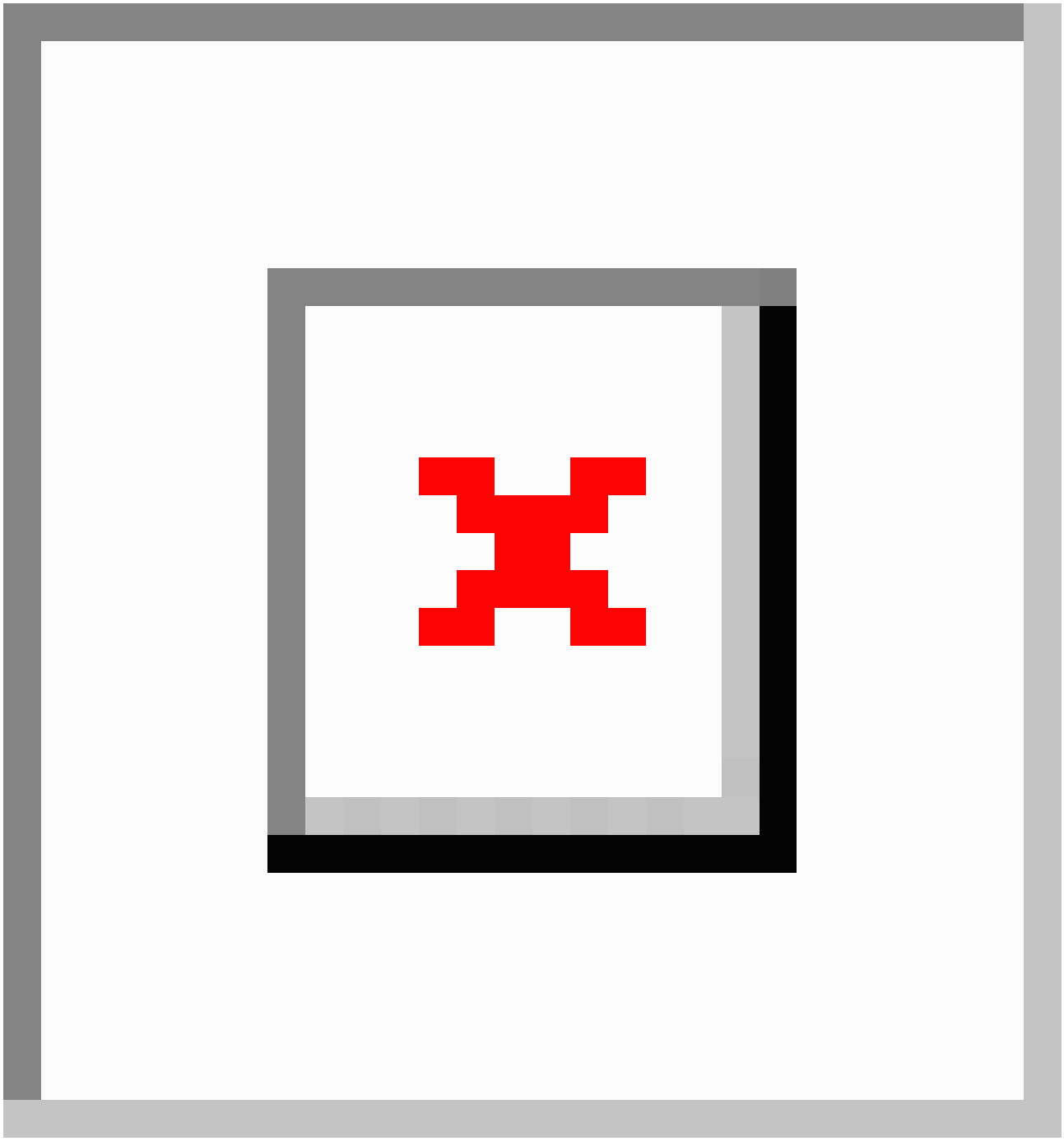
Figure 1. Experimental procedure diagram.



Exergaming

The exergaming selected for this study was Nintendo Switch Ring Fit Adventure, which combines exercise, adventure, and entertainment, allowing players to enjoy both physical workouts and gaming fun simultaneously. The game features an intuitive and user-friendly interface, suitable for players of all ages. It comes with a specialized fitness ring device (Ring-Con), an intelligent accessory that connects to the Nintendo Switch console. Through this ring, players can engage in various physical activities such as weightlifting, yoga, and aerobic exercises. The fitness ring sensor accurately captures players' movements and incorporates them into the gameplay. The game content involves unlocking levels and participating in fitness competitions through real-life physical movements. It offers a variety of fitness activities, each targeting different muscle groups, while also providing enjoyable gaming challenges. The trained muscle groups were the pectoralis major, deltoid, and latissimus dorsi muscles. The testing consisted of 2 modes: (1) maximum repetition test and (2) single-round test. The maximum repetition test was conducted using the extreme challenge mode. Participants were instructed to follow the game's pace of 60 beats per minute as closely as possible and maintain proper posture during each muscle group's testing to avoid compensation from other muscles. The single-round test was conducted using the challenge mode. Participants were instructed to perform repetitive actions as quickly as possible for 20 seconds (Figure 2).

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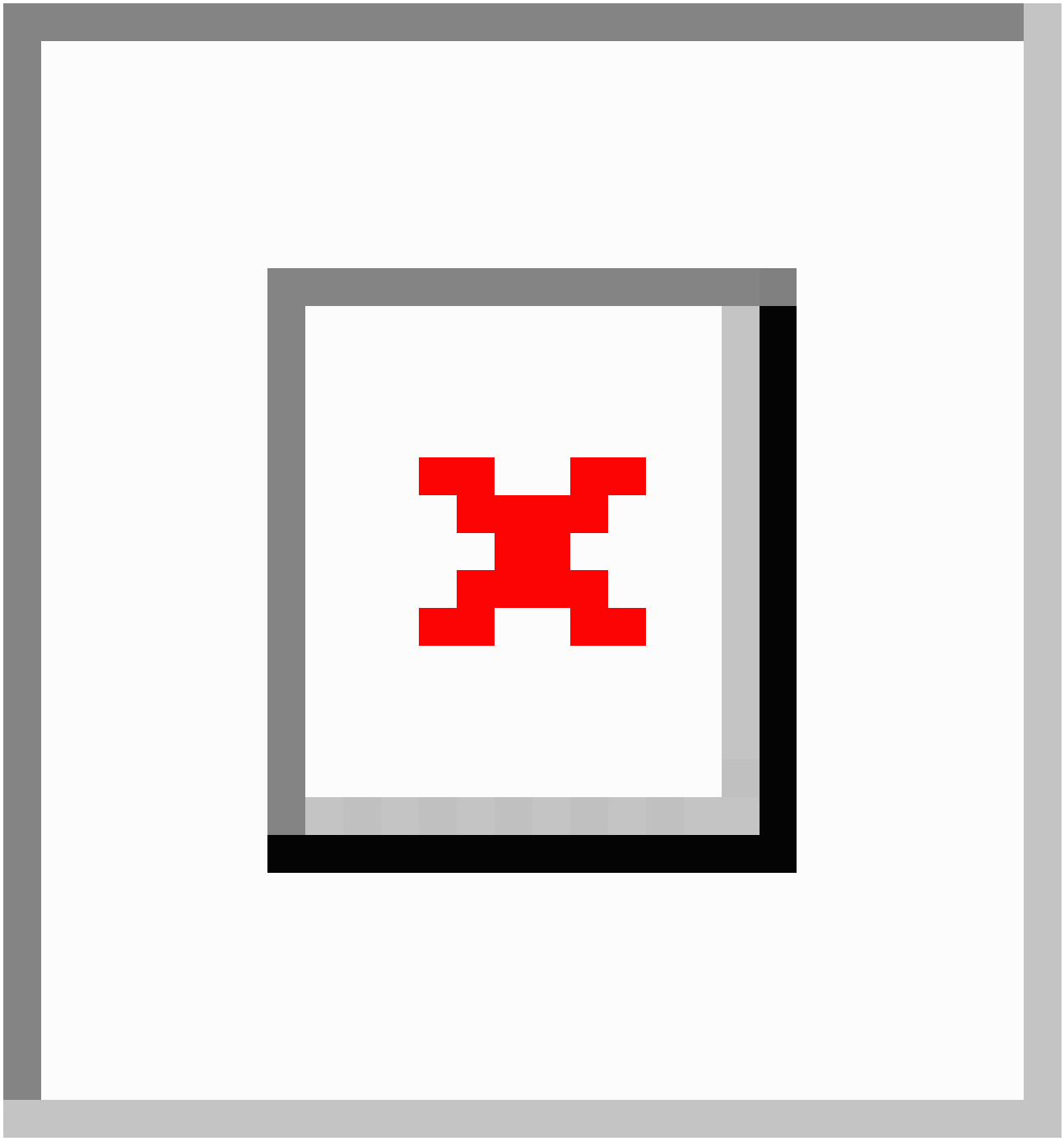
Figure 2. Exercise training and exergaming model: (A) pectoralis major, (B) deltoid, and (C) latissimus dorsi.



Push-Up Tests

The push-up tests included 2 types of tests: (1) maximum repetition test and (2) single-round test. The maximum repetition test was based on the testing method described by Eckel et al [25]. Participants were guided to execute the test while in sync with a metronome set at 60 beats per minute, ensuring each movement, 1 second downward and 1 second upward, matched the rhythm precisely. This cadence was chosen to align with the pace of exercises conducted in the Nintendo Switch Ring Fit Adventure exercise, facilitating a consistent and controlled environment for comparison. During the test, the distance between the hands at the sternal notch level was measured and must be the same as the distance used in the single-round test. The elbow must be bent at 90° and the elbow must be fully extended when straightened. The single-round test was designed to match the duration of a single round of the Nintendo Switch Ring Fit Adventure exercise and involved performing the maximum number of squats possible within 20 seconds.

Heart Rate Tests

Heart rate measurements were taken using the iHeart heart rate sensor (Hexin) during push-up tests and exergaming sessions. The heart rate sensor was worn directly below the sternum and in direct contact with the skin, ensuring a comfortable fit that remained secure without slipping, even during exercise. After being fitted, the sensor was connected to the Polar Beat app (Polar Electro) for monitoring and recording purposes.

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Electromyography

MVC Testing

In MVC testing, each muscle group underwent an isometric MVC prior to the test. After a running warm-up and a 3-minute rest period, the MVC test was performed according to the movements described by Konrad [26]. The test consisted of 3 attempts, each lasting 5 seconds with 1-minute rest intervals in between, and the participant was encouraged to exert maximum effort during each attempt. If the peak MVC values differed by more than 5%, additional testing was performed. The test procedures for each muscle group were as follows. (1) Deltoid: the participants were seated with their backs supported, and their arms were abducted to a position where they formed a 90° angle with the trunk, maintaining a horizontal plane. A rope, fixed to the arm, was then pulled upward to measure the force exerted. (2) Pectoralis major: the participants performed the test in a lying position with the elbows extended and flexed at 90°, holding onto a long bar with a fixed rope attached to each side of the bar and pulling upward as hard as possible to measure the force exerted. (3) Latissimus dorsi: the participants performed the test in a seated position, simulating the movement of a pull-up. The axis joint was flexed and abducted at 90°, and the rope was pulled downward the measure the force exerted, as shown in Figure 3. After the MVC testing, electromyography (EMG) electrodes were placed on the skin over the belly of the tested muscles for subsequent signal recording and analysis.

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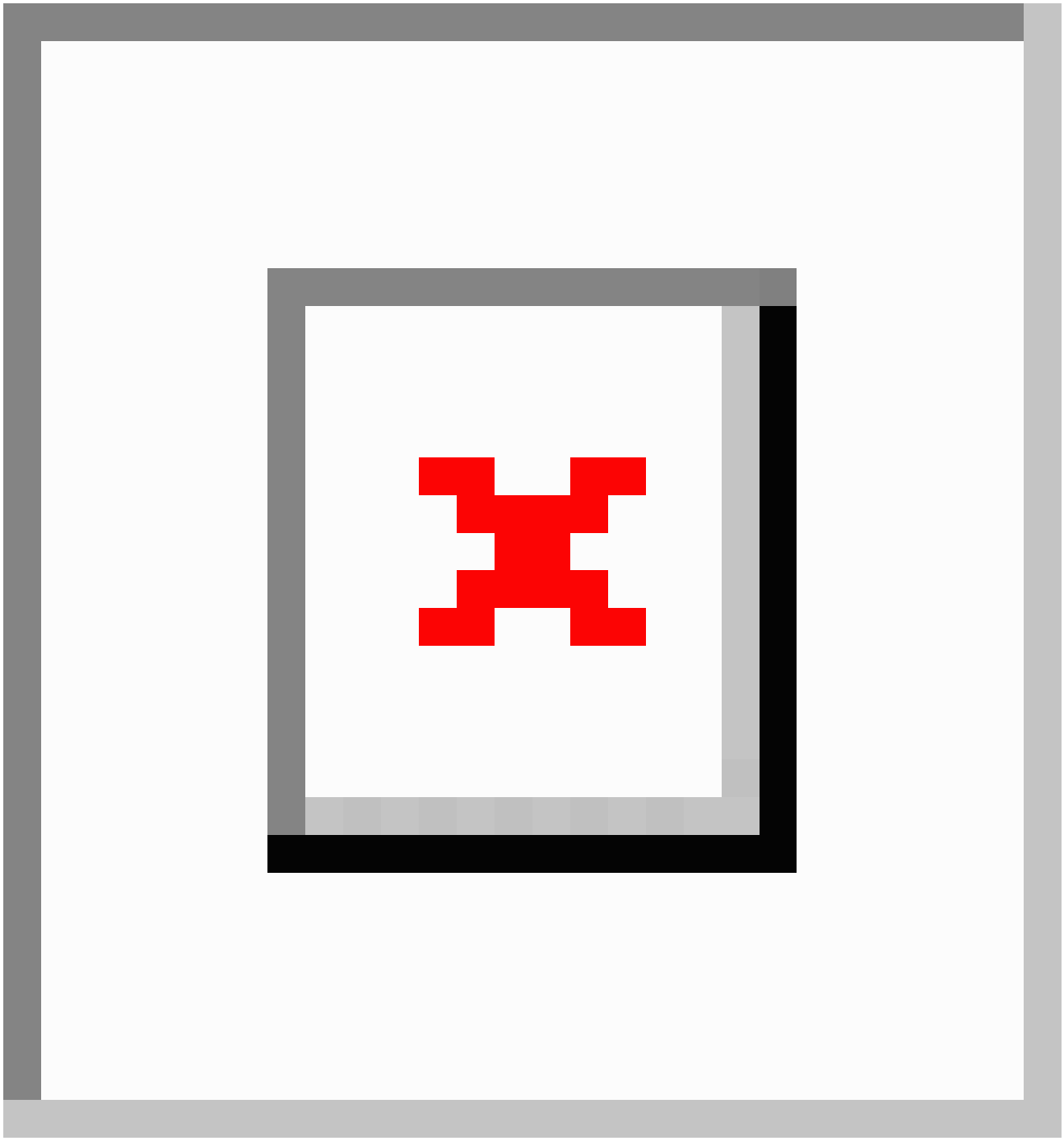
Figure 3. (A) Standardized illustrations for the MVC action of each muscle. (B) MVC sensor placement for each muscle. MVC: maximal voluntary contraction.



EMG Measurement and Analysis

The Trigno TM wireless foundation system (Delsys-EMGworks) was used for data collection in this study, measuring the anterior and lateral portions of the deltoid muscle, the sternal and clavicular heads of the pectoralis major muscle, and the latissimus dorsi muscle [11,23,24]. The system was configured with a sampling rate set at 2000 Hz per channel, tailored to the desired sample rate specifications. For the processing of EMG data, we used the EMGwork analysis software, which included steps of filtering and smoothing the EMG signals to ensure clarity and accuracy. The filtering process used a band-pass filter with a low-frequency cutoff at 20 Hz and a high-frequency cutoff at 500 Hz. Following this, the rectified EMG signals underwent further refinement using the root mean square method, which facilitated a detailed analysis of the signal's magnitude. During the MVC test, we determined the highest EMG amplitude recorded for each muscle group, referred to as EMGmax. The data processing method in exergaming was the same as the above, and the degree of muscle activation was calculated based on the values obtained from the standardized action test, expressed as a percentage of EMGmax.

Statistical Analysis

Data processing and analysis were performed using SPSS for Windows (version 20.0; IBM Corp). The data were presented as mean and SD. To investigate the variance in motion and heart rate across different movements derived from the 2 exercise

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models—strength endurance and single round—we used a repeated measures ANOVA. Furthermore, to assess the discrepancies in muscle activation elicited by the 2 distinct types of exercises, namely push-ups and exergaming, a paired-samples 2-tailed *t* test was used. Cohen *d* for effect size (ES) was calculated by the G*Power 3.1 software program (Heinrich-Heine-Universität), where the ESs of 0.2, 0.5, and 0.8 were considered small, medium, and large, respectively. Statistical significance was set as $P<.05$.

Results

Study Participants

For this study, a total of 15 male participants from the community were recruited. These participants were generally in good health. However, finding healthy female participants capable of performing push-ups was challenging due to their limited availability. Therefore, this study predominantly concentrated on male participants.

Comparing Strength, Performance, and Heart Rate: Push-Ups Versus Exergaming

The results showed that regardless of the exhaustive or single-round mode, the number of single-site repetitions in exergaming was significantly higher than that of push-ups (exhaustive: deltoid, mean 55.67, SD17.83; pectoralis major, mean 52.53, SD 13.61; and latissimus dorsi, mean 82.30, SD 20.82 vs push-up, 23.13, SD 6.36; $P=.001$; ES: 2.43, 2.77, and 3.84, respectively; single round: deltoid, mean 92.40, SD 20.47; pectoralis major, mean 104.27, SD 13.48; and latissimus dorsi, mean 97.33, SD 16.77 vs push-ups mean 21.93, SD 7.67; $P=.001$; ES: 4.56, 7.51, and 5.78, respectively). However, there was no difference in heart rate between the 2 modes (all $P>.05$). Taken together, these results suggest that both whole-body push-ups and single-site exergaming training can increase heart rate and can be used to train cardiorespiratory fitness (Table 1).

Table . Comparison of strength endurance, single-round performance, and heart rate between push-ups and exergaming.

Model and motion		Repetitions, mean (SD)	*F* test (*df*)	*P* value	Heart rate (bpm[a]), mean (SD)	*F* test (*df*)	*P* value
Strength endurance test			50.83	.001		3.92	.07
	Push-up	23.13 (06.36)			101.27 (14.79)		
	Exergaming, deltoid	55.67 (17.83)			96.80 (21.29)		
	Exergaming, pectoralis major	52.53 (13.61)			98.06 (18.76)		
	Exergaming, latissimus dorsi	82.30 (20.82)			91.40 (14.23)		
Single-round performance (20 s)			143.27	.001		1.56	.21
	Push-up	21.93 (07.67)			100.33 (16.32)		
	Exergaming, deltoid	92.40 (20.47)			104.80 (14.63)		
	Exergaming, pectoralis major	104.27 (13.48)			93.67 (17.11)		
	Exergaming, latissimus dorsi	97.33 (16.77)			104.13 (16.05)		

[a]bpm: beats per minute.

Strength Endurance: Push-Ups Versus Exergaming

According to the statistical results, in the exhaustive mode, the activation levels of the right anterior deltoid (mean 48.00%, SD 7.66% vs mean 32.84%, SD 10.27%; $P=.001$; ES: 1.67), right pectoralis major—sternal head (mean 38.99%, SD 9.98% vs mean 26.90%, SD 12.97%; $P=.001$; ES: 1.04), and right pectoralis major—clavicular head (mean 43.54%, SD 9.59% vs mean 30.09%, SD 11.59%; $P=.002$; ES:1.26) were significantly greater in the exergaming group than in the push-up group. Thus, these results suggest that exergaming have a better training effect on specific muscle groups (Table 2).

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Table . Comparison of muscle activation between traditional push-ups and exergaming in the strength endurance test.

Muscle	Push-up activation (%), mean (SD)	Exergaming activation (%), mean (SD)	*t* test (*df*)	*P* value
Anterior deltoid	32.84 (10.27)	48.00 (7.66)	−4.096	.001
Lateral deltoid	37.36 (13.79)	44.56 (8.82)	−1.737	.10
Pectoralis major, sternal head	26.90 (12.97)	38.99 (9.98)	−4.358	.001
Pectoralis major, clavicular head	30.09 (11.59)	43.54 (9.59)	−3.784	.002
Latissimus dorsi	35.43 (10.39)	34.01 (18.05)	0.329	.75

Single-Round Test: Push-Ups Versus Exergaming

Based on the statistical analysis, in the single-round mode, the activation levels of the right anterior deltoid (mean 51.37%, SD 11.76% vs mean 35.47%, SD 12.72%; *P*=.002; ES: 1.30), right lateral deltoid (mean 52.08%, SD 10.79% vs mean 43.86%, SD 10.48%; *P*=.046; ES: 0.77), right pectoralis major–sternum head (mean 53.27%, SD 10.79% vs mean 31.56%, SD 16.92%; *P*=.001; ES: 1.53), and right pectoralis major–clavicle head (mean 53.75%, SD 13.01% vs mean 37.95%, SD 14.67%; *P*=.006; ES: 1.14) were significantly greater in the exergaming group than the push-up group. These results suggest that the exergaming designed as an HIIT exercise targeting a specific muscle group resulted in significantly higher muscle activation compared to push-ups (Table 3).

Table . Comparison of muscle activation between traditional push-ups and exergaming in the single-round test.

Muscle	Push-up activation (%), mean (SD)	Exergaming activation (%), mean (SD)	*t* test (*df*)	*P* value
Anterior deltoid	35.47 (12.72)	51.37 (11.76)	−3.705	.002
Lateral deltoid	43.86 (10.48)	52.08 (10.79)	−2.190	.046
Pectoralis major, sternal head	31.56 (16.92)	53.27 (10.79)	−4.266	.001
Pectoralis major, clavicular head	37.95 (14.67)	53.75 (13.01)	−3.236	.006
Latissimus dorsi	41.49 (11.00)	38.17 (16.87)	0.645	.529

Discussion

Principal Findings

The results indicated that, in terms of the number of repetitions performed, both the strength endurance and single-round tests showed significantly higher execution rates for the exergaming training mode compared to push-ups. However, there were no significant differences in heart rate between the 2 modes. Regarding muscle activation, in the strength endurance test, exergaming exhibited significantly higher activation levels than push-ups in the anterior deltoid, pectoralis major–sternal head, and pectoralis major–clavicular head muscles. In the single-round test, exergaming demonstrated significantly higher activation levels than push-ups in the anterior deltoid, lateral deltoid, pectoralis major–sternal head, and pectoralis major–clavicular head muscles.

Heart Rate Response in Exergaming

Interestingly, the study did not observe significant differences in heart rate between the exergaming and push-up groups. This result contrasts with previous studies indicating that exergaming can lead to higher heart rates due to the immersive and stimulating nature of video game–based exercises [27,28]. The lack of significant heart rate differences could be attributed to the individual variability in cardiovascular responses and the adaptability of participants to the exergaming interface. HIIT has been shown to be an effective way to improve cardiovascular fitness and overall health [7]. Heart rate is an important factor in both exergaming and HIIT. Monitoring heart rate can help individuals ensure that they are working at an appropriate intensity level to achieve their fitness goals. In HIIT, heart rate can be used to guide the high-intensity intervals and rest periods to optimize the workout's effectiveness [29]. Overall, the use of exergaming and HIIT can provide a fun and effective way to improve physical fitness and health, with heart rate monitoring serving as an important tool to help individuals achieve their goals.

Another potential explanation for these results is that the use of exergaming may increase motivation and engagement in physical activity, leading to greater adherence to exercise programs [30]. This is especially important given the high rates of sedentary behavior and physical inactivity in modern society. Exergaming may provide a fun and enjoyable way to engage in physical activity, potentially leading to increased frequency and duration of exercise sessions [31,32]. This is particularly relevant for individuals who may struggle to engage in more traditional forms of exercise due to boredom, lack of motivation, or physical limitations.

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EMG Response in Exergaming

This study investigated the effects of HIIT on muscle activation in the upper extremities. The results suggest that exergaming may be a more effective training method for upper extremity muscle activation compared to push-up exercises. The reason for this difference may be due to the specific muscles activated during exergaming, as the Nintendo Switch Ring-Con requires movements that engage the lateral and anterior parts of the deltoid muscle, pectoralis major muscle, and latissimus dorsi muscle. These findings suggest that exergaming can be a viable option for those looking to improve upper extremity muscle activation.

In interpreting the results, the study found that the exergaming training mode exhibited superior performance in terms of the number of repetitions compared to traditional push-ups, both in the strength endurance test and the single-round test. This finding aligns with previous research indicating the effectiveness of exergaming in enhancing endurance and strength capacities [33,34]. The higher execution rates in the exergaming group suggest that this interactive gaming approach offers a more engaging and motivating environment, encouraging participants to perform better and prolong their workout sessions compared to conventional push-ups. EMG can reflect the response of muscles during strength training. Alizadeh et al [11] investigated 2 common strength training exercises, push-ups and sit-ups, and measured muscle activation in the major muscle groups involved, such as the lateral and anterior portions of the deltoid and the sternal and clavicular heads of the pectoralis major. The results showed that even with the same exercise, different muscle groups were activated to varying degrees, indicating the importance of focusing on specific muscle group activation for muscle training. Compared to traditional strength training, there has been relatively little research on exergaming, but Putra et al [12] investigated the activation levels of upper limb muscles during a punching game while in standing and sitting positions. The results showed significant differences in the activation of the upper trapezius muscle during the execution of an uppercut punch, but not for straight or hook punches, indicating that the fixedness of the movements also affects the activation levels of different muscle groups in exergaming. Taken together, these studies suggest that different movements can affect muscle activation levels in different muscle groups. Therefore, choosing appropriate exercises and training modes is important for muscle strength training. Push-ups are a common exercise that mainly trains muscle groups, such as the deltoid, pectoralis major, and latissimus dorsi muscles, and are commonly used in HIIT. Training modes in exergaming are also available for these muscle groups, providing more diverse options for muscle training. Overall, these research results indicate the importance of understanding the relationship between movements and muscle groups.

Regarding muscle activation patterns, the exergaming group demonstrated significantly higher activation levels in specific muscles compared to traditional push-ups. In the strength endurance test, the anterior deltoid, pectoralis major–sternal head, and pectoralis major–clavicular head muscles exhibited increased activation during exergaming sessions. These findings corroborate with prior studies highlighting the targeted muscle engagement achieved through exergaming interventions [21]. The single-round test further showed elevated muscle activation in the anterior deltoid, lateral deltoid, pectoralis major–sternal head, and pectoralis major–clavicular head muscles during exergaming activities. This specific muscle activation pattern emphasizes the comprehensive nature of exergaming exercises, engaging various upper body muscles simultaneously [35]. One potential explanation for these results is that the Ring-Con is a novel type of resistance training that provides a more targeted and isolated workout for specific muscle groups [36]. This may allow individuals to activate and recruit more muscle fibers, leading to increased muscle activation compared to more traditional exercises such as push-ups. Additionally, the Ring-Con provides a unique form of resistance that can be adjusted to individual fitness levels, potentially allowing for greater customization and variety in workout routines [12].

Conclusions

In conclusion, this study demonstrated that exergaming may be a more effective strategy for upper extremity muscle activation compared to push-up exercises during HIIT. The specific movements required by the Nintendo Switch Ring-Con may activate the lateral and anterior parts of the deltoid muscle, pectoralis major muscle, and latissimus dorsi muscle more effectively. Furthermore, the HIIT protocol used in this study provides a time-efficient method for strength training. Incorporating exergaming into an HIIT program may provide a more engaging and effective strategy for improving upper extremity muscle activation. Further research is needed to investigate the long-term effects of exergaming on upper extremity muscle activation and strength.

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Authors' Contributions

SCL carried out the laboratory experiments, analyzed the data, interpreted the results, prepared the figures and tables, and prepared the manuscript. JYL, HLF, YY and CCF assisted in the data collection and the discussion of the literature. THH designed the study, supervised the experimental procedure, and reviewed the entire preparation of the manuscript.

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Conflicts of Interest

None declared.

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Abbreviations

EMG: electromyography
ES: effect size
HIIT: high-intensity interval training
MVC: maximal voluntary contraction

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Effects of a Serious Game for Adolescent Mental Health on Cognitive Vulnerability: Pilot Usability Study

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Abstract

Background: Adolescent mental health is of utmost importance. E-mental health interventions, and serious games in particular, are appealing to adolescents and can have beneficial effects on their mental health. A serious game aimed at improving cognitive vulnerability (ie, beliefs or attitudes), which can predispose an individual to mental health problems, can contribute to the prevention of these problems in adolescents.

Objective: This study aimed to assess the feasibility of the prototype of a serious game called "Silver."

Methods: The prototype of the serious game was developed using a user-centered participatory design. The prototype of Silver focused on 1 aspect of a serious game for improving cognitive vulnerability in adolescents, that is, the recognition and identification of cognitive distortions. Through the game, players were required to identify and classify the character's thoughts as helpful or unhelpful. Upon successful advancement to the next level, the task becomes more challenging, as players must also identify specific types of cognitive distortions. A pre- and posttest uncontrolled design was used to evaluate the game, with a 1-week intervention phase in which participants were asked to play the game. Participants aged 12-16 years were recruited in schools. The outcomes of interest were the recognition of cognitive distortions and presence of participants' cognitive distortions. The game was also evaluated on its effects, content, and usefulness.

Results: A total of 630 adolescents played Silver and completed the assessments. Adolescents were significantly better at recognizing cognitive distortions at the pretest (mean 13.09, SD 4.08) compared to the posttest (mean 13.82, SD 5.09; $t_{629}=-4.00$, $P<.001$). Furthermore, their cognitive distortions decreased significantly at the posttest (mean 38.73, SD 12.79) compared to the pretest (mean 41.43, SD 10.90; $t_{629}=7.98$, $P<.001$). Participants also indicated that the game helped them recognize cognitive distortions. Many participants considered the game appealing (294/610, 48.2%) but boring (317/610, 52%) and preferred a more comprehensive game (299/610, 49%).

Conclusions: Findings from this study suggest that a serious game may be an effective tool for improving cognitive vulnerability in adolescents. The development of such a serious game, based on the prototype, is recommended. It may be an important and innovative tool for the universal prevention of mental health problems in adolescents. Future research on the effects of the game is warranted.

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KEYWORDS

e-health; cognitive psychology; cognitive distortion; cognitive vulnerability; digital health; serious games; adolescent mental health; prototype; adolescent; prevention; eHealth

Introduction

Mental illness is one of the biggest health burdens worldwide, and adolescent mental health is a particular global concern [1]. According to the United Nations' recently published report on children's mental health, approximately 1 in 7 adolescents aged between 10 and 19 years experience a diagnosed mental disorder globally [2]. Approximately 40% of these disorders are attributable to anxiety and depression [1]. The psychological distress and economic costs due to adolescent mental health problems are enormous. In 2021, the invisible economic cost due to mental health problems in adolescents was estimated at US $387 billion per year globally [2]. Moreover, these mental health problems are important risk factors for self-harm and suicide among adolescents [3,4].

Early access to treatment can improve outcomes, but limited treatment resources result in long waiting lists and

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undertreatment [5]. Society, and health systems in particular, need to cope with the increasingly high demands to reduce costs and prevent self-harm and suicide among adolescents. E-mental health interventions are already being used across health care and may be more accessible, engaging, and acceptable options [6-8]. These can take various forms, such as text-based programs, multimedia and interactive programs, virtual reality–based programs, and serious games [9-12]. Evidence of their beneficial effects is increasingly provided [6,13-15]. Regarding serious games, a recent review concluded that the limited evidence indicates a beneficial effect on reducing mental health problems [11,16-19]. Thus, there is a massive potential for serious games to be a new, emerging treatment modality that is more acceptable and engaging, as it uses game mechanics, especially for adolescents who are major users of computerized games in the present-day digital world. However, more research is needed [11,18,20].

This study therefore aimed at providing further evidence of the beneficial effects of serious games by piloting a prototype ("Silver") developed to counter cognitive characteristics, which are known to increase the vulnerability to common mental health problems such as depression and anxiety [21]. More specifically, the prototype targets adolescents (aged 12-16 years), aiming to gain insight into cognitive distortions (ie, negative, biased thoughts that influence people's interpretation of themselves or the world [22]) and their effect on feelings and behaviors. Cognitive distortions, including all-or-nothing thinking, overgeneralization, or mind reading, can contribute to the development of mental health issues such as depression or anxiety during adolescence [23-25]. Identifying and modifying these distortions and replacing them with more balanced, helpful thoughts—that is, cognitive restructuring—is a common technique used in cognitive behavioral therapy (CBT) [22], which has been demonstrated to prevent mental health issues during this vulnerable development phase [26,27] and improve mental well-being [28]. Given the relationship between cognitive distortions and adolescent mental health, as well as the potential of CBT-based techniques to address these distortions, this study aimed to investigate the specific impact of the prototype on adolescents' cognitive processing. Therefore, the primary hypothesis was that adolescents would improve at recognizing and categorizing helpful and unhelpful thoughts (ie, cognitive distortions) after playing Silver. Furthermore, playing the game was expected to lead to a decline in cognitive distortions. Finally, the usability of Silver was assessed, focusing on the appeal of the game.

Methods

Participants and Recruitment

Participants were aged between 12 and 16 years and had a smartphone or tablet. Participants were excluded if they were not proficient in Dutch. Recruitment took place from August 2017 to October 2017 via schools.

Ethical Considerations

School directors of 8 secondary schools with different curricula across Flanders (ie, the Dutch-speaking region in Belgium) consented to participate in the study. Parents or guardians were informed about the study and given the opportunity to decline their child's participation (opt out). Web-based assent was obtained from the adolescents before the start of the study. Participants did not receive any form of compensation for their involvement in this study. The data were deidentified prior to analysis to safeguard participants' privacy. The study was approved by the Commission for Medical Ethics of the University Hospital Ghent (Belgian registration B670201731975).

Design and Procedure

The prototype was evaluated using a pre- and posttest uncontrolled design with a 1-week intervention phase. Before participants received access to the prototype, they were asked to fill in a web-based questionnaire (pretest). Immediately after completing the questionnaire, they received access to Silver, which they were asked to play daily for 1 week. After 1 week, they were asked to fill in the second web-based questionnaire (posttest).

Intervention

The prototype of the serious game Silver aims to reduce cognitive distortions in adolescents. The prototype is based on a cognitive behavioral framework and focuses on 1 element of mental health improvement, that is, gaining insight into cognitive distortions and their effects on feelings and behaviors. The prototype was designed and developed in a cocreative manner, in which the target users themselves (ie, adolescents aged 12-16 years) were involved, as well as a clinical child psychologist, a child and adolescent psychiatrist, and professional game designers. The design, therefore, was user centered and participatory. The cocreation process was managed by the company that developed the game's prototype.

The game is set up in 3 different worlds inhabited by anthropomorphic animals. Each world has different chapters that can be played. The more a player progresses in the game, the more difficult it becomes. The game always starts with an animal that is stuck in his or her mind and therefore is in a "glitch." The incident preceding the "glitch" is explained through a flashback where the player is shown how this came about (see Figure 1). The events represent difficult situations that are very relatable for adolescents (eg, not getting likes on a social media post). Afterward, the player is shown the character's thoughts. Each time after reading a thought, the player must decide whether it is a helpful or unhelpful thought (ie, cognitive distortion). If the thoughts are correctly recognized, the unhelpful thoughts are fired upon by little robots and the helpful thoughts return to the character's head. When enough helpful thoughts have been collected, the character is released from his or her "glitch" and the chapter is completed. At higher levels, the player is also asked to indicate which type of unhelpful thought it is. At first, 2 types of cognitive distortions are introduced, that is, future thinking and all-or-nothing thinking. Afterward, 1 more type of cognitive distortion is added, that is, mind reading (see Figure 2). Thus, the further you progress through the game, the more difficult it becomes as the thoughts can be categorized into more types of cognitive distortions. In this way, the player learns to gain insight into the different types of cognitive distortions.

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Figure 1. Screenshot of Silver, showing a flashback to the incident before the glitch. “Maar vanochtend stak zijn moeder nog een kakelvers woestijnvosje in zijn lunchbox.” means “But this morning, his mother stuck another brand-new desert fox in his lunch box.”

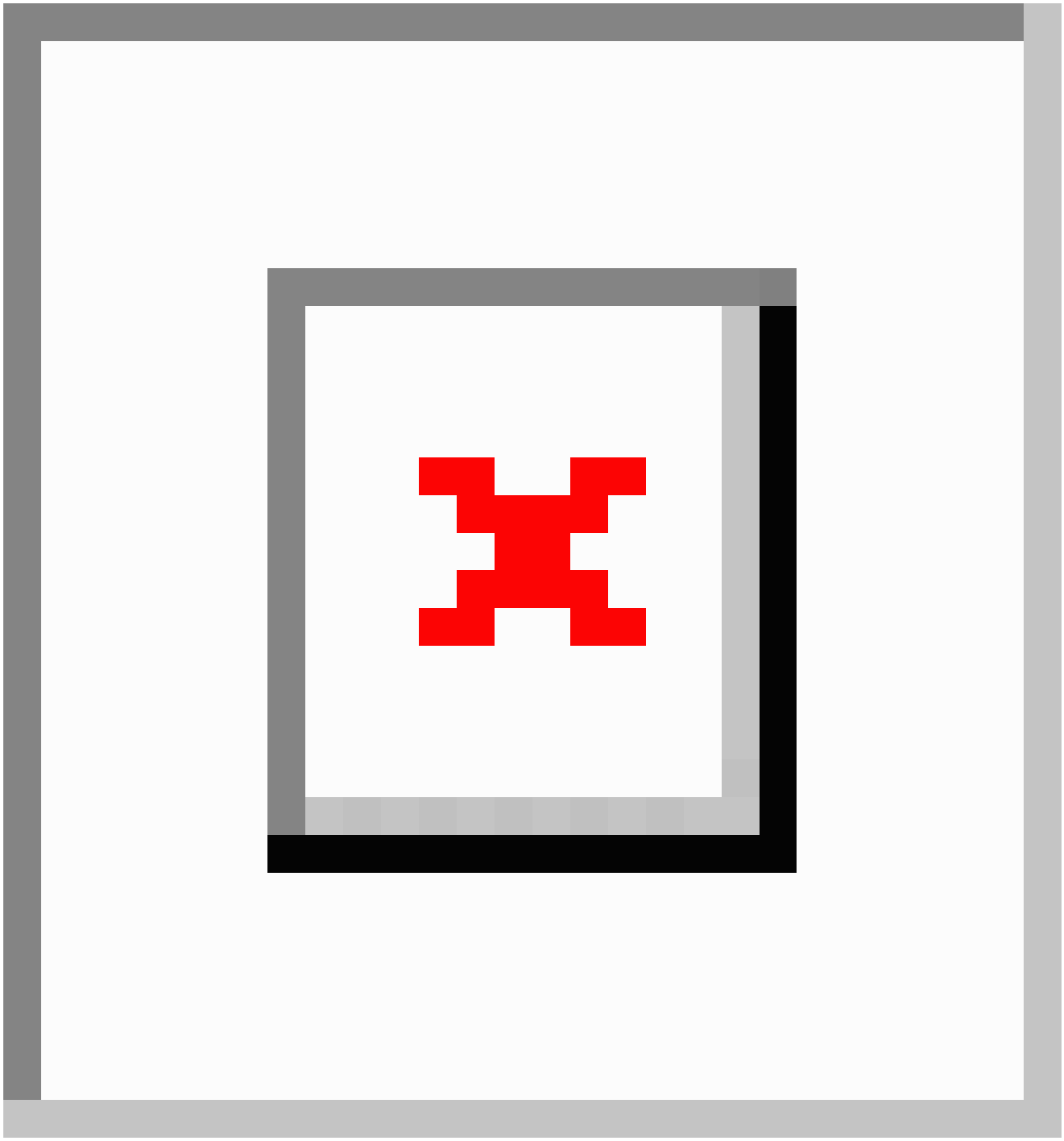

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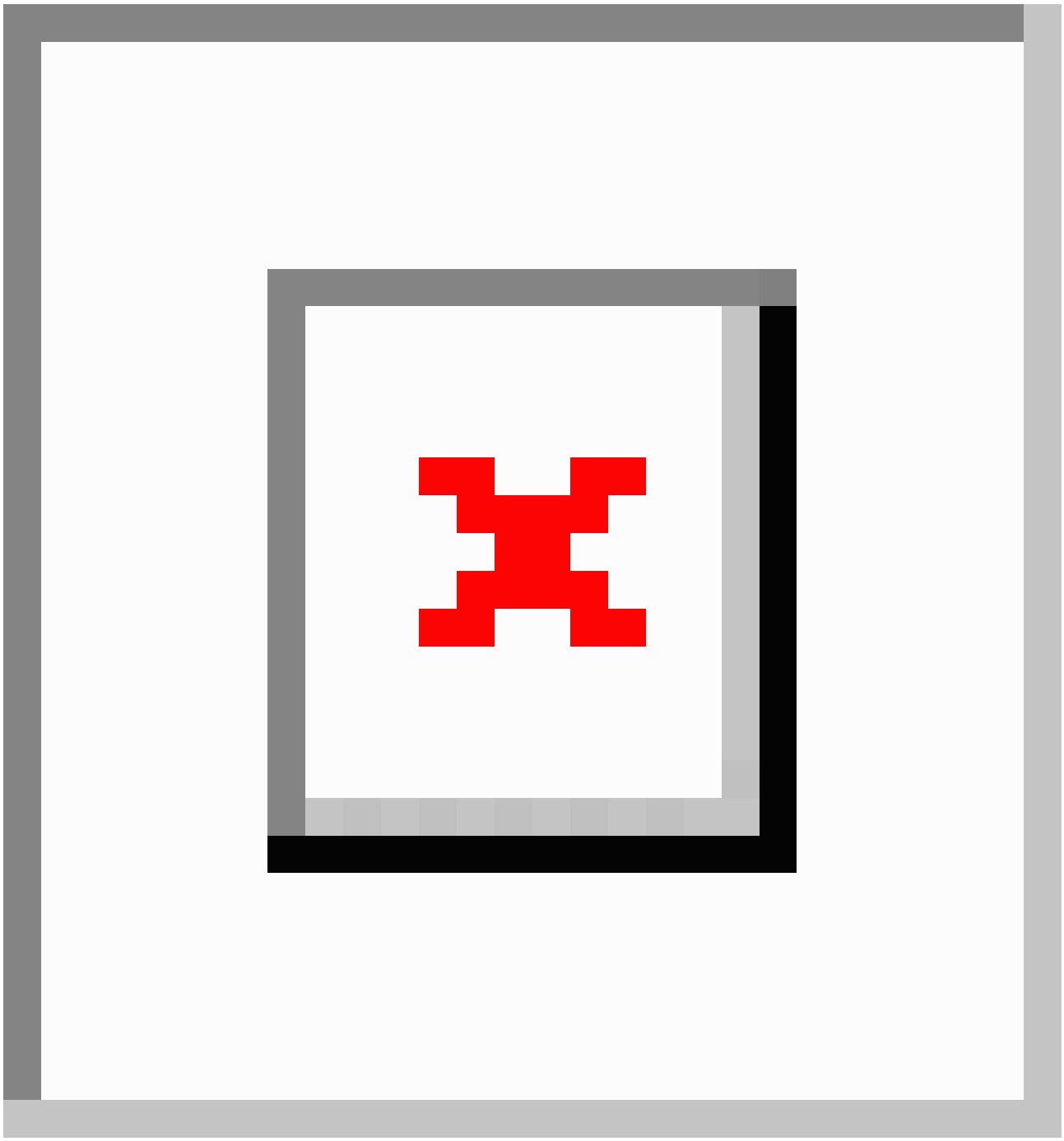
Figure 2. Screenshot of Silver, showing the process of identifying types of cognitive distortions. “Aan tafel zijn ze al zeker met mij aan het lachen.” means “At the table, they are already definitely laughing at me.“; “Helpend” means “Helpful”; “Toekomst” means ”Future”; “Gedachten lezen” means “Read minds”; and “Zwart-wit” means “Black and white.”



Measures

All outcome measures were collected via self-report questionnaires, which were administered on the web.

Demographics

Sociodemographic information (ie, gender, age, and education) was assessed at the pretest. Data on sex (male, female, or other), age (in years), and education (first or second grade and type of curriculum, ie, general secondary education, technical secondary education, secondary education in the arts, and vocational education) were obtained. In addition, participants were asked if they had ever been in therapy for psychological problems.

Media and Game Use

At baseline, data were collected regarding participants’ use of media by asking participants what type of media they used and how often they used it on a 5-point scale (1=“never”; 5=“daily”). Items regarding game use assessed whether they ever played computer or video games and whether they still played them. Furthermore, participants were asked on which devices they played the games and how often they did this on a 5-point scale (1=“never”; 5=“daily”). They also gave an estimate about their knowledge about games, ranging from 1= “no knowledge” to 4=“expert.”

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Primary Outcome Measure: Recognition of Negative and Positive Automatic Thoughts

The primary outcome measure focused on recognizing helpful and unhelpful thoughts. A questionnaire was developed, in which 20 items of the Dysfunctional Attitude Scale, Form A, Dutch translation [29,30] were used. Participants were asked to classify each item as helpful, unhelpful, or "I do not know." Items were scored as true or false. Scores ranged from 0 to 20, with higher scores indicating a better identification of negative and positive automatic thoughts. The internal consistency of the scale in this study was α=.82.

Secondary Outcome Measure: Presence of Cognitive Distortions

The Children's Negative Cognitive Error Questionnaire–Revised [31] is a 16-item self-report questionnaire that assesses cognitive distortions in those aged 9-17 years. The questionnaire consists of 5 subscales that measure 5 categories of cognitive distortions: "underestimation of the ability to cope," "personalizing without mind reading," "mind reading," "selective abstraction," and "overgeneralizing." In each item, a situation is described, followed by a possible thought about the situation. Participants are asked to rate on a 5-point Likert scale how much the thought corresponds to what they would think in that situation, ranging from "almost exactly like I would think" (5 points) to "not at all like I would think" (1 point). Total scores range from 16 to 80, with a higher score reflecting more distorted cognitive errors. The total scale has a good level of internal consistency and good test-retest reliability [31,32].

Game Evaluation

At the posttest, participants were asked to rate various statements regarding the effects, content, and usefulness of the game. Items were rated on a 5-point Likert scale (1="completely disagree"; 5="completely agree"). An example of an item is "By playing the game I will be able to recognize my own cognitive distortions." Participants were also asked how they would rate the game overall on a scale from 0 to 10.

Statistical Analysis

Power and sample size could not be based on previous studies due to a lack of comparable studies. An effect size of 0.3 was assumed. To detect such an effect size with α=.05 and β=.80, a total sample of 500 participants was calculated. However, since a possible high dropout of 70% to 75% was expected [33], the total required sample size was estimated at 1753.

Differences between the participants of the study and those who dropped out during the study, as well as differences between those who played the game (ie, gamers) and those who did not play it (ie, nongamers), were examined with χ^2 tests (for categorical variables) and 2-tailed independent-sample *t* tests (for continuous variables). Mean changes between the pre- and posttests were carried out using 2-tailed paired-samples *t* tests. The corresponding effect sizes were assessed using Cohen *d*. A significance level of .05 was used for all outcome analyses. All data were analyzed using SPSS software (version 27; IBM Corp).

Results

Sociodemographic Characteristics and Baseline Outcome Measure

A total of 1654 adolescents signed up to take part in the study. Among these, 1140 took part in the pre- and posttests. Table 1 presents the differences between the participants who completed both the pre- and posttests and those who only completed the pretest.

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Table . Sociodemographic characteristics and baseline outcome measures of participants who completed both the pre- and posttests and participants who only completed the pretest.

Characteristics		Pre- and posttests (n=1140)	Pretest only (n=514)	*P* value
Sex, n (%)				
	Female	700 (61.4)	303 (58.9)	.34
	Male	429 (37.6)	206 (40.1)	.34
	Other	11 (1)	5 (1)	.59
Age (y), mean (SD)		13.40 (1.32)	13.86 (1.36)	.001
Education curriculum, n (%)				
	First-grade GSE[a]	306 (26.8)	84 (16.4)	<.001
	First-grade VE[b]	55 (4.8)	79 (15.4)	<.001
	Second-grade GSE	513 (45)	158 (30.8)	<.001
	Second-grade TSE[c]	173 (15.2)	56 (10.9)	.02
	Second-grade SEA[d]	20 (1.8)	51 (9.9)	<.001
	Second-grade VE	73 (6.4)	85 (16.6)	<.001
Treatment for psychological problems, n (%)				
	Never been to therapy	984 (86.3)	419 (81.7)	.02
	More than a year ago	68 (6)	32 (6.2)	.83
	Less than a year ago	50 (4.4)	31 (6)	.15
	In therapy	38 (3.3)	31 (6)	.01
Baseline outcome measures, mean (SD)				
	Recognizing automatic thoughts	12.64 (4.37)	11.51 (4.82)	<.001
	CNCEQ-R[e]	40.81 (10.97)	40.66 (12.13)	.82

[a]GSE: general secondary education.

[b]VE: vocational education.

[c]TSE: technical secondary education.

[d]SEA: secondary education in the arts.

[e]CNCEQ-R: Children's Negative Cognitive Error Questionnaire–Revised.

Of the 1140 adolescents who completed the pre- and posttests, 510 (44.7%) reported that they did not engage with the game (hereafter referred to as nongamers). The primary reason for nonengagement was technical problems (233/510, 45.7%) such as inability to download the game. Other reasons included a lack of time or forgetfulness (198/510, 38.8%), a disinterest in the game (51/510, 10%), and other unspecified reasons (59/510, 5.5%). In contrast, 630 (55.3%) of the 1140 adolescents indicated that they played the game (hereafter referred to as gamers). There were no significant differences in all baseline sociodemographic characteristics between gamers and nongamers except for type of education curriculum (*P*=.02; see Table 2). Additionally, adolescents who played the game scored significantly higher on recognizing automatic thoughts (mean 13.09, SD 4.08 vs mean 12.08, SD 4.65; t_{1020}=–3.86, *P*<.001) and significantly higher on the Children's Negative Cognitive Error Questionnaire–Revised (mean 41.43, SD 10.90 vs mean 40.05, SD 11.01; t_{1138}=–2.10, *P*=.04) at baseline (see Table 2).

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Table . Sociodemographic characteristics and baseline outcome measures of gamers and nongamers in schools.

Characteristics		Gamers (n=630)	Nongamers (n=510)	*P* value
Sex, n (%)				
	Female	371 (58.9)	329 (64.5)	.053
	Male	251 (39.8)	178 (34.9)	.09
	Other	8 (1.3)	3 (0.6)	.24
Age (y), mean (SD)		13.43 (1.30)	13.36 (1.33)	.40
Education curriculum, n (%)				
	First-grade GSE[a]	186 (29.5)	120 (23.5)	.02
	First-grade VE[b]	25 (4)	30 (5.9)	.13
	Second-grade GSE	264 (41.9)	249 (48.8)	.02
	Second-grade TSE[c]	99 (15.7)	74 (14.5)	.57
	Second-grade SEA[d]	14 (2.2)	6 (1.2)	.18
	Second-grade VE	42 (6.7)	31 (6.1)	.69
Treatment for psychological problems, n (%)				
	Never been to therapy	542 (86)	442 (86.7)	.76
	More than a year ago	39 (6.2)	29 (5.7)	.72
	Less than a year ago	31 (4.9)	19 (3.7)	.33
	In therapy	18 (2.9)	20 (3.9)	.32
Baseline outcome measures, mean (SD)				
	Recognizing automatic thoughts	13.09 (4.08)	12.08 (4.65)	<.001
	CNCEQ-R[e]	41.43 (10.90)	40.05 (11.01)	.04

[a]GSE: general secondary education.

[b]VE: vocational education.

[c]TSE: technical secondary education.

[d]SEA: secondary education in the arts.

[e]CNCEQ-R: Children's Negative Cognitive Error Questionnaire–Revised.

Media and Game Use

Table 3 shows media and game use of the gamers versus the nongamers. The nongamers were significantly less likely to play games currently (270/510, 52.9% vs 405/630, 64.3%; χ^2_1=15.02, *P*<.001) and were significantly more likely to have "no knowledge" about games than the gamers (69/510, 13.5% vs 54/630, 8.6%; χ^2_1=7.20, *P*=.007).

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Table . Media and game use of gamers and nongamers in schools.

Media and game use		Gamers (n=630)	Nongamers (n=510)	*P* value
Media use, n (%)				
	Smartphone use	615 (97.6)	496 (97.3)	.70
	Tablet use	466 (74)	360 (70.6)	.20
	Desktop use	226 (35.9)	179 (35.1)	.79
	Laptop use	501 (79.5)	409 (80.2)	.78
	Game console use	367 (58.3)	279 (54.7)	.23
Game playing, n (%)				
	Ever	601 (95.4)	476 (93.3)	.13
	Currently	405 (64.3)	270 (52.9)	<.001
Game knowledge, n (%)				
	No knowledge	54 (8.6)	69 (13.5)	.007
	Beginner	260 (41.3)	211 (41.4)	.97
	Advanced	255 (40.5)	198 (38.8)	.57
	Expert	61 (9.7)	32 (6.3)	.04

Outcome Measures

Table 4 shows the mean changes in the outcome measures from pre- to posttest and its effect sizes for the group that played the game. The gamers significantly improved in recognizing automatic thoughts ($P<.001$) and had significantly fewer distorted cognitive errors ($P<.001$). On both measures, the difference represented a small effect size (0.16 and 0.23, respectively).

Table . Pre- and posttest scores on outcome measures and 2-tailed paired *t* test results.

Outcome measures	Pretest score, mean (SD)	Posttest score, mean (SD)	*t* test (*df*)	*d* (95% CI)	*P* value
Recognizing automatic thoughts	13.09 (4.08)	13.82 (5.09)	−4.00 (629)	0.16 (−1.09 to −0.37)	<.001
CNCEQ-R[a]	41.43 (10.90)	38.73 (12.79)	7.98 (629)	0.23 (3.36 to 7.98)	<.001

[a]CNCEQ-R: Children's Negative Cognitive Error Questionnaire–Revised.

Game Evaluation

A total of 610 gamers gave a score on the various evaluation items (see Table 5). Besides the high number of neutral responses, they generally moderately or highly agreed with the items. The median overall satisfaction rating of 599 gamers, which was scored on a scale of 1 to 10, was 6 and the mean was 5.51 (SD 2.30).

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Table . Game evaluation ratings (n=610).

Statements	Disagree, n (%)	Neutral, n (%)	Agree, n (%)	Score, mean (SD)
By playing the game I learned about different ways of thinking.	134 (22)	278 (45.6)	198 (32.5)	2.10 (0.73)
By playing the game I will recognize my unhelpful thoughts.	123 (20.2)	244 (40)	243 (39.8)	2.20 (0.75)
The game helps me to reflect more upon my thoughts.	164 (26.9)	272 (44.6)	174 (28.5)	2.02 (0.75)
I can empathize with the stories in the game.	202 (33.1)	204 (33.4)	204 (33.4)	2.00 (0.82)
I think the game is beautifully made.	96 (15.7)	220 (36.1)	294 (48.2)	2.32 (0.73)
I find the game difficult.	283 (46.4)	198 (32.5)	129 (21.1)	1.75 (0.78)
I find the game boring.	122 (20)	171 (28)	317 (52)	2.32 (0.79)
I would like it if the game was not only about thoughts but also about feelings and relaxation.	102 (16.7)	209 (34.3)	299 (49)	2.32 (0.74)

Discussion

Principal Findings

The aim of this pilot study was to test the efficacy and usability of the prototype of Silver, a serious game aimed at reducing cognitive distortions in adolescents and thus decreasing cognitive vulnerability to mental health problems. The trial supports our hypothesis that automatic thoughts are better recognized after playing Silver. This enhancement in cognitive awareness was also reflected in the evaluation of the game, wherein gamers indicate that playing the game helps in recognizing unhelpful thoughts. Furthermore, after having played the game, adolescents showed fewer cognitive distortions than before playing. These findings are in line with prior studies, underscoring the positive impact of serious games on cognitive beliefs and modification [19,34-37]. This study contributes to the growing evidence on digital interventions that incorporate core components of CBT, such as cognitive restructuring, and their beneficial effects on well-being and mental health issues [38]. Silver's emphasis on identifying and mitigating cognitive distortions aligns closely with the principles of rational emotive behavior therapy (REBT), a type of CBT [39]. This therapeutic approach focuses on the identification, challenge, and substitution of irrational beliefs with rational counterparts, alongside learning to manage emotions and behavior in a more helpful way. Literature suggests that serious games focusing on REBT techniques seem to have a strong positive effect in mitigating symptoms of depression and anxiety [19]. Considering the significant outcomes associated with the current version of Silver, which primarily targets cognitive distortions, an expanded version of the game that includes elements intended to address emotional and behavioral aspects could potentially have a greater positive impact on mental health. The inclusion of these additional components could further enhance the game's therapeutic effectiveness, aligning with REBT's approach to mental health improvement [19].

Regarding the evaluation of Silver, the majority (294/610, 48.2%) of gamers indicated that Silver is appealing. Research has shown that nonappealing interfaces may be off-putting and may cause adolescents to disengage from the game. The cocreation of Silver with the target audience probably has ensured that it has attractive aesthetics [40]. In contrast, the majority (317/610, 52%) also perceived Silver as boring. Adolescents may experience serious games in such a manner since they often have very didactic content that does not match commercial, off-the-shelf games, and as a result, the adolescents may cease playing these games [40]. This dichotomy can be attributed to the prototype's focus on a single aspect of cognitive vulnerability (ie, cognitive distortions), which, although important, may lack the variety necessary to sustain players' interest over time. Therefore, this may be a critical area for further development in diversifying the game's content and mechanics. The game could be broadened to include a range of elements. This could mitigate the issue of monotony, thereby improving overall engagement and effectiveness [19]. Furthermore, the gamers indicated that they would like a more comprehensive game that also deals with feelings and relaxation. Such a game may be more eventful, more fascinating, and less boring.

Preceding a discussion of potential implications of the study findings for the development of serious games, methodological issues need to be addressed. First, as this was a pre- and posttest study, a control group was lacking. Therefore, we were unable to compare the effects on the gamers with those in a random control group that did not play the game. A convenience sample was used, which can lead to a selection bias and consequently underrepresent or overrepresent particular groups. Efforts were made to counter this as much as possible by recruiting a large

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number of adolescents from 8 different schools with various curricula. However, it is also unclear why some adolescents agreed to take part in the study but others did not. As the sample was not chosen at random, the inherent bias in convenience sampling means that any generalizations of findings must be made with caution. Second, a large group did not adhere to the study protocol. The main reason for dropout were technical difficulties. These were largely due to the prototypic nature of our app; as it was not readily available on app stores, it required adolescents to undertake multiple steps before receiving access to the game. Moreover, participants' feedback showed time constraints and forgetfulness as additional factors for not engaging with the game. To mitigate these issues in future studies, it is imperative to streamline the app's accessibility, potentially by securing its availability on common digital distribution platforms. Furthermore, incorporating human support may serve to enhance participant engagement and possibly the overall effectiveness of the intervention [41]. Addressing these aspects is critical for improving study adherence and ensuring the robust evaluation of the app's therapeutic potential. Furthermore, participants who dropped out were older and had a lower education level. Additionally, they may have experienced more mental health problems, as baseline measurements showed that they were less skilled at recognizing automatic thoughts and were currently more likely to be in treatment for psychological problems. The nongamer group encompassed more adolescents with little interest in games, as they currently played no games or had less knowledge about them. In addition, they were less skilled at recognizing automatic thoughts but had fewer cognitive distortions themselves. However, high attrition rates are not uncommon when studying e-mental health interventions. A systematic review and meta-analysis of computer-based psychological treatments showed an overall dropout rate of 57%, which further increased to 74% in unsupported digital programs [6,42]. In this study, the adolescents were also not offered any support, and this may have had a major effect on adherence. Adding human support could decrease the attrition rate and may even increase the effectiveness of the serious game [43,44]. Moreover, the effectiveness of serious games is often assessed in pragmatic study trials. The real-life settings in which these studies are carried out can also have an impact on the attrition rate. Nevertheless, this type of study can improve the generalizability of the results, as the environments in which they will be implemented are similar to the ones in the trials [45]. Third, no standardized questionnaire for the recognition of automatic thoughts was used. The questionnaire was based on an existing standardized questionnaire [29,30] but was adapted for this study. Fourth, participants often responded with "neutral" in the game evaluation. Although they may have used the neutral midpoint response because they did not comprehend the items or were undecided, offering these neutral responses may decrease the quality and reliability of a questionnaire, particularly in adolescents, since they are more sensitive to pleasing by selecting a neutral answer. Future studies should consider omitting the neutral midpoint [46,47]. Fifth, the study's emphasis on quantitative measures may have introduced acquiescence bias. Adding qualitative methodologies may provide a more nuanced perspective of the participants' experiences with the prototype. Future studies should consider using a mixed methods approach to enhance understanding of the intervention's impact [48].

Lastly, the eligibility criterion requiring participants to possess a smartphone or tablet may have introduced a selection bias, potentially excluding adolescents without access to such technology or those reluctant to use it. This could inadvertently reinforce the digital divide, that is, inequalities in accessing and using information and communication technologies [49], and limit the generalizability of the findings. Future research should address this limitation by using more inclusive recruitment strategies to minimize technological barriers and ensure broader participation.

It is difficult to assess the effect of these methodological issues on the validity of the current findings, more so as the current results are difficult to compare to those from similar previous studies. The few available studies of serious games aimed at cognitive training had targeted adults or children with particular mental health problems such as anxiety, alcohol use disorder, or attention-deficit/hyperactivity disorder [11,20]. To the best of the authors' knowledge, only 2 serious games were studied regarding effects on emotional resilience or mental health promotion in a community sample of adolescents. The results of these studies are comparable to our findings [20,35,36].

Conclusions

In conclusion, and keeping the limitations mentioned above in mind, this pilot study demonstrates the promising effects of the Silver prototype. Notably, participants exhibited not only an enhanced ability to recognize cognitive distortions but also a significant decrease in their own experiences of such distortions after engaging with the prototype. This observation suggests a potential positive influence on cognitive characteristics, which are commonly associated with mental health issues. It is therefore recommended that a serious game aimed at decreasing cognitive vulnerability and therefore improving mental health in a general population of adolescents should be developed further and that its efficacy should be studied in future research. This study provides a few cues for further research. The dropout of adolescents who may have the greatest need for cognitive restructuring is a matter of concern, and reasons and remedies for this worrisome issue should be targeted in future research. Randomized controlled trials should be used to further explore the effects of serious games on adolescents in the general population, preferably using an active control group that engages with a different type of digital intervention [50]. Follow-up periods should be sufficiently long to study potential preventative effects among adolescents (Reynard et al [20]).

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Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy
REBT: rational emotive behavior therapy

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The Effect of a Novel Video Game on Young Soccer Players' Sports Performance and Attention: Randomized Controlled Trial

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Abstract

Background: Currently, the fusion of technology and sports is inevitable. The integration of various systems and devices has brought about significant transformations in established sports practices, impacting not only the rules but also physiological, biomechanical, and even psychological aspects.

Objective: The purpose of this study was to analyze the effect of an attention intervention through a video game on young soccer players.

Methods: Twelve young male soccer players (age: mean 8.5, SD 1 years) were divided into 2 groups: a control group (CG; n=10) and an experimental group (EG; n=10). During the 6-week training program, the EG received attention training through a video game twice a week for 15 minutes per session. Pre- and postintervention measurements included a specific decision-making soccer test and interviews with coaching staff. Additionally, success in the video game, muscular activity, and sweat levels were monitored.

Results: The EG demonstrated a significant improvement in video game success following the intervention program, as indicated by the achieved level (P<.001). However, no significant differences were found between groups regarding electromyographic (EMG) activity (P=.21) and sweating (P=.20). Prior to implementing the attention training program, both groups exhibited similar data for variables related to decision-making and execution mechanisms (≤10%). Only 2 decision-making variables exceeded 10% but remained below 15% (Shot_D=13.35%; Marking_with_Ball_D=−12.64%). Furthermore, changes in attacking action variables were more pronounced in execution-related variables, except for dribbling and fixing. Conversely, in defensive action variables, changes were greater in decision-related variables, except for marking with the ball and marking without the ball.

Conclusions: Our findings reveal that incorporating a specific attentional video game into a soccer training program enhances decision-making compared to a program without the video game. Therefore, it is advisable for practitioners to consider using this tool due to its high efficiency in terms of economic and temporal costs, particularly in improving a key psychological variable.

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KEYWORDS

reaction time; serious games; executive function; decision making; game; games; gaming; sport; sports; soccer; football; athlete; athletes; athletic; training; performance; physiological; muscle; muscular; sweat; sweating; attention training; attentional; ball; exercise; physical activity; exergame; exergames; interview; interviews

Introduction

Currently, technology use is inseparable from sports. The integration of various systems and devices has brought about significant transformations in established sports practices, impacting not only the rules but also physiological, biomechanical, and even psychological aspects. This revolution is particularly evident in soccer, where the implementation of technology has primarily concentrated on the professional sphere. From a physiological perspective, technology has facilitated notable advancements in the understanding and control of physical demands during elite soccer matches. Tools such as the GPS [1,2], accelerometry, and specialized match analysis programs [2] have made it possible for coaches to design training tasks on the basis of data obtained from actual games. Optical tracking systems and GPS devices were compared in professional soccer, revealing no significant differences in analyzed variables such as total distance, distance

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per minute, average speed, and maximum speed [3]. However, limitations were identified, such as the ineffectiveness of the GPS in indoor sports and the inability of optical tracking systems to access internal variables. Nevertheless, researchers concluded that both technologies were suitable for monitoring the physiological demands of soccer players [3].

Technological applications in soccer have also shed light on performance mechanisms in areas such as jumping [4] and the minimization of lower limb injuries [5]. Usually, these technologies rely on 3D movement analysis, muscle activation assessment, and force production evaluation. Nonetheless, the high economic cost and specialized expertise required for their use pose significant challenges, making it difficult to implement them in the daily lives of athletes. Another way to harness the use of technology with a better cost-benefit relationship is through the use of video games; in particular, those with a clear aim to improve performance and learning, known as serious games [6]. Games have been used to introduce challenging concepts or develop skills in different areas such as surgery [7] and rehabilitation [8] or to enhance team coordination via cooperative training—the latter being called "small side games" [9,10]. All manner of play seeks to achieve improvements in skill acquisition in a more attractive way over and above traditional forms [11,12]; in particular, among pediatric populations with special attention and motivation characteristics [13,14]. Playful forms of intervention have improved affective responses in children compared to traditional teaching methodologies [15], having achieved benefits with the use of video games that optimize performance in variables as attention and executive control [16] and other psychological variables [17]. Serious games are emerging as valuable tools with positive impacts on cognitive aspects, providing specific value to their users. A pertinent study demonstrated that the implementation of a serious game based on chess, titled "The Secret Trail of Moon," led to notable increases in emotional control levels and a reduction in attention deficits among participants [18]. In the sports domain, literature also highlights benefits, with a serious virtual reality game showing a significant improvement in players' concentration during skiing tasks [13]. These findings underscore the potential positive impact of serious games on diverse cognitive and sports-related domains. Studies have increasingly focused on the psychological and cognitive aspects of athletes over the years [19,20], having highlighted attention, memory, and motivation as crucial psychological variables for athletes [21,22]. While the relationship among technology, games, and the psychological behavior of athletes has been explored, research specifically focusing on technology training in soccer remains scarce compared with other areas of knowledge. A notable study [23] revealed that young soccer players who trained with a computerized attention training system called Rejilla (version 1.0) [24] experienced significant improvements in their attention. However, these improvements were not directly linked to on-field performance variables. The literature has primarily centered around elite soccer, with limited attention given to youth soccer. Providing information to youth soccer coaches regarding how technology can impact the psychological and cognitive variables of their athletes will help optimize performance and achieve long-term success.

Methods

Participants

The study involved 12 young male soccer players aged between 8 and 9 years from a club in Seville, Spain. The participants underwent training sessions 3 days a week, each lasting approximately 120 minutes. The sample was divided into 2 groups: a control group (CG) and an experimental group (EG). Both groups were informed about their participation in a program aimed at enhancing their soccer skills. For the CG, the training involved watching videos of goals scored by the first team in previous seasons, followed by researchers posing questions to elicit responses. In search of a placebo effect, the EG was informed that the activity they were engaging in was attention training. This involved the visualization of videos showcasing goals scored by the first team in past seasons. After the video session, participants were required to answer questions related to the content (eg, "how many goals did the player with the number 9 score?"). Alternatively, the EG engaged in attention training using a video game.

Sample size calculation was convenience-based. For this, the study participants were players from a youth team belonging to a top-tier club in the Spanish Professional Football League. As an inclusion criterion, participants had to be 8 or 9 years old. Additionally, they should have been free from injuries that would have prevented them from participating in training or competitions. Their required training frequency was 3 times per week. During the 6 weeks, if any player reduced their training frequency to once a week, they were withdrawn from the study. Finally, a simple randomization method was chosen to randomize the groups, using the toss of a coin.

Procedure

The study spanned a duration of 6 weeks (Figure 1). Initially, all players underwent an evaluation of their decision-making skills in relation to soccer performance using the Game Performance Evaluation Tool (GPET) test [25]. The GPET is a tool to assess performance in invasion sports, specifically in soccer. Subsequently, both groups were assessed on the basis of their success in the video game, electromyographic (EMG) activity during the test, and sweat level. Throughout the study, all participants maintained their regular training routine, consisting of 3 sessions per week and a competitive game. The intervention varied, in that, on the one hand, the CG attended a room session twice a week where videos showcasing goals scored by the first team in past seasons were shown during 15 minutes, and after each video, the investigators posed a question to elicit a response; on the other hand, the EG attended a room session where attention training was conducted using a video game, with sessions lasting 15 minutes and taking place twice a week. Upon completion of the 6-week intervention, all players were reassessed regarding their decision-making abilities in relation to soccer performance using the GPET, as well as their performance in the video game, EMG activity, and sweat level during video game practice. Finally, an interview was conducted with the coaching staff to gauge the subjective attention levels of each soccer player, assigning them a score ranging from 1

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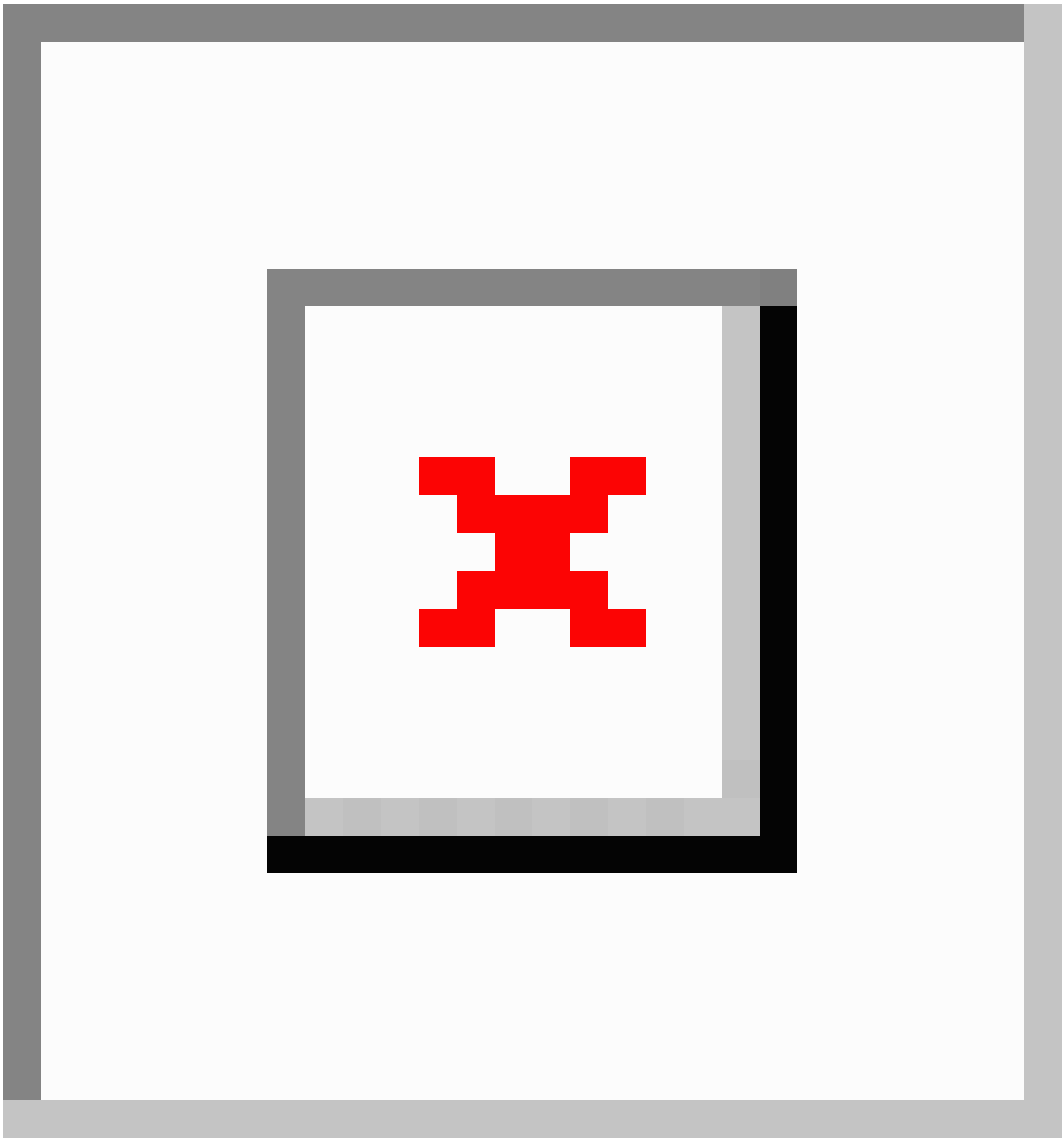
(very low attentional level) to 3 (optimal attentional level) in relation to competitive situations.

Figure 1. Study design. Left to right: participants were randomized into 2 groups. Subsequently, all soccer players were assessed using the Game Performance Evaluation Tool (GPET), in addition to being evaluated for success in the video game, electromyographic (EMG) activity, and sweating levels. Afterward, the intervention proceeded for 6 weeks. Thereafter, both groups were evaluated again with the GPET, EMG activity, and sweating levels. Finally, the coaching staff was interviewed.



Instruments

The Video Game: BallApp

The video game used in the study involved the task of memorizing a ball with a distinct color among others displayed on the screen. After a period of 5 seconds, all the balls would change to the same color and move randomly across the screen. The participants were then required to identify the ball that initially had a different color. Accomplishments in the video game were measured in both groups, with the criterion being the ability to advance to the next level 3 consecutive times to mitigate the influence of luck. As the levels progressed, the speed of the balls, the number of selectable balls, and the presence of distractors such as noise increased. To replicate the environment of competitive soccer matches, specific background noise recordings from the soccer players' actual matches were provided.

The attention game for soccer players, BallApp, is designed to enhance their attention processes, aiming for a positive impact

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on attentional mechanisms when playing soccer. The game has been developed as an application using various technologies, including HTML for structural aspects, JavaScript for functionality, and Material Design for Bootstrap for design. The game is tailored for young soccer players and has been designed for individual play, although multiple players can participate on multiple screens.

The game involves selecting a ball of a different color than the others, and after a few seconds, all the balls turn into the same color and move randomly across the screen. The speed of movement, number of balls, depth of movement, and added noise vary as the difficulty levels progress. For example, in level 1, three balls appeared (one of them being of a different color), and the task was to choose 1 ball. All the balls moved without depth, and the speed was low. As levels increased, the difficulty level also increased on the basis of the number of balls on the screen. In subsequent levels, such as level 3, four balls appeared (one of them being of a different color), and the task was to choose 1 ball. The balls moved without depth, at a low speed, and without added noise. In total, the maximum number of programmed levels in the game was 8.

Level 4 onward, an ambient sound replicating those in real-world soccer matches was introduced. The aggressiveness of the noise increased with an increase in the difficulty level (Table 1). The aggressiveness of the noise was described on the basis of whether it was a murmur (low noise), cheering noise (medium noise), cheering noise with chants (moderate noise), noise with chants where specific phrases from a fan stood out (aggressive noise), or noise with chants and synchronized disturbances in the form of complaints or disgust toward plays (very aggressive noise).

Table . Overview of the characteristics of each level of the game.

Level	Number of balls on the display	Number of eligible balls	Depth of the movement	Speed of the balls	Sound
1	3	1	No depth	Low	Noiseless
2	3	1	With depth	Low	Noiseless
3	4	1	No depth	Low	Noiseless
4	5	1	No depth	Moderate	Slight noise
5	6	2	No depth	Moderate	Medium noise
6	6	2	With depth	Moderate	Moderate noise
7	7	2	No depth	High	Loud noise
8	8	2	With depth	High	Very loud noise

Regardless, to progress to a higher level, the player had to win the played level 3 times consecutively, eliminating luck as a factor for level progression. If the player correctly identified the balls of a different color in each level, they were awarded a score. This score depended on not only accuracy but also the time taken to make their choice.

The game has a configuration for individual use, although competitions can also be held with other players. Thus, it provides players with a leaderboard that compares scores among players, and this ranking changes on the basis of the following variables: the number of games played, the number of points achieved per game, and the number of levels surpassed by the player.

The selection of this particular video game for implementation is predicated on its consistent engagement of the attentional mechanism. This mechanism holds substantial implications in the developmental processes of young soccer players and, consequently, may yield positive effects on targeted soccer-related tasks.

EMG and Skin Conductance

EMG activity and electrodermal activity (EDA) were assessed on the basis of skin resistance and sweat production (bioPLUX). The EMG activity and EDA of the dominant hand's extensor muscle were evaluated in all participants. Electrodes were applied to the dominant hand, and these variables were analyzed before and after the intervention program during video game practice. These variables were examined from a somatic perspective, allowing for the monitoring of psychophysiological indicators during an attention-demanding task such as playing a video game (Figure 2).

The assessment of somatic variables of anxiety using biofeedback devices appears to be an excellent tool for controlling anxiety during different tests and among different populations [26], specifically in the analysis of EMG activity [27] and EDA variables [28], as specific control of somatic responses seems to be a good indicator of psychological states. Alterations in these variables could indicate somatic states and anxiogenic responses that would hinder the individuals' task performance [29]. Our study monitored these 2 responses while participants played the video game.

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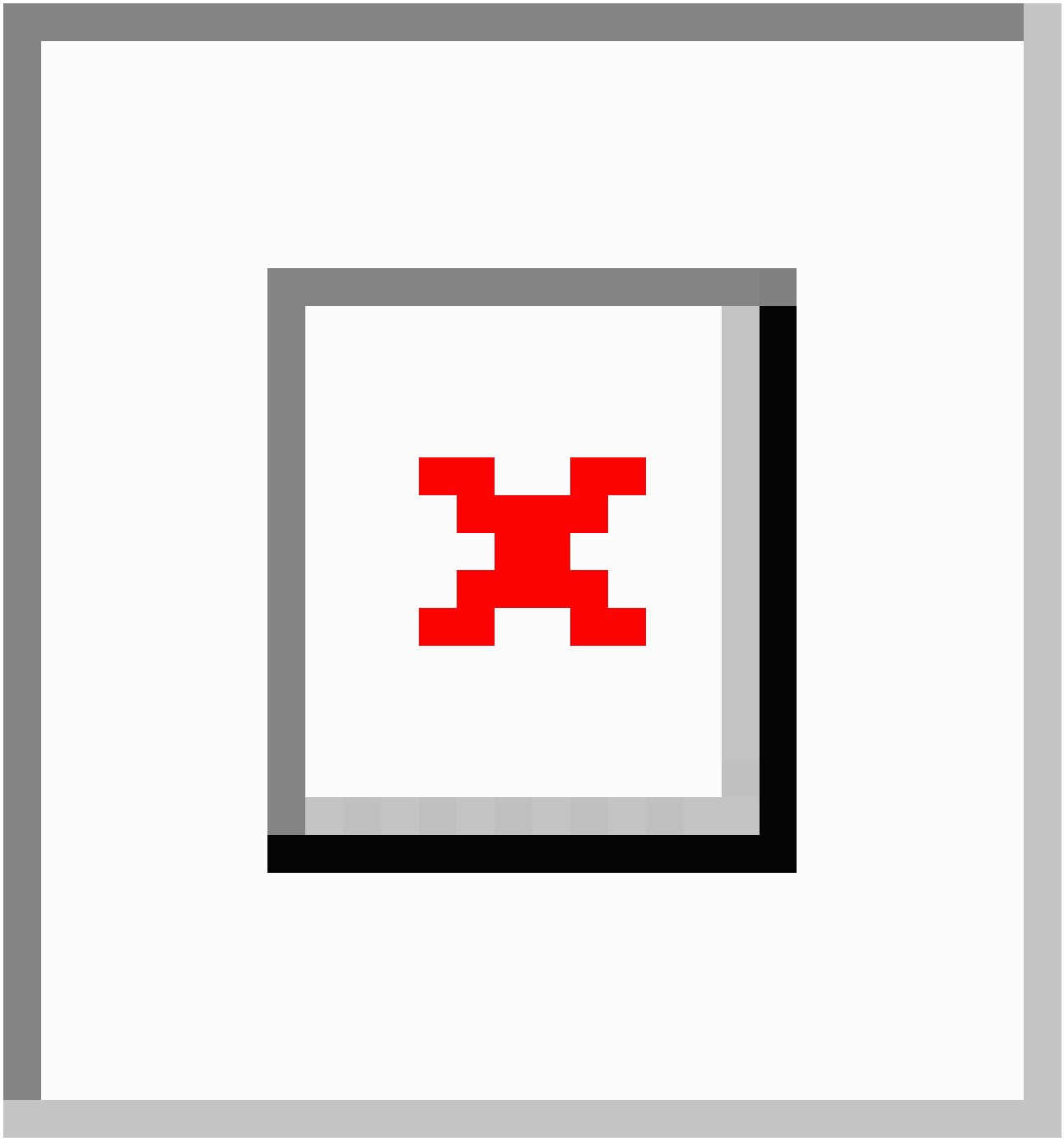
Figure 2. Evaluation of electromyographic activity (**A**) and electrodermal activity (**B**) during video game practice.



GPET

The GPET assessment tool was used to evaluate decision-making in relation to soccer performance. This instrument differentiates the cognitive-decisional aspect of performance from execution. The playing field has dimensions of 20×10 m^2, with delimited areas of 3×4 m^2 and goals measuring 0.95×0.70 m^2. The ball used is an A-7 soccer ball, with a circumference ranging between 0.635 and 0.66 m. The players engage in the task in teams consisting of 2 players each, with two 4-minute halves and a 3-minute break between them. The timer remains active throughout, and there are assistants designated to retrieve the ball. The variables captured by the test are assessed in both attacking and defensive situations, both with and without the ball (as outlined in Table 2). The test is recorded using a video camera for subsequent analysis. Using an observation sheet, successful actions are coded on the basis of the predefined roles into 4 options: appropriate decision (coded as 1), inappropriate decision (coded as 2), successful execution (coded as 1), and unsuccessful execution (coded as 2).

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Table . Description of variables evaluated using the Game Performance Evaluation Tool.

	With the ball	Without the ball
Attack	• Control • Pass • Dribbling • Shot	• Losing one's defender • Fixing
Defense	• Marking with the ball • Defensive blocking • Tackle • Clearing with the ball	• Marking without the ball • Interception • Clearing without the ball

Outcome Measures

All variables evaluated using the GPET are described below and are classified in accordance with two criteria (Table 2): (1) whether the action is carried out with or without the ball and (2) if the actions are those wherein the decisional or execution mechanism predominates. For this purpose, all acronyms used have been "_with_ball" for variables with the ball, "_without_ball" for variables without the ball, "_D" for variables where the decisional mechanism predominates, and "_E" where the execution mechanism predominates. Thus, the variables are the following: (1) control: this refers to situations where the player keeps the ball under control; (2) pass: this is the action where the player successfully makes a pass to another teammate; (3) dribbling: this is an action where the player gets away from his opponent, eliminating any possibility of the ball being taken away from him; (4) shot: the player takes a shot at goal with the aim of scoring; (5) Losing_one's_defender: the player, by means of an attacking action, unmasks themself from their defender; (6) fixing: the player, in an attacking action, fixes the defender, forcing the latter to occupy a specific position on the field; (7) Marking_with_ball: in a defensive action, the player marks the player who has the ball; (8) Defensive_blockin: in a defensive action, the player tackles the player with the ball but does not fall to the floor; (9) tackle: in a defensive action, the player falls to the ground to snatch the ball from the opponent; (10) Clearing_with_Ball: in a defensive action, the player clears the player with the ball, using a free space; (11) Making_without_ball: in a defensive action, the player marks another player of the opposing team who is not in possession of the ball; (12) interception: in a defensive action, the player cuts off a play, preventing the ball from reaching its receiver; and (13) Clearing_without_ball: in a defensive action, the player makes a clearance to the player who does not have the ball, using a free space.

Interview

Traditionally, the coach's role as a key element in understanding the athlete has proven to be crucial [30]. Specifically, the athletes' psychological factors have been tested using various procedures, with the coach playing a pivotal role as a key to understanding the athlete's psychological status [31,32]. Thus, the qualitative insights obtained from interviews with coaches regarding the psychological variables of athletes can be a crucial element that significantly enhances the understanding of these psychological variables, aiding in decision-making about athletes [33].

An individual interview was conducted with the coach to subjectively assess the level of attention concerning decision-making and athletic performance for each soccer player. The coach was asked to rate, using a scale from 1 to 10, the level of attention exhibited by the soccer player in making optimal decisions that contribute to enhanced athletic performance. The coach provided a numerical rating, which was duly recorded by the evaluation team.

Statistical Analysis

A statistical analysis was conducted on the data obtained for each variable. Initially, a parametricity analysis was performed for each variable using the Shapiro-Wilk test. Subsequently, the mean and SD of each variable were assessed. To compare the means between groups, an independent samples *t* test was used, with a significance level set at 95% confidence ($P \leq .05$). Moreover, the effect size for the variables was determined using a 95% confidence limit. To qualitatively evaluate the potential quantitative changes observed after the program, the following categories were used [34]: highly improbable (<1%), very unlikely (1%-5%), unlikely (5%-25%), possible (25%-75%), likely (75%-95%), highly likely (95%-99%), and virtually certain (>99%).

Ethical Considerations

This study received ethical approval from the Ethics Committee of the Center for University Studies affiliated with the University of Seville (20190215) on February 5, 2019. This study complied with the ethical guarantees and requirements for experimentation on human beings and animals and the requirements established in Spanish legislation in the field of biomedical research, protection of personal data, and bioethics, and adhered to the fundamental principles of the Declaration of Helsinki and the European Convention on Human Rights. Informed consent was obtained from the responsible tutors of the players.

Results

The aim of this investigation is to assess the impact of an attention intervention among soccer players, using a video game. To assess the video game's impact on the athletic performance of these players, an analysis of various variables was conducted, categorized into 3 main groups: the first group focused on the video game itself, examining the success rate in the game, EMG activity, and EDA; the second group encompassed decision-making variables related to the athletic performance component in soccer players; and in the third group, a subjective

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evaluation of each soccer player's level of attention was obtained from their coach.

Regarding the variables analyzed in the video game, a significant improvement in the success rate of the soccer task was observed in the EG following the intervention program, as indicated by the level achieved. Both groups exhibited no differences in terms of success rate before undergoing training using the video game. However, after the 6-week duration, the EG demonstrated a substantial increase in the obtained score compared to the CG (Table 3).

Our findings indicate that there were no significant differences in EMG activity and assessed sweat between the 2 groups (Table 4).

Regarding the set of variables assessed using the GPET tool, both groups underwent evaluation before and after the implementation of the attention training program using the video game. The variables were categorized as successful or failed actions based on the prevailing decision or execution mechanism, and they were further classified as attacking or defensive actions. All data were analyzed and are presented as percentages. Furthermore, the change in percentages for each variable was calculated by subtracting the values to determine both inter- and intragroup differences, and these differences were evaluated. See Figures 3 and 4.

Regarding the mean score, a significant difference was observed between the EG and CG after the intervention period (pre-CG mean 46.2, SD 12.5; pre-EG mean 46.9, SD 13.8; P=.95; Cohen d=−0.01; post-CG mean 40.7, SD 13.7; post-EG mean 59.7, SD 17.3; P=.01; Cohen d=−1.73). As indicated, before the application of the attention training program using the video game, both groups showed relatively similar variables in which the decision mechanism predominated, as well as in those in which the execution mechanism predominated, the differences between both groups being less than 10%. Only 2 decision mechanism variables had values above 10% but never exceeding 15% (Shot_D=13/100, 13%; Marking_with_Ball_D=12/100, −12%).

Regarding the EG, following a 6-week intervention, all variables underwent some degree of modification, with minor changes below 15%. The variables that experienced the most substantial changes were Fixing_D (27/100, −27%), Fixing_E (37/100, −37%), Defensive_blocking_D (28/100, −28%), Marking_with_Ball_D (22/100, −22%), and Interception_D (18/100, −18%). The minus sign in these changes indicates that the percentage for each variable decreased after the intervention period. In the case of the CG, 9 variables showed changes exceeding 15%, with 5 of them surpassing 30%. On comparing the percentage changes between the 2 groups after the intervention, all variables had higher values in the EG than in the CG. The only variable that had higher values in the CG was the shot, on evaluation of both the decision mechanism (Shot_D=−1.43) and the execution mechanism (Shot_E=−1.69). However, the differences observed in both cases did not exceed 2 units.

Table . Comparison of success in the video game between groups before and after the intervention.

Variable	Before[a]		After[b]	
	CG[c]	EG[d]	CG	EG
Success, mean (SD)	1.66 (0.51)	1.5 (0.54)	1.83 (0.40)	4.16 (0.75)

[a]P=.61.
[b]P<.001.
[c]GC: control group.
[d]EG: experimental group.

Table . Comparison of EMG[a] activity and EDA[b] between groups before and after the intervention.

Variable	Before			After		
	CG[c]	EG[d]	P value[e]	CG	EG	P value
EMG activity (μV), RMS[f] (SD)	1.66 (0.10)	1.71 (0.09)	.50	1.78 (0.12)	1.72 (0.05)	.21
EDA (μΩ), RMS, (SD)	25.11 (0.07)	25.81 (0.88)	.08	25.51 (0.48)	25.01 (0.85)	.20

[a]EMG: electromyographic.
[b]EDA: electrodermal activity.
[c]CG: control group.
[d]EG: experimental group.
[e]P≤.05 was considered significant.
[f]RMS: root-mean-square.

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Figure 3. Comparison between the groups before the training period. CG: control group; EG: experimental group; GPET: Game Performance Evaluation Tool.

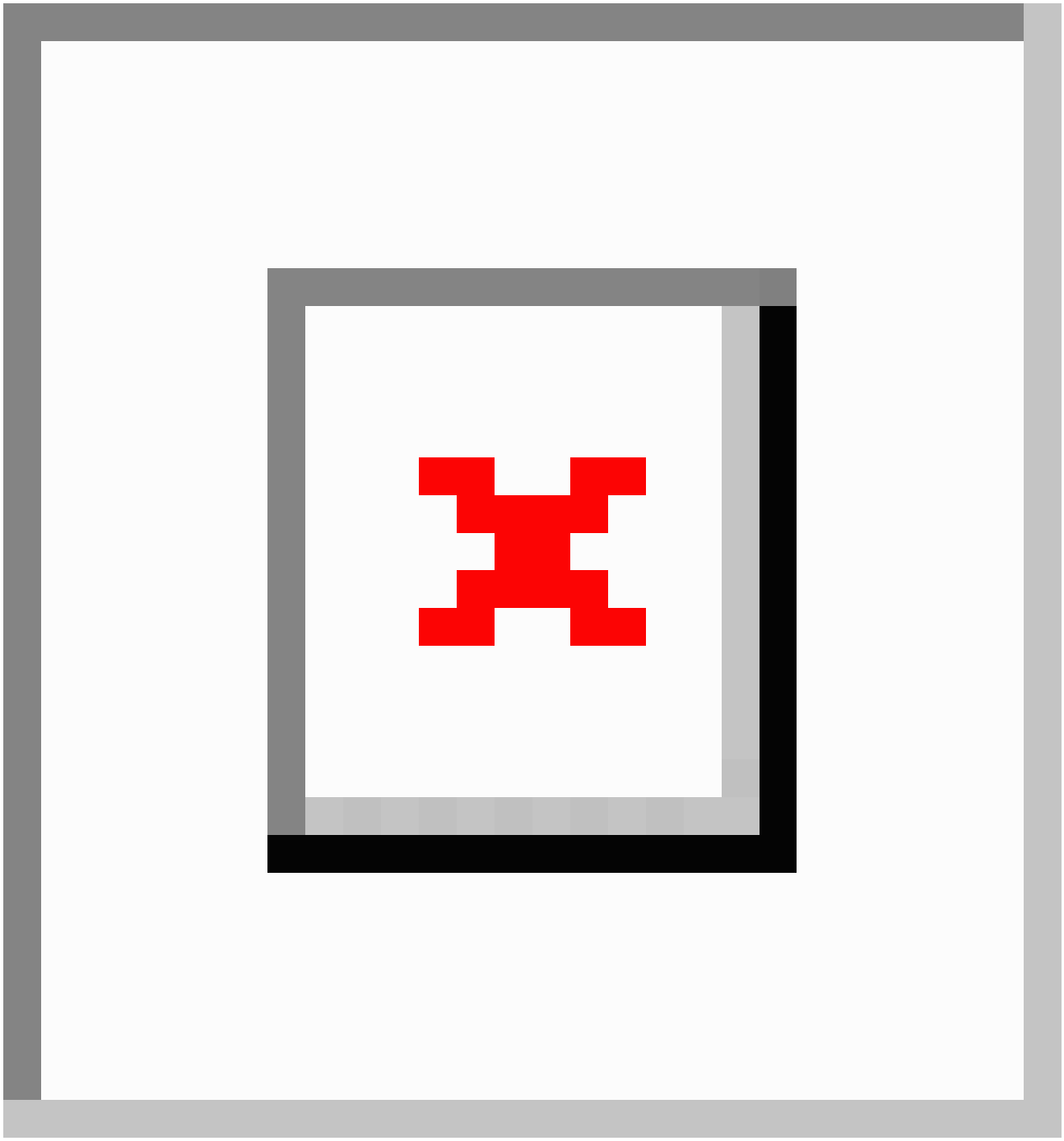

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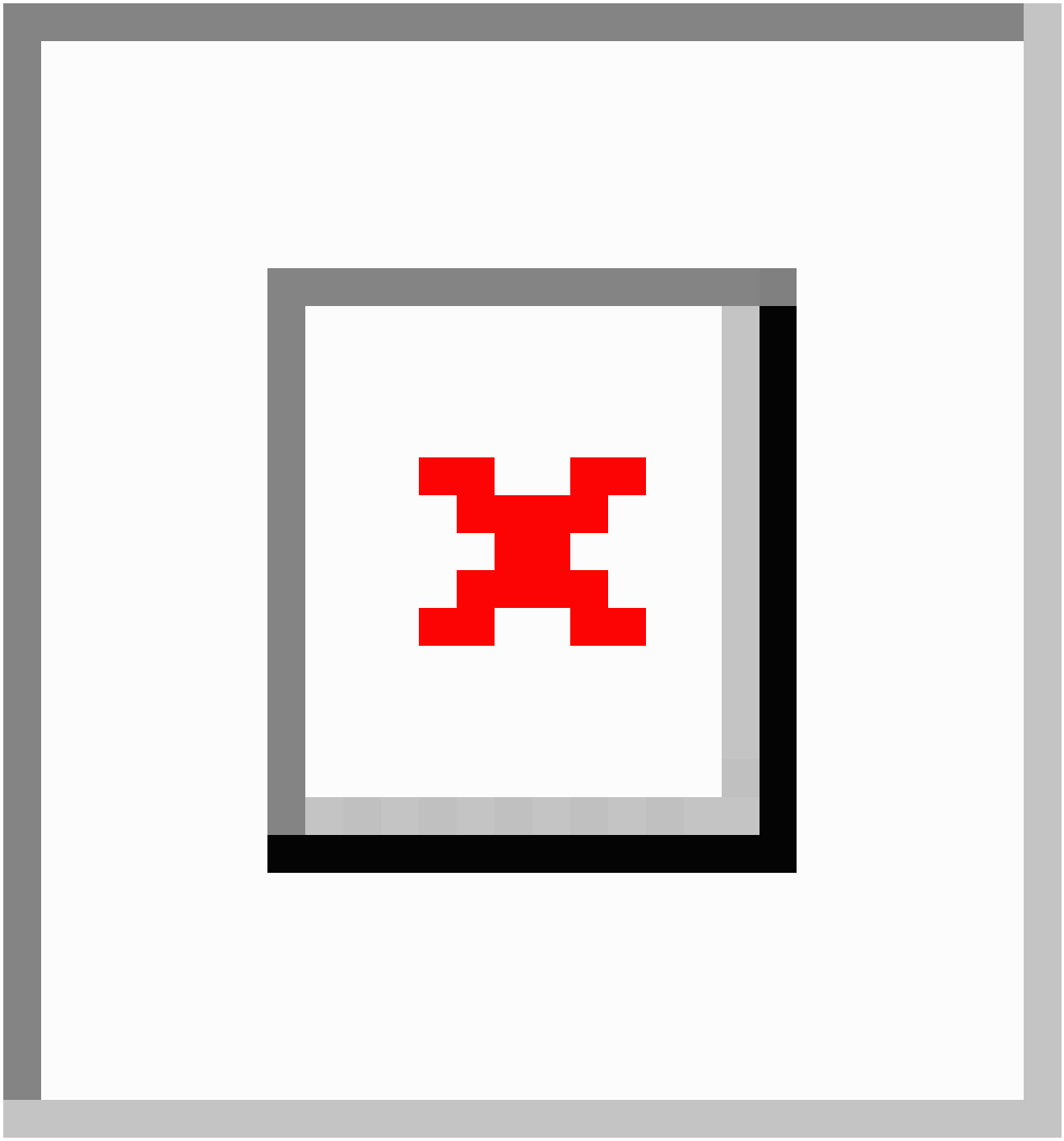
Figure 4. Comparison between groups after the training period. CG: control group; EG: experimental group; GPET: Game Performance Evaluation Tool.



Furthermore, it is evident that in the set of variables related to attack actions, the changes are more pronounced in variables associated with the execution mechanism than with those associated with the decision mechanism, except for dribbling and fixing. Conversely, in the set of variables related to defensive actions, the changes were more significant in the decision variables than in the execution variables, except for the variables of marking with the ball and marking without the ball.

Finally, the results obtained from the interview-based subjective evaluation of the soccer players' attention levels are presented in Table 5.

Table . Subjective levels of attention evaluated by the coach.

Variable	Control group, mean (SD)	Experimental group, mean (SD)	*P* value[a]
Subjective level of attention	4.83 (1.47)	5.83 (1.16)	.22

[a]$P \leq .05$ was considered significant.

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Discussion

Principal Findings

The primary aim of this study was to develop a video game targeted at enhancing the attentional skills of young soccer players. By providing coaches with a tool for training the psychological aspect of attention, positive effects on various performance variables in soccer players could be observed. Following the intervention program, the EG demonstrated improvements in video game performance, indicating significant progress in overcoming the challenges presented by the game. These findings are consistent with those of a previous study [23] that reported improvements in attention execution through software interventions and considered using video games as an interesting tool for improve cognitive variables [35] in this population [36]. While our study did not use a specific attention assessment such as the D2 Attention Test [37] used by Reigal et al [23]x, one of our key findings is that alongside attention training through the video game, we evaluated decision-making related to soccer performance.

To monitor somatic factors such as muscle activity and skin conductance, we used EMG activity and EDA measurements for all participants. Research suggests that cognitive control and management of the somatic aspects of anxiety could impact attention levels [38]. In our study, we specifically collected EMG activity data from the hand extensor muscles. Our evaluation methodology aligned with that developed by Palkowski and Redlarski [39], who assessed EMG activity during various hand gestures. Our results revealed similar EMG activity patterns during hand opening actions, comparable to the postures observed when our sample participants placed their nondominant hand on the table while using the dominant hand to operate the computer mouse.

However, our analysis of EDA did not reveal any significant differences between the groups. This lack of divergence in the somatic response to anxiety suggests potential heightened control over the outward display of anxiety during the test. Surprisingly, both the CG and the EG obtained similar results. One possible explanation for this finding could be the presence of the play component, as both EMG activity and EDA evaluations were conducted during the practice of the video game. These results are aligned with the findings of Pop-Jordanova and Pop-Jordanov [40], who observed similar skin resistance outcomes when assessing individuals using biofeedback in static and calm situations. However, it appears that the video game may not be an effective tool for regulating somatic anxiety.

The evaluation of performance-related variables in soccer players with the GPET confirms the perceptual improvements in decision-making and execution observed in the EG after engaging in the intervention program with the video game. This suggests that enhancing attention through video game practice has a positive impact on decision-making in relation to soccer performance. These findings are aligned with those of González-Víllora et al [41], who assessed decision-making and execution in soccer situations using the same tool and observed significant differences between groups. Thus, our results further support the notion that the video game can serve as a valuable tool for enhancing the psychological aspect of attention in young soccer players, yielding positive effects on various performance variables in soccer.

Regarding shooting decisions, the CG demonstrated higher results than the EG. One possible explanation for this is that the EG developed attentional skills through the video game intervention, leading to improved decision-making during soccer and consequently reducing the frequency of shooting attempts. While no significant differences were observed between the 2 groups in the coach's subjective evaluation of their players' attentional mechanisms, it is evident that the video game serves as an effective tool for decision-making training. Moreover, it shows promise as a tool for detecting attentional impairments or abnormalities, highlighting its potential beyond its training benefits.

Limitations

Despite our study reporting that this video game shows promise in improving attention in young soccer players, there are clear limitations that should be explained. Among the most important limitations of this study is that the sample size was small. This study comprised 12 soccer players, all members of a youth team of a first-level soccer team of the Spanish League. Although they comprised 100% of the team and effectively represented that team, our findings cannot be generalized; hence, it would be interesting to increase the sample size to verify our data.

The duration of the intervention was 6 weeks. Future studies could evaluate the effect of the intervention over a greater period, verifying if the effect on the improvement of some attentional processes assessed using the GPET was positive. In addition, the timing of the season where this attentional training program was integrated through the video game may also have been a limitation. Future studies could evaluate what happens at different times of the season.

Furthermore, somatic variables such as EDA and EMG activity were evaluated. Undoubtedly, the complexity underlying their evaluation is an important limitation in terms of reproducibility. Nevertheless, these variables were analyzed with the aim of determining whether there were any somatic issues that prevented the soccer players from being able to play the video game and obtain the best possible results.

Finally, there is a contextual limitation regarding the analysis of attention in real soccer situations. Although the ecological nature of the GPET has been proven, it is still a test that evaluates only the attention mechanism and the decision mechanism in soccer situations. This limitation could be overcome if future studies investigate what happens during a real match after attention training using the video game. Nevertheless, this evaluation was performed using the GPET to standardize the procedure so that all participants were evaluated in the same way and under the same conditions.

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Acknowledgments

Sevilla FC (Football Club) deserves our heartfelt gratitude for generously granting us the opportunity to conduct this study. Their commitment to advancing knowledge and contributing to the sports community is truly commendable, and we are honored to have had their involvement in this endeavor.

We are very grateful to Enrique Arroyo for the fundamental work he has done in this study. His dedication is a symbol of effort and serves as a mirror for those of us who love sport.

Editorial Notice

This randomized study was only retrospectively registered. The editor granted an exception from ICMJE (International Committee of Medical Journal Editors) rules mandating prospective registration of randomized trials. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Conflicts of Interest

None declared.

Checklist 1
CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) checklist (V 1.6.1).
[PDF File, 367 KB - games_v12i1e52275_app1.pdf]

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Abbreviations

CG: control group
EDA: electrodermal activity
EG: experimental group
EMG: electromyographic
GPET: Game Performance Evaluation Tool

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Effects of a Virtual Reality Cycling Platform on Lower Limb Rehabilitation in Patients With Ataxia and Hemiparesis: Pilot Randomized Controlled Trial

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Abstract

Background: New interventions based on motor learning principles and neural plasticity have been tested among patients with ataxia and hemiparesis. Therapies of pedaling exercises have also shown their potential to induce improvements in muscle activity, strength, and balance. Virtual reality (VR) has been demonstrated as an effective tool for improving the adherence to physical therapy, but it is still undetermined if it promotes greater improvements than conventional therapy.

Objective: Our objective was to compare the effect on lower limb range of motion (ROM) when using VR technology for cycling exercise versus not using VR technology.

Methods: A randomized controlled trial with 20 patients with ataxia and hemiparesis was carried out. The participants were divided into 2 groups: the experimental group (n=10, 50%) performed pedaling exercises using the VR system and the control group (n=10, 50%) performed pedaling exercises without using VR. Measurements of the active and passive ROM of the hip and knee joint were taken before and after a cycling intervention, which consisted of 3 sessions of the same duration but with progressively increasing speeds (4, 5, and 6 km/h). Repeated measures ANOVAs were conducted to compare the preintervention (T_i) and postintervention (T_e) assessments within each group. Additionally, the improvement effect of using the VR system was analyzed by comparing the variation coefficient ($\Delta = 1 - [T_e / T_i]$) between the preintervention and postintervention assessments for each group. Group comparisons were made using independent 1-tailed *t* tests.

Results: Significant improvements were shown in active left hip flexion (*P*=.03) over time, but there was no group-time interaction effect (*P*=.67). Passive left hip flexion (*P*=.93) did not show significant improvements, and similar results were observed for active and passive right hip flexion (*P*=.39 and *P*=.83, respectively). Neither assessments of knee flexion (active left: *P*=.06; passive left: *P*=.76; active right: *P*=.34; passive right: *P*=.06) nor knee extension showed significant changes (active left: *P*=.66; passive left: *P*=.92; active right: *P*=.12; passive right: *P*=.38). However, passive right knee extension (*P*=.04) showed a significant improvement over time. Overall, although active and passive ROM of the knee and hip joints showed a general improvement, no statistically significant differences were found between the groups.

Conclusions: In this study, participants who underwent the cycling intervention using the VR system showed similar improvement in lower limb ROM to the participants who underwent conventional training. Ultimately, the VR system can be used to engage participants in physical activity.

Trial Registration: ClinicalTrials.gov NCT05162040; https://www.clinicaltrials.gov/study/NCT05162040

(JMIR Serious Games 2024;12:e39286) doi:10.2196/39286

KEYWORDS

ataxia; cycling; hemiparesis; lower limb; neuropathology; rehabilitation; virtual reality; limb; intervention; neural; neural plasticity; therapy; muscle; strength; balance; tool; exercise; physical activity; neuroplasticity

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Introduction

Background

Ataxia is an umbrella term for describing deficits in limb movement coordination such as dysmetria, dyspraxia, and dyssynergia [1]. The persistence of these deficits affects an individual's functional ability and poses a health challenge for both patients and clinicians.

Current scientific evidence indicates that the most effective treatment for ataxia should combine balance and coordination retraining and constraint-induced functional movement therapy [2]. However, the scientific literature still lacks a consensus on the details of these interventions and the timing of their implementation to enhance the recovery of the functionality of motor deficits in an individual [3].

On the other hand, in the field of neurophysiology, it is well known that to induce changes in neuroplasticity to achieve the functional recovery of motor deficits, the application of therapies based on the repetition of movements is required [4]. Some studies point out that the principles of motor learning are directly related to the regeneration of structures and the reorganization of neuronal function [5,6]. Moreover, the amount of practice is a key factor in motor learning, as well as the feedback provided during practice [7]. In fact, physical therapists must consider both the error feedback and activity guidance as 2 fundamental components of patient interaction during therapy to promote neuromotor learning [8]. Thus, interventions that promote normal function rather than the compensation of deficits are more recommended and should be applied to generate a physical activity plan based on the principles of motor learning and neural plasticity for patients with ataxic hemiparesis.

Prior Work

The scientific literature in the field of neurorehabilitation shows that pedaling exercises have the potential to induce improvements in muscle activity, strength, and balance [9]. This is mainly due to the fact that pedaling exercises based on the use of a cycloergometer provide a high number of flexion and extension repetitions [10] in the lower extremities for considerable periods of time. Because pedaling and walking are cyclical locomotor tasks that require the lower limb to alternate between flexion and extension [11,12], both share similar locomotor patterns of alternating muscle activation of antagonists [10,13]. Thus, cycling exercises are found to be useful for strengthening the lower limb muscles while acting as a pseudowalking task-oriented exercise. Some studies eluded that those biomechanical functions may be altered by the muscle groups involved in the pedaling tasks [14-16]. In fact, it was found that the degradation of pedaling performance in adults with hemiparesis was related to abnormalities in the execution of specific biomechanical functions [15]. Subsequently, it has been proven that human walking and cycling shared similar muscle synergies [16]. This evidence is the basis for rehabilitation treatments based on pedaling movements with potential positive outcomes for walking [16].

The ergometer is an equipment designed to perform cardiovascular work based on the alternative circular movement of the lower limb. Its use is advantageous for a muscle coordination study because balance is not an applicable factor in this kinematically constrained task [13]. In fact, applying an ergometer-based cycling routine could be useful because it requires no balance. Moreover, the exercise intensity of the ergometer-based cycling can be adapted to the user by adjusting the resistance of the pedal or the target speed. The ability to personalize the intensity of the exercise is a relevant factor for the patient's rehabilitation process. For these reasons, regular ergometer-based cycling is found to be a safer unsupervised exercise that is recommended for lower limb rehabilitation. Nevertheless, cycling exercise is also a static and repetitive form of exercise that leads to boredom and listlessness in patients. To deal with this discouragement factor, emerging technologies have been applied to elicit intrinsic motivation for rehabilitation patients [17]. Several studies pointed out the usefulness of gaming elements and virtual environments as assistive technology [18,19] and their potential effectiveness in physical therapies as opposed to conventional therapies [20].

Quite a few studies have focused on the analysis of functional metrics in virtual pedaling. A recent study evaluated the functionality of a virtual reality (VR) cycling training program that was applied to 10 patients with stroke [21]. It assessed the improvement of the bilateral asymmetry between the experimental group and the control group after the VR cycling intervention program. To evaluate this index, they equipped the ergometer pedals with force plates to determine the effect of the VR cycling training on each limb. The improvement of bilateral strength and standing balance was significantly different between VR cycling training and traditional physical training. Similarly, a previous study compared the effects of a cycling training program with extrinsic biofeedback and a nonimmersive interface versus traditional physical training on lower limb functional recovery in patients with stroke [22]. The results showed that improvements in walking endurance, walking speed, and muscle spasticity of the group using VR were significantly better than the group who underwent traditional physical training.

Objectives

The main objective of this study was to evaluate 2 different interventions: pedaling with VR and pedaling without VR. This study focused on comparing the improvements in lower limb range of motion (ROM) in pedaling activity between the group using VR and the group not using VR. To this end, a randomized controlled trial was carried out with patients with ataxia and hemiparesis. Hip and knee ROMs were measured before and after the cycling intervention. The overall aim of these analyses was to determine the effects of the 2 different interventions on short-term improvement of lower limb function and ROM.

Methods

VR System

The VR system implements extrinsic feedback strategies, gamification by levels, and personalization of the sessions with the aim of achieving greater adherence to pedaling exercise sessions. Its immersive nature means an increase in the sense of "presence," promoting the active involvement of the user.

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The VR system is based on the transmission of the cycling kinematic data captured by the inertial sensors to the Oculus Quest 2 (Meta) head-mounted display (HMD) via Bluetooth. Therefore, the virtual application estimates the pedaling cycles, cadence, and distance during the exercise activity. The VR scenarios generated for this therapy consist of mapping the cycling cadence to the vehicle speed. Thus, the patient is placed inside a vehicle and visualizes the session data on the control panel while moving at the speed of the pedaling motion.

The design of the VR experience has been technically validated computationally to ensure low latency in motion analysis and visual representation of motion [23], thus preserving the embodiment effect and the sense of presence. Subsequently, the platform has also been validated from the point of view of satisfaction and ease of use of the system [24]. Additionally, considering that it is a stationary experience with an HMD that simulates a displacement, we evaluated to which extent the VR experience generates the type of motion sickness that causes fatigue, nausea, disorientation, postural instability, or visual fatigue [25]. Indeed, we verified that the platform does not generate adverse effects due to cybersickness [24].

Recruitment

The participants were patients of both sexes between 18 and 90 years of age, recruited at the Lescer Clinic applying the inclusion and exclusion criteria. Inclusion criteria were as follows: individuals were eligible if they (1) had been prescribed pedaling exercise as treatment for lower limb rehabilitation and (2) were able to perform a pedaling session with VR technology. Exclusion criteria were as follows: (1) an insufficient cognitive state, (2) an unbound bone fracture, (3) severe disorders of vision or audition (inability to perceive visual or auditory information coming from VR), and (4) any incompatibility with the use of a VR system according to the clinical record. A sample of 22 participants (n=13, 59% male and n=7, 32% female; mean age 59.90, SD 13.56 y) volunteered to participate in this pilot randomized controlled trial (Table 1). Of this 22-person cohort, 1 participant dropped out of the study and 1 participant did not complete the study (Figure 1). The cohort was randomly divided into the experimental group (EG; 9/10, 90% male and 1/10, 10% female; mean age 60.80, SD 12.26 y) with VR cycling exercises or the control group (CG; 4/10, 40% male and 6/10, 60% female; mean age 59.00, SD 14.69 y) with traditional cycling exercises.

Table . Clinical and epidemiological features of the experimental group (EG) and control group (CG) participants.

Group and participant number	Sex	Age (y)	Etiology	Condition
EG				
1	Male	57	Ischemic stroke	Hemiparesis
2	Male	71	Hemorrhagic stroke	Ataxia
3	Male	53	Hemorrhagic stroke	Ataxia
4	Male	72	MCA[a] stroke	Hemiparesis
5	Male	53	MCA stroke	Hemiparesis
6	Male	62	Ischemic stroke	Hemiparesis
7	Male	59	Hemorrhagic stroke	Ataxia
8	Male	56	Progressive multifocal leukoencephalopathy	Ataxia
9	Female	86	Hemorrhagic stroke	Hemiparesis
10	Male	39	Ischemic stroke	Hemiparesis
CG				
1	Male	45	MCA stroke	Hemiparesis
2	Female	64	Hemorrhagic stroke	Ataxia
3	Male	58	Guillain-Barré syndrome	Hemiparesis
4	Female	41	Hemorrhagic stroke	Ataxia
5	Female	49	Ischemic stroke	Ataxia
6	Male	83	Ischemic stroke	Ataxia
7	Female	80	Hemorrhagic stroke	Hemiparesis
8	Female	72	Traumatic brain injury	Hemiparesis
9	Male	57	Ischemic stroke	Hemiparesis
10	Female	41	Guillain-Barré syndrome	Ataxia

[a]MCA: middle cerebral artery.

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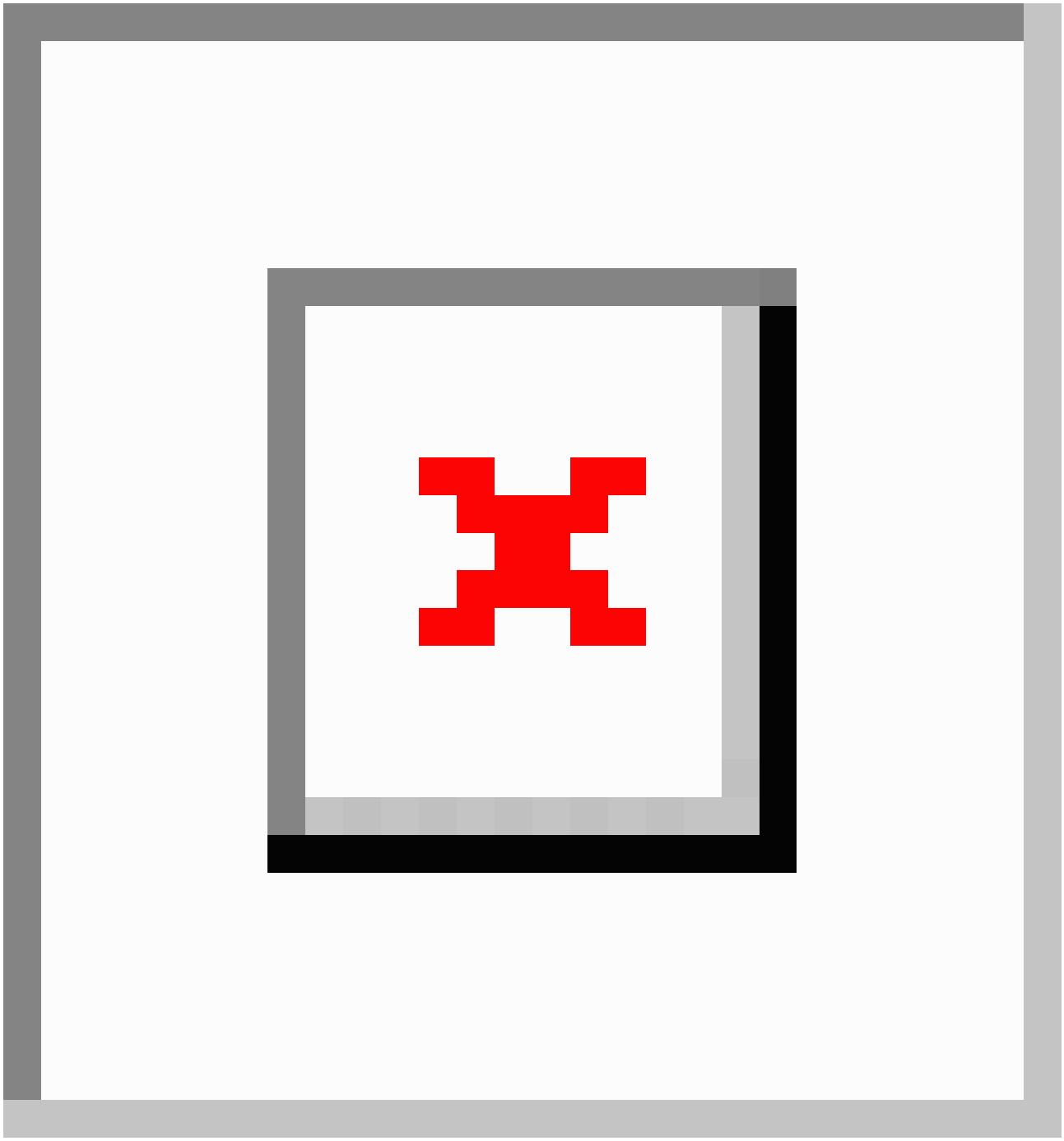
Figure 1. CONSORT (Consolidated Standards of Reporting Trials) diagram.



Ethical Considerations

Ethical approval was obtained from the Research Ethics Committee of the San Pablo CEU University (550/21/51). This study has been registered at ClinicalTrials.gov (NCT05162040). All the participants were given written information in accordance with the Research Ethics Committee. The informed consent and the ability for participants to opt out was provided. Additionally, participants were informed that the data collected in this study can only be used for this study, not for secondary studies. The approval of the Research Ethics Committee of San Pablo CEU University only covers this study and does not cover a secondary analysis without additional consent. However, no additional analysis had been carried out.

To ensure privacy and confidentiality, data are collected by employees of the agencies participating in the study. Each participant is assigned a unique code along with personal sociodemographic data and informed consent. These files remain in the custody of the principal investigator in charge of the project, while the assigned number is the one that identifies the anonymized data that was later analyzed. Finally, the participation in this study is completely voluntary; no compensation of any nature is offered to the human participants.

Intervention

This study was designed as a randomized controlled trial with 20 participants divided into 2 groups, following a block randomization method. The participants of the EG (n=10)

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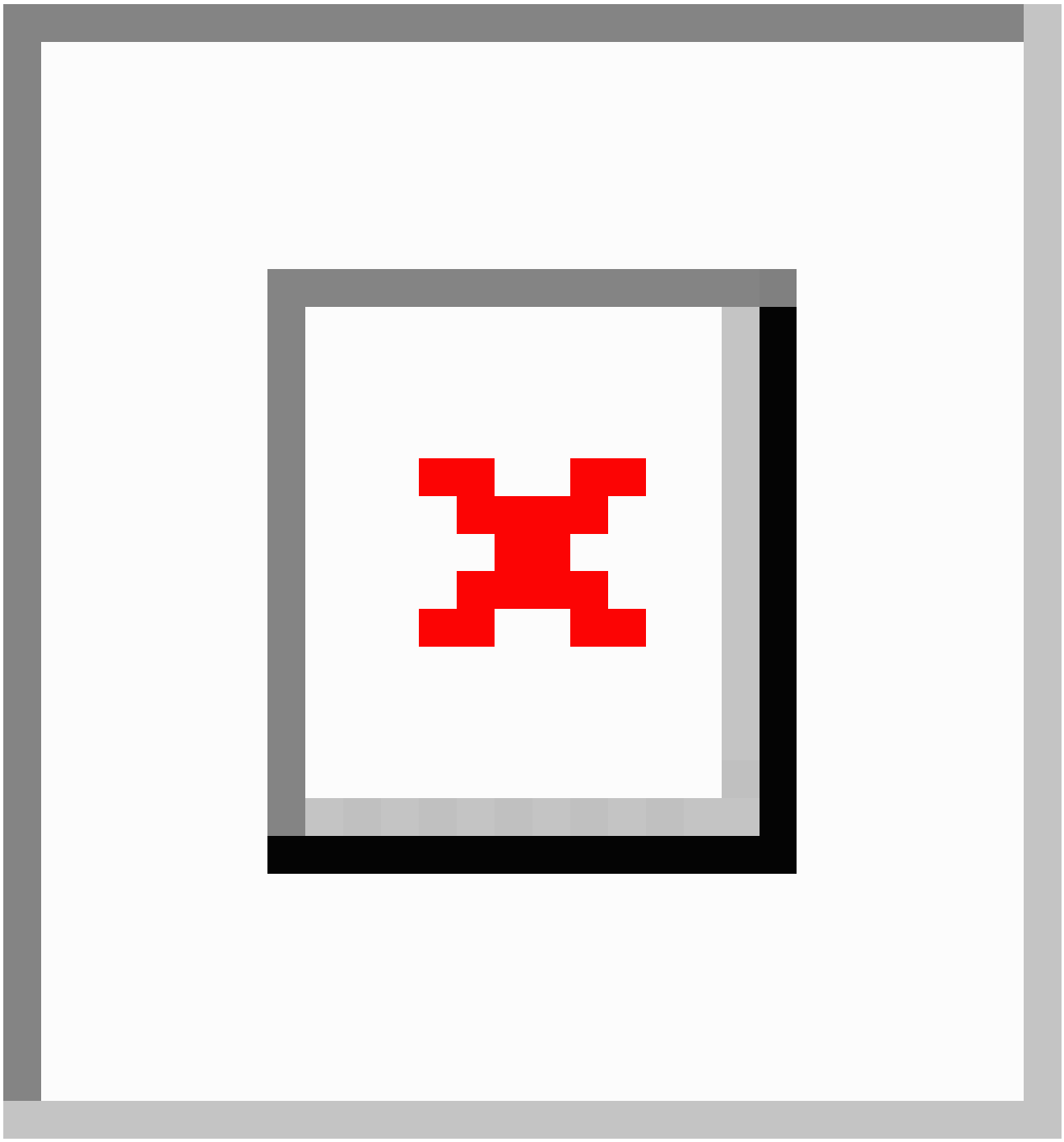
performed pedaling exercises while using the VR system, whereas the participants of the CG (n=10) performed pedaling exercises without using the VR system. Before and after completing the exercise program, measurements of gait function metrics and joint ranges were performed to assess the effect of using VR stimulus during the cycling exercises.

The participants completed the cycling intervention simultaneously with their rehabilitation sessions. Afterward, for each participant, 3 cycling sessions were scheduled over 1 week with a maximum of 48 hours between sessions. Each session consisted of 2 sets of a 5-minute pedaling exercise spaced with a 2-minute break (to rest). Similar studies [19,26] have tested robotic unicycles in pedaling sessions at a cadence of 60 revolutions per minute. In our case, the pedaling speed of 1 cycle per second is equivalent to a target speed of 6 km/h. For this reason, it was decided to set this speed as the maximum speed and to start the first session with a slightly more comfortable speed (4 km/h) and increase it progressively (Figure 2). The participants of both groups performed the exercise following a set pedaling speed so that they received visual feedback according to the set target speed of 4-6 km/h for each session. The EG participants received visual feedback through the immersive VR application, whereas the CG participants received visual feedback on the ergometer display. All participants were instructed to maintain a constant pedaling speed throughout the session at the target cadence.

Figure 2. Summary of the intervention program for experimental and control group participants. VR: virtual reality.



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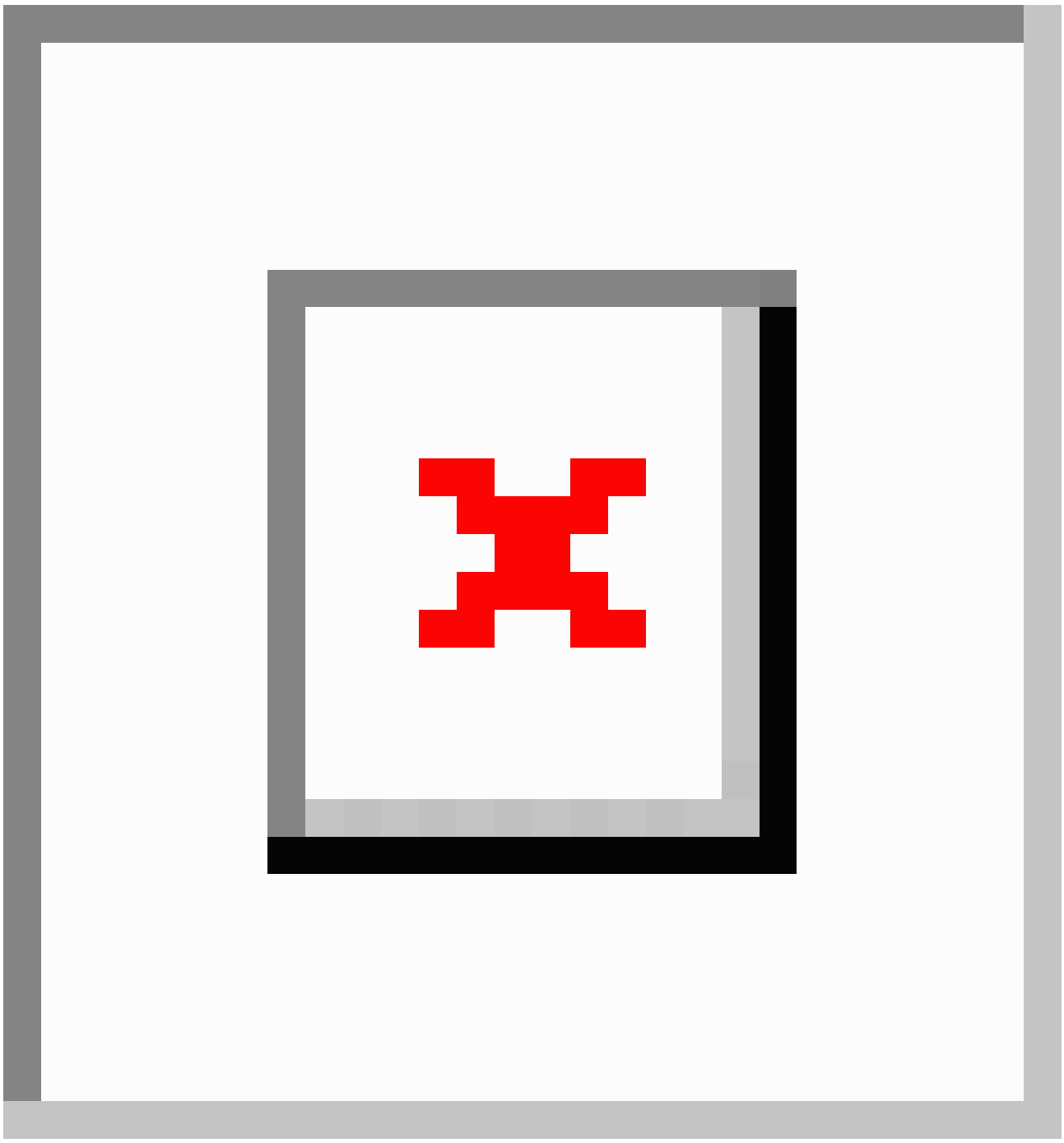
Physical Assessment

For the assessment of active and passive ROM of the hip and knee joint, a specifical ROM assessment tool was used. Measurements were extracted from biomechanical analysis using an inertial motion capture system (Werium; Werium Solutions) consisting of 2 inertial sensors: 1 placed in the distal part of the extremity (moving sensor) and the other in the proximal part (fixed sensor). Both sensors send their measurements via Bluetooth to a PC that runs the data acquisition software, Pro Motion Capture (Werium Solutions). This software computes the relative angle from both angle measurements (avoiding compensations) with an accuracy of 1 degree.

Protocol

The cycling sessions for both groups consisted of the use of a leg ergometer that allows training of the lower limb. Additionally, the EG used an inertial sensor placed on the right thigh and the Oculus Quest 2 HMD (Figure 3).

Figure 3. Cycling session of a participant in the experimental group using the virtual cycling platform.



The EG underwent the following procedure each session:

- The clinician connected the inertial sensor to the Oculus Quest 2 HMD.
- The patient was seated in a nonmovable chair (with no armrests) in front of the pedaling station during the entire session. The inertial sensor was placed on the right thigh

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of the patient by adjusting an elastic band, and the sensor was turned on.

- The clinician fitted the Oculus Quest 2 HMD comfortably on the patient and guided him or her through the selection of the game scene. Once the game environment was entered, the clinician indicated the number of minutes of exercise and the target speed of the session so that the patient could configure these parameters on the interactive settings panel.
- Finally, the user performed 2 sets of a 5-minute cycling exercise with a 2-minute break between the sets.

Similarly, the CG underwent the following procedure each session:

- The patient was seated in a nonmovable chair (with no armrests) in front of the pedaling station during the entire session.
- The clinician turned on the ergometer's display and entered the number of minutes of exercise and the target speed of the session.
- Finally, the user performed 2 sets of a 5-minute cycling exercise with a 2-minute break between the sets.

Statistical Analysis

The data analysis model is the repeated measures model between 2 groups and the analysis of the longitudinal effect in increments of the measurements. Multifactor ANOVA analysis (with $P<.05$) were computed with SPSS Statistics (version 27.0; IBM Corp). The sample size was calculated using the software tool G*Power (version 3.1.9.7; Heinrich Heine Universität Düsseldorf). Ideally, assuming an effect size of 0.7, a minimum sample of 20 participants was required for the study to provide consistent statistical results. Since the effect size shows the strength of the relationships, it represents a minimum clinically meaningful difference. Of the many different types of effect sizes, the G*Power software uses Cohen *d* to characterize effect size by relating the mean difference to variability. Therefore, his study standardized the effect size to 0.7 for sample size calculation and power analysis.

Results

To identify the underlying differences between the preintervention (T_i) and postintervention (T_e) assessments in each group, repeated measures ANOVAs were conducted with time ($T_i - T_e$) as the dependent variable and group as the main within-subjects factor. When the ANOVA was significant, the Bonferroni post hoc test was used. To ensure that the error variance of the dependent variables is equal across groups, the Levene test was applied beforehand for all the metrics.

In addition, to identify the improvement effect due to the use or nonuse of the VR system, the variation coefficient between the preintervention and postintervention assessments was analyzed for each group as follows: $\Delta = 1 - (T_e / T_i)$. The variation coefficient outcomes were compared between groups by the independent 1-tailed *t* test. The mean and SD of the ROM outcomes for the hip and knee of each group are shown in Table 2. The mean increase Δ for each measurement is shown in Figures 4 and 5.

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Table . Hip and knee range-of-motion outcomes.

Outcome	Experimental group, mean (SD)			Control group, mean (SD)		
	Preintervention (°)	Postintervention (°)	Variation coefficient (%)	Preintervention (°)	Postintervention (°)	Variation coefficient (%)
ALHF[a]	81.25 (36.09)	94.23 (32.26)	26.30 (33.52)	92.84 (21.40)	94.37 (25.83)	1.21 (14.20)
PLHF[b]	106.07 (21.16)	107.94 (17.63)	2.61 (5.81)	112.92 (17.76)	110.70 (16.83)	–1.43 (9.40)
ARHF[c]	97.55 (20.94)	97.13 (21.26)	0.28 (10.94)	97.11 (28.05)	101.79 (27.35)	5.60 (10.50)
PRHF[d]	106.63 (17.06)	109.82 (14.99)	3.69 (8.72)	119.74 (14.73)	117.71 (13.42)	–1.13 (8.72)
ALKF[e]	46.07 (14.62)	45.97 (11.47)	4.27 (26.31)	37.47 (12.03)	35.65 (8.47)	1.63 (30.86)
PLKF[f]	58.82 (9.84)	55.96 (9.79)	–3.48 (17.40)	57.14 (13.92)	54.58 (12.15)	–1.66 (19.96)
ARKF[g]	39.13 (16.54)	37.81 (10.68)	8.98 (35.88)	43.03 (10.00)	44.58 (13.32)	5.36 (30.29)
PRKF[h]	50.57 (10.02)	49.81 (10.31)	–0.65 (15.15)	63.35 (12.28)	57.28 (13.95)	–9.35 (15.17)
ALKE[i]	61.72 (14.86)	62.92 (13.11)	3.28 (9.74)	55.57 (17.13)	63.41 (11.77)	26.70 (51.68)
PLKE[j]	66.46 (11.74)	69.95 (15.09)	4.94 (15.92)	64.75 (11.94)	72.30 (12.46)	14.91 (24.40)
ARKE[k]	64.00 (10.11)	68.02 (10.14)	8.33 (20.67)	57.49 (14.91)	57.19 (14.76)	2.22 (23.52)
PRKE[l]	66.67 (11.53)	67.18 (10.93)	1.58 (14.10)	57.65 (11.21)	68.78 (6.67)	25.29 (34.70)

[a]ALHF: active left hip flexion.
[b]PLHF: passive left hip flexion.
[c]ARHF: active right hip flexion.
[d]PRHF: passive right hip flexion.
[e]ALKF: active left knee flexion.
[f]PLKF: passive left knee flexion.
[g]ARKF: active right knee flexion.
[h]PRKF: passive right knee flexion.
[i]ALKE: active left knee extension.
[j]PLKE: passive left knee extension.
[k]ARKE: active right knee extension.
[l]PRKE: passive right knee extension.

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Figure 4. Summary of increments in active and passive hip ROM parameters with SD bars. The vertical axis represents the percentage of postintervention increase or decrease of each hip ROM parameter. ALHF: active left hip flexion; ARHF: active right hip flexion; PLHF: passive left hip flexion; PRHF: passive right hip flexion; ROM: range of motion.

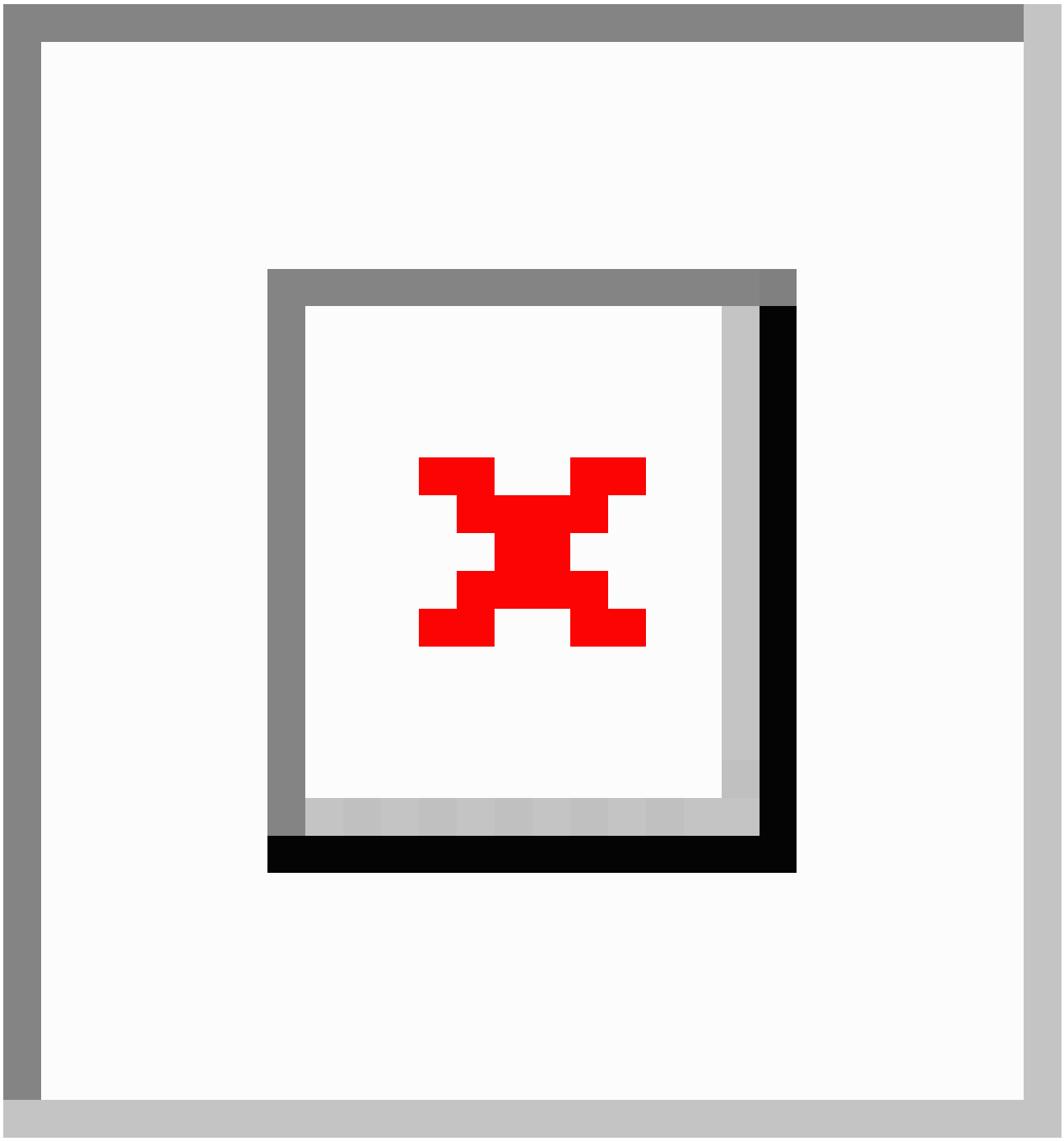

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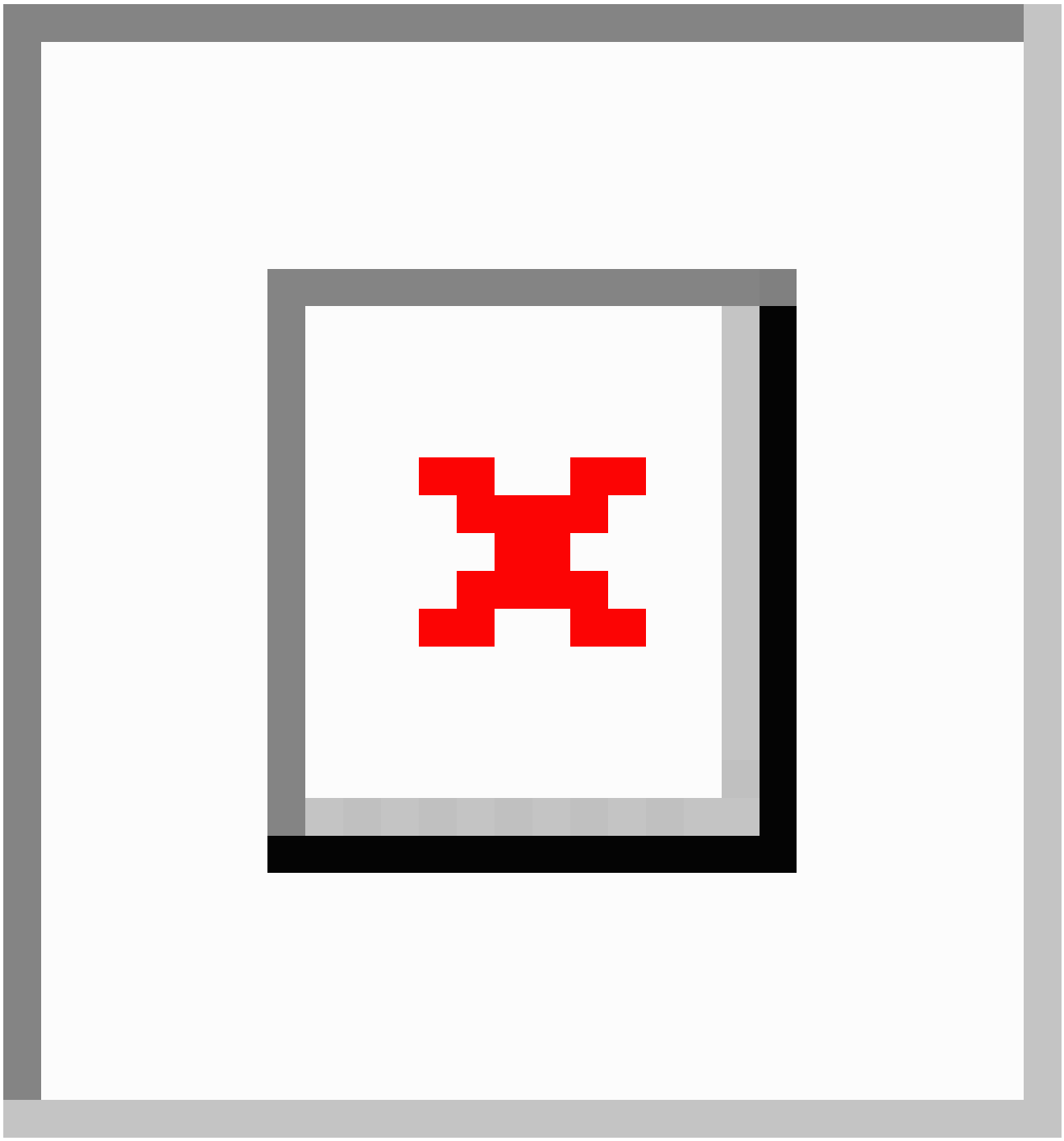
Figure 5. Summary of increments in active and passive knee ROM parameters with SD bars. The vertical axis represents the percentage of postintervention increase or decrease of each knee ROM parameter. ALKE: active left knee extension; ALKF: active left knee flexion; ARKE: active right knee extension; ARKF: active right knee flexion; PLKE: passive left knee extension; PLKF: passive left knee flexion; PRKE: passive right knee extension; PRKF: passive right knee flexion; ROM: range of motion.



With regard to the hip flexion outcomes, the active left hip flexion results were significant by ANOVA (*P*=.03), with no significance observed for the between-subjects effects test (*P*=.67). However, the within-subjects effects test was significant for the time factor (*P*=.03), but no significant group-time interaction effect was found (*P*=.08). Despite the opposing results showing passive left hip flexion improvements for each group, there was no significance difference by ANOVA (*P*=.93) and no statistically significant result was obtained by the between-subjects effects test. Passive left hip flexion was statistically significant in the within-subjects effects test for the time factor (*P*=.008). The active and passive right hip flexion results were not significant by ANOVA (*P*=.39 and *P*=.83, respectively). In both cases, no significant results were obtained for the between- and within-subjects effects tests.

For the knee ROM measurements, when analyzing the left knee assessments, the active and passive left knee flexion outcomes were not significant by ANOVA (*P*=.06 and *P*=.76, respectively). No statistically significant results were obtained by the between- and within-subjects effects tests in both cases. Similar results were obtained for the active left knee extension outcomes. Although reasonable differences in the active and passive left knee extension increases between groups can be

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observed in Figure 5, neither active nor passive left knee extension were significant by ANOVA (*P*=.66 and *P*=.92, respectively). No statistically significant results were obtained by the between- and within-subjects effects tests in both cases.

Regarding the right knee assessments outcomes, all outcomes were not significant by ANOVA (active flexion: *P*=.34; passive flexion: *P*=.06; active extension: *P*=.12; passive extension: *P*=.38). No statistically significant results were obtained by the between- and within-subjects effects tests for all cases, except for passive right knee extension, which was statistically significant for the time factor (*P*=.04) by the within-subjects effects test.

Discussion

Principal Findings

The aim of this study was to test the short-term effects of 2 different interventions on short-term improvement of lower limb function and ROM. For this purpose, a randomized controlled trial was carried out with participants with ataxia and hemiparesis.

In this study, the improvement outcomes of active and passive knee and hip joint ROMs due to the use of VR technology were inconclusive. Likewise, no statistically significant differences in the results between groups can be indicated. Even so, all the active ROMs measured—that is, performed by the patients—showed an increase with respect to the initial values. A greater disparity was observed in the passive measurements, although this may be attributed to the different passive mobilizations performed at each time by different physiotherapists. In this case, the active measurement is of special relevance in clinical terms because it indicates a ROM that the patient is able to achieve autonomously. On the other hand, large SDs in outcome variables clearly indicate that the improvements in the functional gait outcomes are not entirely consistent or represent a group effect. We observe that no significant effect can be attributed to VR intervention based on the statistical analysis of the immediate effects on gait function and joint ROM.

However, considering this similarity between groups, it can be pointed out that the use of VR has similar positive effects as the use of the conventional pedaling treatment. Thus, this immediate observation of effects leads us to conclude that the use of VR during pedaling exercise has similar effects to non-VR exercise training. Therefore, given that the use of VR technology does not worsen the improvement of lower limb ROM, and in line with the scientific literature [17-20], it may be advantageous to use it to maintain the patient's motivation.

Strengths and Limitations

A limitation of this study is the short-term nature of the intervention program. It is arguable that a longer intervention program would have shown more notable effects on functional improvement. However, assuming that it is precisely the treatment time that is one of the main causes of progress in physical improvement, the motivational impact of VR technology over time would need to be assessed. Therefore, further studies on the motivational impact of VR cycling versus conventional cycling on long-term physical activity remain to be addressed. Regarding these future studies, we suggest that cohort studies should be conducted among a population with more homogeneous neurological conditions. This recommendation is based on the limitations encountered in this study, where the difficulty of drawing conclusions about group changes or improvements with such wide SDs is presumably a reflection of the heterogeneity of the group.

Another factor to consider is that different physiotherapists were involved in taking the ROM measurements of the participants, although the measurement system was the same. This fact could be considered in future studies to evaluate interrater effects.

Future Directions

We consider it relevant to analyze, in future studies, whether these improvements in active and passive ROM are accompanied by greater muscle activation, in particular, the hamstrings, rectus femoris, gastrocnemius, and tibialis anterior muscles, as suggested by scientific literature [27].

Conclusions

The results of this trial demonstrate that pedaling exercises coordinated with VR technology works as successfully as conventional training for patients with lower limb disorders such as ataxia and hemiparesis. In this study, it was found that participants who performed the pedaling exercise program using the VR system showed similar results to the participants who performed the exercise activity without using VR technology. Overall, VR technologies can be a useful tool to help patients with ataxia and hemiparesis engage in lower limb exercise therapies.

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The funding sponsors have no role in the design of the study; the collection, analyses, or interpretation of data; the writing of the manuscript; and the decision to publish the result

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Data Availability

The data sets generated or analyzed during this study are available on the GitHub repository [28].

Authors' Contributions

AR contributed to software, data curation, formal analysis, and writing–original draft. ACC contributed to data curation and methodology. CL contributed to methodology, resources, and supervision. RR contributed to funding acquisition, supervision, and writing–review and editing. JCM contributed to funding acquisition, supervision, and writing–review and editing.

Conflicts of Interest

RR is the chief executive officer of Werium Solutions, and AR is a software developer at Werium Solutions. The other authors declare no conflicts of interest.

Checklist 1
CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) checklist (V 1.6.1).
[PDF File, 1274 KB - games_v12i1e39286_app1.pdf]

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Abbreviations

CG: control group
EG: experimental group
HMD: head-mounted display
ROM: range of motion
VR: virtual reality

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Original Paper

Exploring the Use of a Learning-Based Exergame to Enhance Physical Literacy, Soft Skills, and Academic Learning in School-Age Children: Pilot Interventional Study

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Abstract

Background: There is ample evidence that most children do not perform enough physical activity (PA). To address this major public health problem, the French government implemented 30 minutes of daily PA (DPA) at schools but did not provide any supplemental resources or concrete guidance. Considering both children's interest in video games and the need for teachers to complete their curriculum, the use of a learning-based exergame that combines PA and learning appears particularly relevant.

Objective: The first objective of this study was to evaluate the feasibility of implementing 30 minutes of DPA through exergaming among school-age children. The second objective was to examine the effects of an exergaming program on physical literacy, academic learning, and soft skills (motivation, self-efficacy, and concentration).

Methods: This interventional study had a pre-post design and used the Play LÜ exergame platform. The study included 79 children with a mean age of 8.9 (SD 1.2) years from grade 2 (7 years old) to grade 5 (11 years old). Play LÜ requires players to throw balls against a wall to reach a target or to activate an object and provides an interactive game area for educational activities linked to specific learning themes. After a 4-session familiarization phase during which the teachers chose to prioritize mathematics learning in 30-minute DPA sessions, students took part in DPA sessions over a period of 3 weeks with Play LÜ and a motor skills circuit behind the LÜ setup to keep them continuously active. All sessions were carried out by PA specialists. Each session started with a warm-up using the Grööve application, continued with main activities promoting mathematics learning adapted to each grade level, and ended with a 3-minute meditation for returning to a calm and serene state using the Gaïa application. Before (T0) and after (T1) the program, students completed a self-evaluation booklet to assess their levels of physical literacy, academic performance, and soft skills.

Results: The implementation of this exergaming program was welcomed by the school's administration, teaching staff, and parents. After the program, we observed increased scores for physical literacy (difference +2.6, percentage change +3.6%; W=933.0; P=.002; r_{rb}=−0.39, 95% CI −0.58 to −0.16) and motivation in mathematics (+0.7, +9.8%; W=381.5; P=.005; r_{rb}=−0.44, 95% CI −0.66 to −0.16). In addition, it is important to note that some measures progressed differently across learning levels and age groups.

Conclusions: The study results indicate positive impacts of learning-based exergaming on physical literacy and motivation in mathematics among school-age children.

(JMIR Serious Games 2024;12:e53072) doi:10.2196/53072

KEYWORDS

learning support; exergaming; physics playground; educational games; primary school; children

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Introduction

Background

Regular exercise and physical activity (PA) have been shown to benefit children's physical and social health, as well as their academic performance [1-3]. For children, the World Health Organization (WHO) recommends a minimum PA practice of 60 minutes of daily moderate-to-vigorous PA [4]. Yet, in France, only 41.8% of children reach these recommendations [5]. In other words, nearly 6 out of 10 children are physically inactive. In this context, the French national health strategy [6] has set as a major objective the implementation of a comprehensive policy of prevention and health promotion. As a result, since September 2022, primary schools have been required to provide 30 minutes of daily PA (DPA) to promote PA and encourage the development of children's motor skills and physical abilities. Distinct from the teaching of physical education (PE), the 30 minutes of DPA can take a variety of forms, adapted to the context of each school. They can be split up and combined over the various school and extra-curricular periods. This was extended to all elementary schools after 2 years of testing in 11,000 volunteer schools [7].

Given the significant amount of time children spend in school throughout their childhood, schools represent an ideal setting to achieve maximum impact with regard to improving PA levels [8,9]. Furthermore, several studies have suggested that combining PA with academic activities can improve children's health and cognitive functioning, which could subsequently lead to an improvement in children's academic performance [10-12]. Attention, in particular, which is a prerequisite for learning, is often targeted during classroom-based PA [13]. However, other variables, such as motivation and self-efficacy (referring to the child's perception of his or her capabilities), are well known to influence children's school performance and acquisition [14-17] and could be influenced by a more entertaining approach to learning via exergaming.

Despite all the benefits of implementing regular PA at school, in a systematic review, Nathan et al [18] highlighted several barriers, such as environmental context and resources with "a lack of time in the curriculum;" goals with "competing curriculum demands of other subjects" or "physical activity considered a lower priority than other subjects;" and beliefs about capabilities, such as a lack of teacher expertise and confidence in delivering PA, and intentions with "a lack of teacher motivation to implement PA" [18]. By contrast, the authors also mentioned several facilitators. Among them, the knowledge domain was indicated to play a facilitating role, for example, "sufficient knowledge about PA and health to effectively conduct PA" [18]. This dimension could be explored through the notion of physical literacy (PL), which corresponds to "the motivation, confidence, physical competence, knowledge, and understanding to value and take responsibility for engagement in physical activities for life" [19]. Indeed, PL is particularly important in early childhood, a crucial period for the development of fundamental movement skills [20] and the adoption of PA habits. Physically literate individuals are more physically active, spend more time playing sports, and are less sedentary. PL is a multi-level concept that is increasingly taken into consideration in the field of public health as it is a key determinant of PA habits across the lifespan [21].

One of the factors behind children's low levels of PA and high levels of sedentary behaviors is screen time use. Indeed, 71.7% of French boys and 58.5% of French girls aged 6 to 10 years have more than 2 hours a day of screen time [5]. Children aged between 8 and 12 years have 1.5 hours of daily screen time attributable to video games [22]. Over the last decades, video games have emerged as one of the most popular forms of global entertainment. Given children's keen interest in video games, it seems particularly appropriate to use gamification to encourage PA. For staying active while enjoying the pleasures of video games, a worthwhile alternative is exergaming. Indeed, exergaming or active video gaming requires bodily movements to play the game and encourages PA, with a focus on children's interest in the game's dynamics and stimulation. Our approach to exergaming takes into account a health dimension and can be associated with the conceptualization proposed by Oh and Yang [23], defining an exergame as "a video game that promotes (either via using or requiring) players' physical movements (exertion) that is generally more than sedentary and includes strength, balance, and flexibility activities."

Given that children spend most of their time at school, that they have a particular appeal for video games, and that exergaming seems to have beneficial effects on school learning [24], the use of exergaming at school appears to be an ideal solution for promoting PA, PL [25-27], and learning [28]. Furthermore, it appears that the use of a technology-based learning environment at school can increase soft skills, such as motivation and concentration on academic tasks [29]. Similarly, it has been shown that incorporating technology into an instructional intervention can improve students' sense of self-efficacy [30], which is a key variable for academic learning. Exergames, in particular, have been found to promote cognitive functions, motor skill training, enjoyment, and motivation to play among school-age children [31], and improve self-efficacy over traditional exercises [32]. Supporting this idea, it has been shown that exergaming (eg, Nintendo Wii Games [33]) incorporated into PE classes combined with health messages has a higher potential to enhance PA-related attitudes and behaviors than regular PE classes, especially in elementary school children [27]. An interesting exergaming tool for reconciling learning and DPA is the Play LÜ exergame platform (LÜ Interactive Playground) [34]. This technology can be used to change the traditional sports-school atmosphere into an interactive learning environment through interactive wall projection and a synchronized sound system. LÜ Playground activities are designed to improve the learning of children and adolescents by allowing them to respond to questions in specific fields (eg, mathematics, history, and natural sciences) by throwing balls against an interactive wall. This tool would therefore allow the practice of PA within non-PE curricula and thus ensure the 30 minutes of DPA among primary school children. Moreover, given the associations among cognitive functioning, soft skills, learning, and PA demonstrated in the literature, it appears essential to assess whether an exergaming program can improve these different variables.

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Objectives, Research Questions, and Hypotheses

The first objective was to study the feasibility of implementing 30 minutes of DPA through exergaming. Given that exergaming combines the interests of children (for video games) and teachers (for learning and respecting the curriculum) while promoting PA, we hypothesized that it will enable effective implementation of the 30 minutes of DPA in schools.

The second objective of this study was to evaluate the effects of an exergaming program on PL, academic learning, and soft skills (motivation, self-efficacy, and concentration). We hypothesized that implementing a DPA program involving exergaming on a specific academic course combined with information on health-promoting behaviors daily could increase children's PL (hypothesis 1) and increase academic performance (hypothesis 2). Indirectly, allowing students to work on an academic subject more entertainingly through exergaming could improve students' motivation in the academic discipline (hypothesis 3), their sense of self-efficacy in the subject (hypothesis 4), and their concentration in class and the academic subject (hypothesis 5).

Methods

Population

This study was conducted with children aged 7 to 11 years as part of the implementation of the 30 minutes of DPA policy. The study was designed as an interventional study with a pre-post design. It included children from grade 2 (7 years old) to grade 5 (11 years old) in a mid-sized city school in the southern part of France, who had never benefited from any intervention in the field of exergaming. Before the project, the study and objectives of this research were presented to the school administration and then to the teachers. This pilot study took place in a small school with 1 class per level and 1 teacher per grade, with each of them (n=4) having no experience of exergaming and volunteering to take part in the research protocol. This school was selected for its pre-existing collaboration with the research team and middle-school students (8th grade), as well as for the availability of a space that could be used to install the LÜ mobile setup over a period of several weeks.

Subsequently, the parents of the children in the classes concerned were informed that their children would be part of a research protocol on 30 minutes of DPA during school time. A request for parental consent was sent via the school administration to each parent. In the event of parental refusal (only 3 parents refused), the children's data were not analyzed. A habituation phase was then proposed, and the teachers were able to learn about the various potentialities of the LÜ tool, as well as the implementation of the 30 minutes of DPA by the project team. The intervention then began and lasted 3 weeks, and preintervention (T0) and postintervention (T1) assessments were conducted.

During the enrollment period, 102 children were eligible (Figure 1). However, owing to the absence of parental consent (n=3) or the absence of children at evaluation time 0 (n=6) or time 1 (n=11), the analyses were carried out on 79 children. This final sample was made up of 34 girls and 45 boys, with a mean age of 8.9 (SD 1.2) years.

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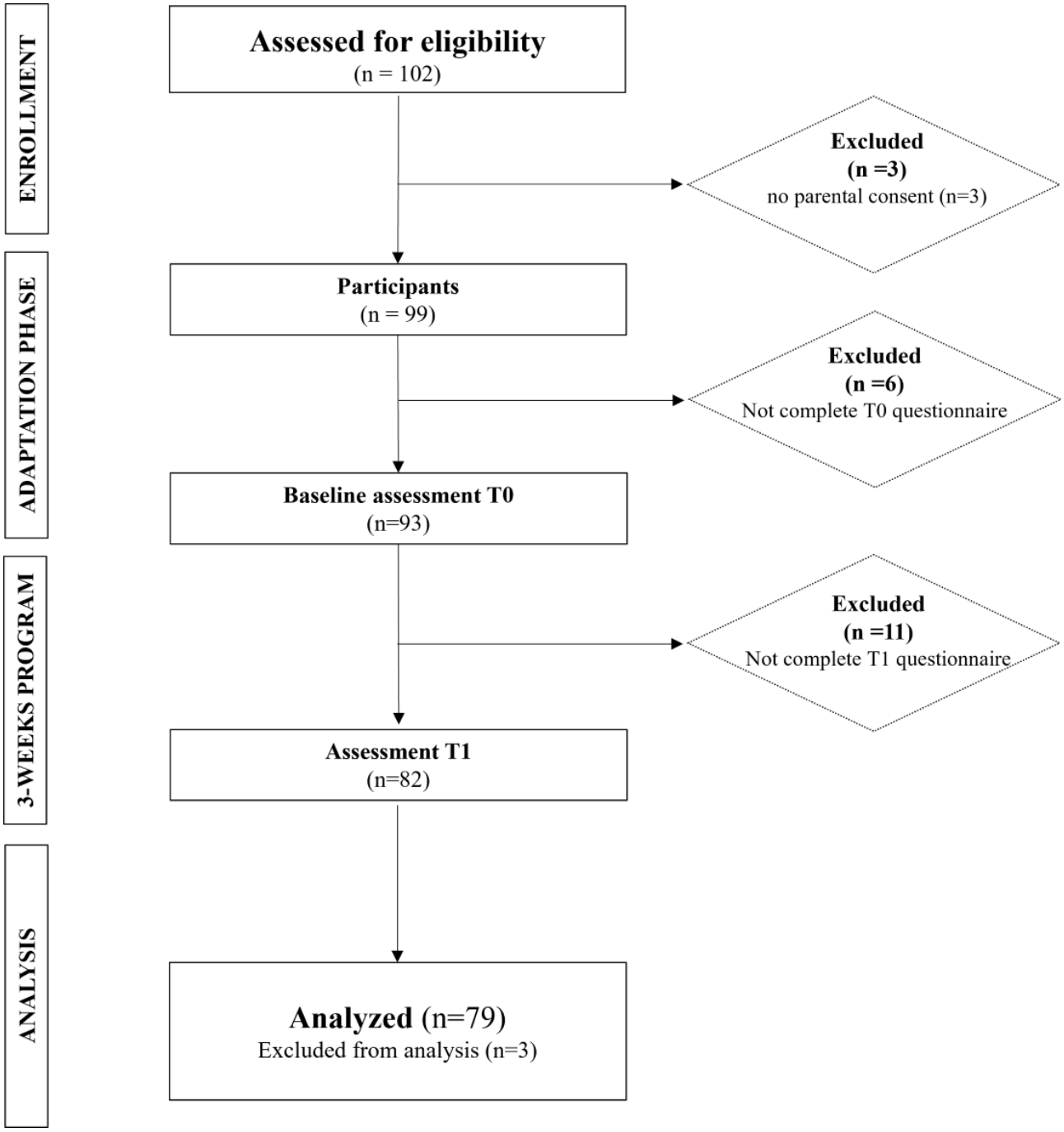
Figure 1. Study flow chart.



Class Measures

All the teachers expressed the wish to work on mathematics (geometry and arithmetic). A planning schedule was drawn up with the classes concerned so that the sessions could be scheduled during mathematics lessons.

Teacher Measures

At the end of the program, teachers were asked the following questions: On a scale from 0 to 10, how would you rate (1) your students' motivation for mathematics before the program? (2) your students' concentration for mathematics before the program? (3) your students' motivation for physical activity before the program? (4) your students' motivation for mathematics today? (5) your students' concentration for mathematics today? (6) your students' motivation for physical activity today?

Child Measures

At T0 and T1, students completed a questionnaire consisting mainly of analog visualization scales or checkboxes on different variables of interest (PL, motivation, self-efficacy, and concentration), which are described in the following sections. In addition, exercises adapted according to grade level were proposed in the target subject (mathematics) and a control subject (French).

Physical Literacy

PL was assessed using the Physical Literacy Assessment for Youth Self (PLAYself), designed for children aged 7 years or

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older, to explore children's perceptions of their PL [35]. PLAYself demonstrated robust psychometric properties, with good fit statistics, internal reliability, and a lack of item bias and problematic local dependency [36]. For a better understanding of the different dimensions of PL in the PLAYself questionnaire, the forms are available in English [37] and French [38] versions. The adaptation of this form within the evaluation booklet of this pilot project is available in Multimedia Appendix 1.

PLAYself consists of 22 questions divided into the following four subsections: (1) *Fitness*, which involves children's perceived fitness level with "disagree" and "agree" response categories for a single item; (2) *Environment*, which involves measures of 6 different environments in which children can do sports and activities (eg, "How good are you at doing sports and activities in the gym?") on a 5-point Likert scale ranging from 1 ("never tried") to 5 ("excellent"); (3) *Physical literacy self-description*, which involves 12 statements about doing sports and activities based on cognitive and affective factors (eg, "It doesn't take me long to learn new skills, sports, or activities"), where the children are asked to rank how well they agree on a 4-point Likert scale ranging from 1 ("not true at all") to 4 ("very true"); and (4) *Relative ranking of literacies*, which involves children's ranking of the importance of literacies in school, at home with family, and with friends (eg, "Math and numbers are very important in school") on a 4-point Likert scale ranging from 1 ("strongly disagree") to 4 ("strongly agree").

The first section is informative, while in the other 3 subsections, a separate score can be calculated and a total score can be obtained for PLAYself. The total PLAYself score is the average across the scores of each subsection, excluding the fitness question. A higher score (range 0-100) indicates a higher self-perceived PL.

Academic Achievement

To measure academic achievement, exercises in French and mathematics were retrieved from the national program by level following teacher school year progression. The test evaluated students' academic knowledge and skills related to specific subject areas, including French and mathematics. The test was grade-specific; did not contain any bias regarding age, gender, or ethnicity; and was scored as a percentage of achievement in French on one side and mathematics on the other.

Motivation, Self-efficacy, and Concentration

Motivation and self-efficacy were assessed by 2 items each, one for mathematics and the other for French. For motivation, children were asked: "How much do you enjoy doing [mathematics/French] exercises?" For self-efficacy, children were asked: "How well do you think you did on the [mathematics/French] exercises?" Concentration was assessed by 3 items, one for mathematics, one for French, and a more general one targeting concentration in class. For this variable, children were asked: "How easy is it to concentrate in [class/mathematics/French]?" We used a simple question per variable to reduce the time needed to complete the entire protocol. The items were formulated as clearly as possible to be adapted to the children's age and to ensure that they measure the core component of each variable. For all items, children were asked to respond using a 10-cm–long visual analog scale representing their feelings and marked by extreme labels at 0 cm (eg, very hard) and 10 cm (eg, very easy), which appeared as reliable response options in children's questionnaires [39].

Procedure

Habituation Phase

On Thursdays in March 2023, students had 4 LÜ 30-minute habituation sessions, spaced 1 week apart, enabling them to familiarize themselves with the interactive gymnasium. Activities linked to the academic development of the LÜ catalog were proposed, targeting language (ie, Minewörd), mathematics (ie, Wäk, Newton, Constello, and SphYnX), science and technology (ie, Brüsh and Grüb), history (ie, Stória), and arts (ie, Pixël). With mathematics accounting for one-fifth of the school program in each grade and the LÜ catalog offering more mathematics-related applications (except PE, which was not at the center of the project), the 4 teachers wanted to work on mathematics during the 3-week DPA immersion phase (Figure 2).

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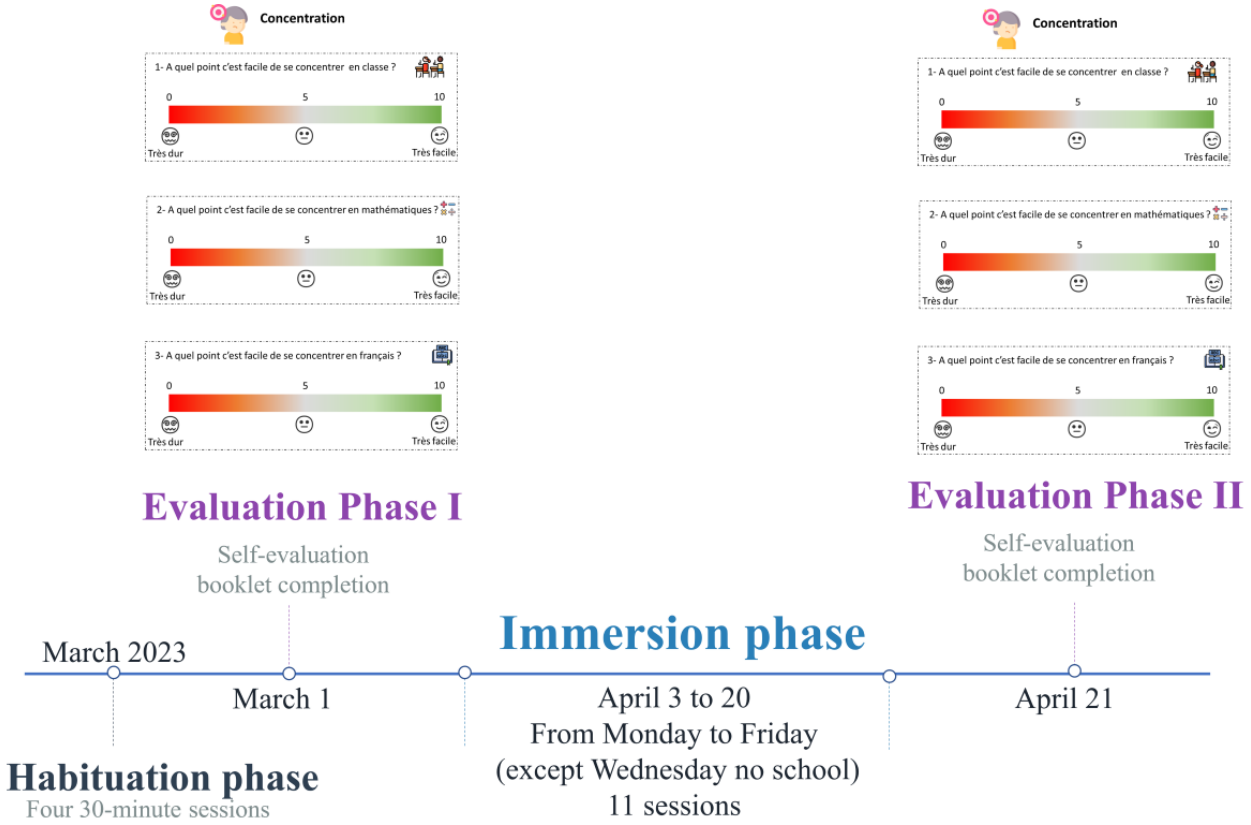
Figure 2. Timeline of the project.



Immersion Phase

After the habituation phase, students took part in 30-minute DPA sessions using the Play LÜ exergame platform and worked on a single subject selected by the teacher (Figure 2).

Exergame Setting

For this research protocol, the LÜ mobile equipment owned by the research team was made available to the school for this pilot project and was installed in a designated space for the duration of the project. The Play LÜ exergame platform (LÜ Interactive Playground) has the potential to overcome the limitations of a physical room. With Play LÜ, the participants are immersed in the games displayed on a giant projection wall (6×3 m). The principal mechanism of Play LÜ requires the players to throw balls against the wall (eg, to reach a target or to activate an object; Step 1 in Figure 3). In addition, this mobile platform offers an interactive game area for educational activities linked to specific learning themes (calculations, puzzles, etc). For this research protocol, a work area with a daily changing activity circuit was implemented behind the LÜ mobile setup (without the interactive wall). With class compositions ranging from 26 to 30 students, this "with" and "without" interactive wall configuration was essential to keep students active during the 30-minute session. Once the ball was sent to the interactive wall (Step 1), the student was required to go behind the LÜ mobile setup toward the back of the room (Step 2) to carry out various exercises to promote different motor skills (eg, jumping, throwing, and balancing) and perform other exercises on the way back (Step 3). At the end of the circuit behind the LÜ setup (Steps 2 and 3), the student waited for his or her turn in front of the interactive wall (Step 4).

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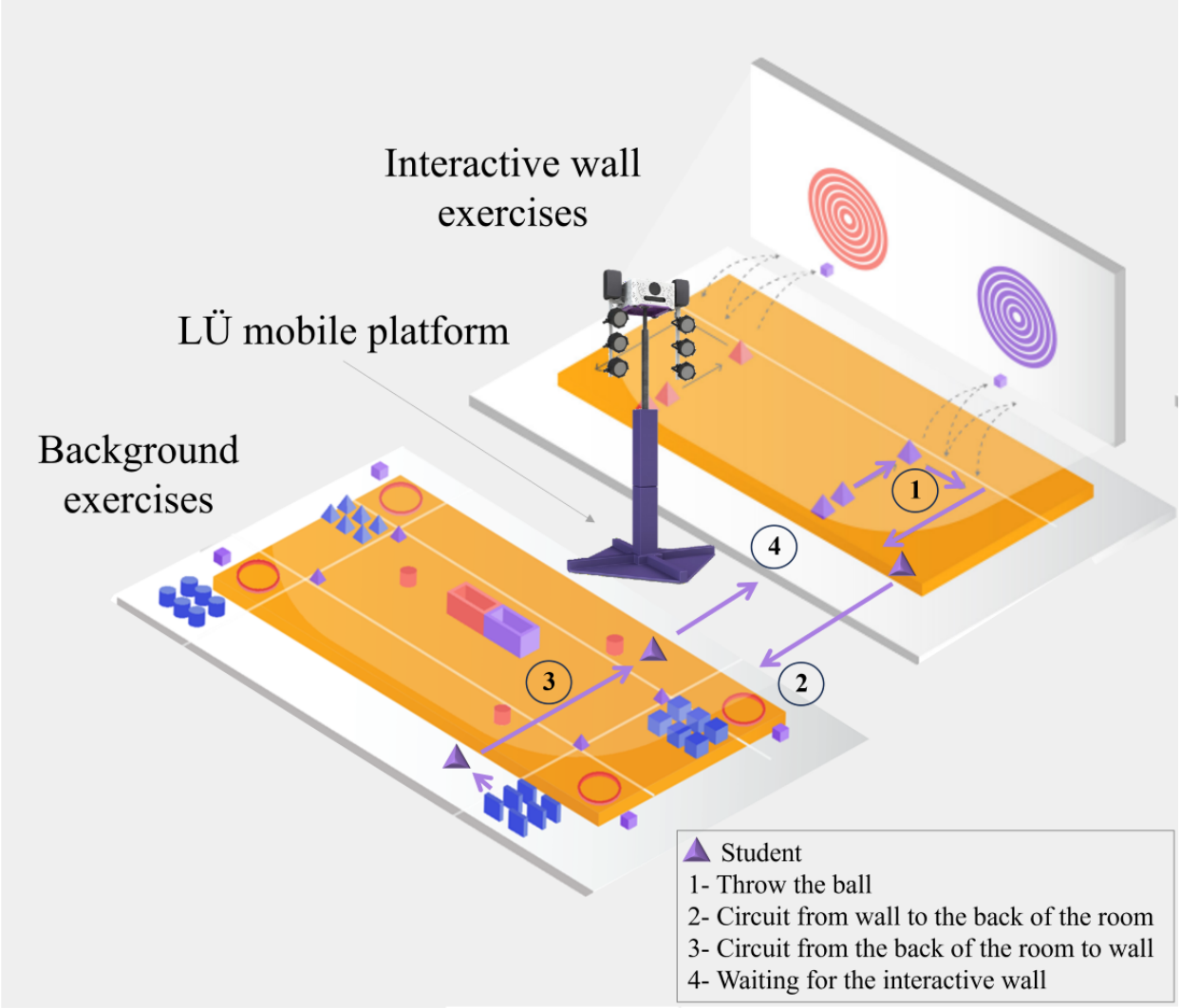
Figure 3. Practice environment implementation.



Daily Session Exercises With Play LÜ

During the 3-week immersion phase, sessions were structured in the same way, with a warm-up using the Grööve application at the beginning (Figure 4), which can be assimilated with the active video game Just Dance (Nintendo) [40], and then a core session promoting mathematics learning adapted to each grade, involving a section in front of the interactive wall with the Newton application for arithmetic and Puzz application for geometry (ie, with picture geometric forms or rules), and a section without the interactive wall consisting of a motor skills circuit (eg, throwing, jumping, and balancing) that enabled the child to be as active as possible (Figure 4). During break times (mainly while waiting for their turn on the interactive wall), the children had access to posters presenting active health behaviors with their favorite heroes according to age (ie, The Minions, Miraculous, and a successful French singer or Youtuber, depending on student age). The session ended with a 3-minute meditation for a return to peace and quiet, using the Gaïa application (Figure 4).

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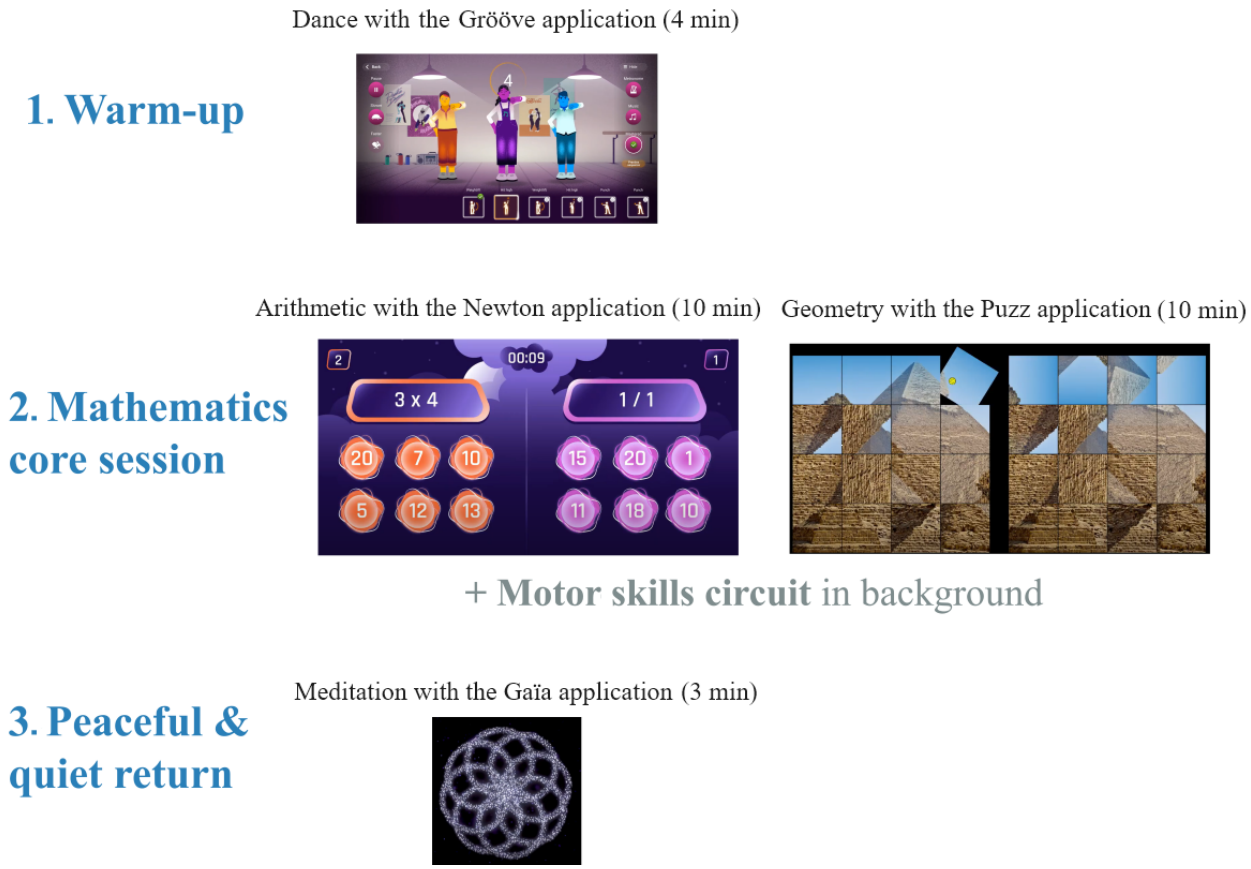
Figure 4. Daily physical activity core session details.



Focus on LÜ Applications

The Play LÜ exergame platform allows the use of applications (with or without customization) that can be used to meet general or specific learning objectives. The applications used during the immersion phase and their pedagogical benefits are summarized in Table 1.

Table 1. Play LÜ applications.

Application	Duration (min)	Description	Learning objectives		
			Academic development	Physical and motor development	Sociocognitive development
Grööve	4	This is a perfect warm-up and allows the development of gross motor skills.	• Movement • Dance	• Coordination • Cardiovascular endurance	• Cognitive flexibility • Inhibition
Newton	10	Newton is a fun way to combine physical activity and mathematics with the customization of equations by grade.	• Arithmetic	• Manipulation (throw the ball and aim at the target)	• Inhibition
Puzz	10	Throw the ball at a piece of the puzzle to rotate it and allow it to create an active knowledge competition.	• Puzzle created with geometry-related images • Spatial orientation	• Manipulation (throw the ball and aim at the target)	• Task engagement
Gaïa	3-5	This application helps students cool down after they have been active.	• Health and healthy habits	• Proprioception	• Emotional regulation

The customization of pre-existing games in LÜ was carried out on the Newton and Puzz applications for mathematics learning. For the Newton application, the difficulty of the operations proposed depended on each grade (eg, addition and subtraction calculations for grades 2 and 3, and multiplication calculations for grades 4 and 5). For the Puzz application, the images to be assembled were linked to the geometry program (eg, polygons

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and nonpolygons for grades 2 and 3, and complex polygons for grades 4 and 5).

Evaluation Phase

Before (T0) and after (T1) the 3 weeks of DPA (Figure 2), students completed a self-evaluation booklet to assess their levels of PL, academic performance, and soft skills that could be impacted by the program (eg, motivation, concentration, and self-efficacy).

At the end of the 3-week immersion phase, the students retook the same questionnaire, with only minor changes to the exercises (eg, 12+18 replaced by 14+15), but with the same instructions and level of difficulty. Following this, a short interview was conducted with the teachers, asking them to assess the changes observed in their classrooms.

All DPA sessions were carried out by sports science students specializing in adapted PA and health, under the supervision of a qualified teacher of adapted PA and health.

Statistical Analysis

Power analyses were conducted using G*Power (Heinrich-Heine-Universität Düsseldorf). For a pre-post comparison, with a medium effect size (0.50), an alpha error probability of .05, and a power of 0.95, we obtained a total sample size of 45. We then adjusted according to the number of participants available in the school, which allowed us to reach the sample size of 45.

As our data did not follow a normal distribution and given the characteristics of our sample, the intervention impact was tested with nonparametric within-group comparisons (T0 vs T1; Wilcoxon test, bilateral *P* values) for all participants and then by school-grade grouping. Effect sizes were expressed as the rank biserial correlation (r_{rb}) and its 95% CI. We also provided the score differences between T1 and T0, and expressed them as a percentage of improvement. Data were analyzed using JASP software (version 0.17.2.1; JASP Team).

Ethical Considerations

This pilot study involved an experiment in human and social sciences in the field of health. As mentioned in article R1121-1 section II subsection D of the French Public Health Code, this type of experimentation in human and social sciences does not require the authorization of the Committee for the Protection of Persons. Before the start of the study, a favorable opinion was obtained from the president of the University of Nîmes ethics committee. This individual verified that the study was conducted in accordance with institutional and national ethical standards, as well as the Declaration of Helsinki (2008). Moreover, this study was integrated into the school's activities and projects, and the protocol was validated by the school administration.

Consent to Participate

Concerning consent and information, the study was first presented to the school's teaching staff and administration who gave their approval to take part. Next, an online information notice and online informed consent form with the names and university affiliations of the experimenters were provided to the parents of all children in the classes involved in the study before initiation. Finally, the information and informed consent of the children and their teachers were collected face-to-face. Recruitment was based on voluntary participation, with no compensation for participants. Participants were informed that they could withdraw their consent at any time, whether at the request of the child, parent, or teacher.

Specific Measures Taken

To assure safety and security, all activities took place during class hours, under the supervision of the teacher, and the exercises were led by an associate professor specializing in public health and PA and two 3rd-year students in adapted PA from the University of Nimes. The expertise of the 3 animators enabled them to adapt the PA to the children's abilities in order to prevent any risk of injury. Moreover, the number of animators made it possible to provide individual support when needed. Finally, to guarantee the security of the data, they were stored on a secure university computer, and the printed versions of the data were kept in a secure cupboard in a university office.

Results

Feasibility of DPA and Exergaming

With regard to our first objective, which was to study the feasibility of implementing 30 minutes of DPA through exergaming, our results showed that implementing exergaming during school time is entirely feasible. First, regarding the parents, all but 3 were in favor of their children taking part in the project. Second, regarding the teachers, all agreed to take part in the project. Third, all scheduled sessions (n=11) were carried out, with no sessions canceled. External constraints, such as educational visits or other activities, could have led to cancellations, but the teachers expressed a desire not to miss any sessions and agreed to exchange schedules with other classes when constraints arose, demonstrating their interest.

Effects of the Exergaming Program

Effects on the Entire Cohort

With regard to our second objective for the whole cohort, the 3-week intervention of DPA led to increased scores in PL (in accordance with hypothesis 1) and motivation in mathematics, which was the subject covered in the intervention (in accordance with hypothesis 3). There was a general improvement regarding concentration in class, and we expected (hypothesis 5) this increase to be observed for mathematics as well (Table 2). In addition, contrary to our assumptions, we did not observe any changes in academic performance (hypothesis 2) or feelings of self-efficacy (hypothesis 4) in mathematics. Surprisingly, the intervention also favored French learning, which was not covered in the intervention, with academic performance, concentration, and self-efficacy in French being higher after the intervention.

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Table 2. Descriptive analyses of variables of interest before (T0) vs after (T1) the 3 weeks of daily physical activity in the whole cohort (N=79).

Variable	Score before the program (T0), mean (SD)	Score after the program (T1), mean (SD)	Difference (T1-T0), value (% change)	*W*	*P* value	r_{rb}[a], value (95% CI)
Physical literacy	70.8 (13.6)	73.4 (13.3)	+2.6 (+3.6%)	933.0	.002[b]	−0.39 (−0.58 to −0.16)
Academic achievement						
Mathematics	63.6 (32.5)	60.8 (31.0)	−2.8 (−4.4%)	1440.0	.35	0.12 (−0.13 to 0.37)
French	59.3 (26.2)	65.0 (27.9)	+5.7 (+9.6%)	858.0	.05[b]	−0.26 (−0.50 to 0.00)
Motivation						
Mathematics	7.1 (3.6)	7.8 (3.0)	+0.7 (+9.8%)	381.5	.005[b]	−0.44 (−0.66 to −0.16)
French	5.3 (3.2)	5.6 (2.9)	+0.3 (+5.6%)	1222.0	.48	−0.09 (−0.34 to 0.16)
Concentration						
Classroom (general)	5.5 (3.0)	6.0 (2.7)	+0.5 (+9.0%)	934.5	.07	−0.24 (−0.48 to 0.01)
Mathematics	7.0 (3.2)	7.2 (2.8)	+0.2 (+2.8%)	580.0	.16	−0.21 (−0.48 to 0.08)
French	5.6 (2.7)	6.4 (2.8)	+0.8 (+14.2%)	838.0	.01[b]	−0.34 (−0.55 to −0.09)
Self-efficacy						
Mathematics	6.8 (2.8)	7.2 (3.1)	+0.4 (+5.8%)	887.5	.30	−0.14 (−0.40 to 0.13)
French	6.1 (3.1)	6.7 (2.8)	+0.6 (+9.8%)	728.5	.02[b]	−0.32 (−0.54 to −0.05)

[a]Rank biserial correlation.

[b]Statistically significant.

Effects on Grade 5 Participants

Focusing specifically on each grade (see Multimedia Appendix 2 for full details), participants in grade 5 were those most affected by the intervention.

After the intervention, grade 5 participants showed an increase in PL (difference +5.6, percentage change +7.9%; *W*=9.0; *P*<.001; r_{rb}=−0.91, 95% CI −0.96 to −0.78; hypothesis 1), mathematics motivation (+1.1, +20.0%; *W*=15.5; *P*=.007; r_{rb}=−0.77, 95% CI −0.91 to −0.43; hypothesis 3), and mathematics concentration (+0.8, +12.7%; *W*=21.5; *P*=.01; r_{rb}=−0.68, 95% CI −0.88 to −0.27; hypothesis 5) scores. Regarding French classes (even though they were not targeted by the intervention), grade 5 participants demonstrated an increase in motivation (+0.8, +17.7%; *W*=60.0; *P*=.05; r_{rb}=−0.48, 95% CI −0.76 to −0.03) and self-efficacy (+1.5, +29.4%; *W*=45.0; *P*=.02; r_{rb}=−0.57, 95% CI −0.81 to −0.14) scores after the intervention. They also tended to show an increase in academic achievement scores in French after the intervention (+7.3, +11.4%; *W*=53.0; *P*=.09; r_{rb}=−0.44, 95% CI −0.75 to −0.03). Contrary to hypothesis 1, grade 5 participants showed a decrease in academic achievement scores in mathematics after the intervention (−10.7, −13.6%; *W*=192.0; *P*=.006; r_{rb}=0.66, 95% CI 0.29 to 0.85).

Effects on Grade 2 to 4 Participants

The other grades also benefited from the intervention but to a lesser extent. After the intervention, grade 2 participants showed an increase in PL scores (difference +5.2, percentage change +7.1%; *W*=28.0; *P*=.03; r_{rb}=−0.58, 95% CI −0.84 to −0.11; hypothesis 1) and a marginal increase in academic performance in mathematics (+15.1, +33.7%; *W*=18.5; *P*=.06; r_{rb}=−0.59, 95% CI −0.86 to −0.06; hypothesis 2). Grade 3 participants showed an increase in mathematics concentration (+0.5, +7.5%; *W*=50.5; *P*=.04; r_{rb}=−0.51, 95% CI −0.79 to −0.07; hypothesis 5) after the intervention. Regarding French classes, grade 2 participants showed a marginal increase in self-efficacy scores (+1.0, +14.4%; *W*=24.0; *P*=.07; r_{rb}=−0.54, 95% CI −0.83 to −0.01), grade 3 participants showed a significant increase in academic performance (+16.8, +40.1%; *W*=68.0; *P*=.01; r_{rb}=−0.58, 95% CI −0.80 to −0.21), and grade 4 participants showed a marginal increase in concentration (+1.1, +20.7%; *W*=25.0; *P*=.09; r_{rb}=−0.52, 95% CI −0.82 to 0.01) after the intervention. Grade 4 participants showed a decrease in academic performance in French after the intervention (−15.0, −19.8%; *W*=103.5; *P*=.01; r_{rb}=0.72, 95% CI 0.33 to 0.90).

Effects on Teachers' Perceptions

Concerning the results obtained from teachers, 3 out of 4 teachers observed an improvement in their students' motivation for mathematics after the program (grade 2, T0=5.5 vs T1=7.5; grade 3, T0=7.0 vs T1=7.5; grade 5, T0=8.0 vs T1=8.5), and 1 teacher observed no change (grade 4, T0=6.0 vs T1=6.0). In addition, 2 out of 4 teachers observed an improvement in their students' concentration for mathematics after the program (grade 2, T0=6.0 vs T1=6.5; grade 4, T0=3.0 vs T1=5.0), and the other 2 teachers observed no change (grade 3, T0=6.0 vs T1=6.0; grade 5, T0=6.5 vs T1=6.5). Finally, regarding students' motivation for PA, only 1 teacher observed an increase (grade 2, T0=8.0 vs T1=9.0). It should be noted that 2 of the teachers who observed no change (grades 4 and 5) had already identified

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the maximum motivation score before the start of the program. The last teacher rated the students' motivation at 9.0 before and after the program.

Discussion

Principal Findings

Since September 2022, primary schools have been required to provide 30 minutes of DPA. In this pilot study, the implementation of an exergaming program as part of the 30 minutes of DPA policy was welcomed by the school's administration, parents, and teachers, with an increase in perceived motivation for mathematics.

After the program, we observed that children showed increased scores in PL and motivation in mathematics following 11 learning-based exergaming sessions.

Exergaming Implementation

Although this PA reform is recent in France, it has already been introduced in other countries several years ago. Indeed, the DPA school policy has been implemented since 2005 in Canada to promote active lifestyles for children in school settings [41], and in the province of Ontario, all elementary school children perform DPA during instructional time [42]. Yet, 10 years later (in 2015), it was revealed that only half of Ontario teachers were meeting this expectation [43], and this number dropped to 23% 5 years later in the report by Martyn et al [44]. The Canadian experience underscores the need to explore effective and sustainable methods for implementing the 30 minutes of DPA in schools. Consequently, this pilot study shows that exergaming can be used as a valuable tool in the deployment of DPA at schools.

Efficiency and Usefulness of Exergaming

Our second objective was to find out whether an exergaming intervention could be effective and useful. We hypothesized that implementing a DPA program involving exergaming on a specific academic course could have an impact on different aspects of a child's experience. First, in line with hypothesis 1, our results showed a significant increase in the PL of the entire cohort, with significant increases of over 7% for both grades 2 and 5. This result is all the more important as it has been highlighted that elevated PL leads to greater PA participation, resulting in positive physiological, social, and psychosocial adaptations, and thus improved physical, mental, and social health [45]. In other words, PL could play a role across the lifespan in promoting positive health. Therefore, exergaming seems to be an effective and useful instrument to promote PL. This observation is in line with the review by Sun [46], which highlighted that active video gaming could contribute to enhancing children's PL, in particular on the motivational aspect of exergaming, making it possible to provide a variety of opportunities to develop or reinforce basic motor skills among children.

Second, concerning motivational aspects, in line with hypothesis 3, our results showed an overall positive effect on students' motivation toward the discipline. Indeed, we found an increase in motivation for mathematics (target subject), with a significant increase of almost 10% for the total cohort, while motivation for French (control subject) was not impacted. It seems that allowing students to work on mathematics more entertainingly (ie, by throwing balls onto calculation operations) helps to increase their appeal in this course.

Third, contrary to hypotheses 2, 4, and 5, our results showed no increase in academic performance, motivation, and sense of efficacy in mathematics, but they showed an increase in these variables in French, even though this subject was not directly targeted in the sessions. Although the interpretation is limited without a control group that did not benefit from the intervention, it is conceivable that the participants benefited from additional motivational resources provided by the 30 minutes of DPA toward learning at school, in accordance with the results of Vazou et al [16] regarding motivation and self-efficacy. An argument in support of this explanation may be the marginal increase in general concentration in class for the total cohort, as has been observed in the review by Taras [47], which noted an immediate increase in concentration in students after PA. This overall concentration may have benefited all subjects, especially those frequently considered less difficult than mathematics (ie, French).

Finally, it is important to note that the positive effects of the intervention were found in all school grades, even if a greater benefit was observed in grade 5. As the ability to apply skills or knowledge learned during one activity to another activity is evidence of a transfer process, older children are likely to be more sensitive to it [48]. Indeed, in this study's intervention, the children were learning with different tasks and objectives (in DPA exergaming and their normal lessons). The transfer of skills from one to the other was therefore not obvious (even if the "mathematics" cue was common to both) and remains a particularly demanding cognitive process for which the children need to be motivated. Decreases in academic performance in French and mathematics (grades 4 and 5) may be explained by constraints in the classrooms, as the teachers were rotated during the semester and the last data collection took place the day before the vacation (the participants were less involved overall in the academic exercises required). However, the marginal increase in mathematics performance in grade 2 and the increase in French performance (overall cohort and grade 3) demonstrate the importance of continuing to test this intervention.

Practical Implications in the Educational Context

Learning-based exergames can be powerful allies in the implementation of the DPA policy at schools. For schools and educational teams, the first obstacle could be the associated cost. In France, the Ministry of Education has launched a call for projects entitled, "Pour un socle numérique dans les écoles élémentaires" ("for a digital base in elementary schools") [49] to equip the schools of tomorrow. In this context, it is necessary to create links between the worlds of research and education. Researchers need to present teachers with the advantages (ie, academic performance, self-efficacy, motivation, PL, PA, and sedentary behavior) and constraints (ie, update, group management, and security) of this type of practice to make the teachers as efficient as possible in different teaching situations. Indeed, as part of the 30 minutes of DPA policy in elementary

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schools, one of the major difficulties is sustaining the actions and motivation of teachers, as presented in the Canadian study [43,44]. Once the equipment has been acquired and installed in a fixed position (ceiling-mounted model), one of the solutions for maintaining motivation among teaching teams would be to integrate PA professionals into the internship framework. This option enables teachers to not only benefit from the specific skills of the trainees but also position themselves as observers of the class, to be able to work on specific notions during PE teaching [18].

Limitations

In the context of this pilot study, which focused mainly on implementation feasibility and learning, it would have been interesting to consider the children's physical fitness (ie, muscular strength, agility, and cardiorespiratory fitness) and general state of health. Indeed, a French longitudinal study with a 3-year follow-up of children aged 7.7 years at the start of the study showed that the physical fitness of French youth decreased between childhood and early adolescence [50].

It would also have been interesting to compare the effects of this program with a control group. For example, it would have been worthwhile to compare the scores of the experimental group involving exergaming and targeted school exercises to 2 control groups: the first one with no PA and no school exercises, and the second one with no PA but with school exercises identical to the experimental group (eg, on a tablet computer). To verify the validity of the results, it would also have been necessary to vary the targeted school exercises (eg, mathematics and French; randomizing their inclusion in the intervention to ensure that the most difficult material is not the only one tested). Moreover, this study was carried out in a single school with a single class per level. It would be worthwhile to increase the size of the cohort by increasing the number of classes per level in different schools. Furthermore, our program had a limited duration (3 weeks), and a longer program (at least 1 trimester) with more DPA sessions would undoubtedly have increased the effects we observed and allowed additional benefits to be observed. In future studies, it would be interesting to compare the effects of a short program like ours with those of a longer program, and this could shed light on the duration of effects through time (in particular, following longer interventions).

Perspectives

Future studies could explore the possible diffusion effects of enhanced DPA interventions with or without exergaming on various PA indicators (eg, physical fitness, increased mobility by accelerometry, sedentary time and breaks, and increased implication in PE curricula at school). It would also be useful to conduct a longitudinal study to measure the impact of exergaming on not only PA and fitness levels but also the evolution of overweight and obesity in children.

Furthermore, in future studies, it could be relevant to assess intervention effects on students' academic performance, motivation, and self-efficacy in specific academic courses during interventions, or general attitudes and performances in different courses. Finally, specifying various student profiles concerning these measures (eg, depending on the initial levels of PL and PA, and depending on age or grade) could provide information on the subgroups of children benefiting the most from such exergaming interventions. In addition to student characteristics, it might be useful to consider teacher characteristics (eg, attitudes toward exergaming) to better understand the individual and environmental factors likely to moderate the effects of such interventions.

Conclusions

As part of the 30-minute implementation of DPA, the use of learning-based exergaming showed very interesting results in increasing PL as well as student motivation toward mathematics. Furthermore, supporting pedagogical teams with qualified teachers in PA has been proven to be beneficial for both students and staff.

With this encouraging pilot study, it is necessary to continue investigations by increasing the number of students per grade and to carry out research over a longer school period with a control group to confirm these results regarding the use of learning-based exergaming with Play LÜ within the framework of DPA.

Acknowledgments

We would like to thank the school (administration and teaching staff) for allowing us to carry out this pilot study.

Authors' Contributions

AG conceptualized and supervised the project, and contributed to the data collection and processing, project administration, and writing of the original draft. FL, GB, EVC, and EC conceptualized and supervised the project and were involved in reviewing and editing the manuscript. FL contributed to the statistical analysis. AP was involved in daily physical activity implementation supervision and physical literacy during the session. ED and NAB were students in adapted physical activity who carried out the daily physical activity sessions as part of their end-of-year internship.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PlaySELF adaptation questionnaire.

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[PDF File (Adobe PDF File), 255 KB - games_v12i1e53072_app1.pdf]

Multimedia Appendix 2
Effects of the exergaming program according to grade.
[DOCX File , 39 KB - games_v12i1e53072_app2.docx]

Multimedia Appendix 3
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1325 KB - games_v12i1e53072_app3.pdf]

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Abbreviations

DPA: daily physical activity
PA: physical activity
PE: physical education
PL: physical literacy

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Original Paper

Understanding Senior Adults' Needs, Preferences, and Experiences of Commercial Exergames for Health: Usability Study

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Abstract

Background: Many senior adults are at risk of mental and physical disorders due to a lack of sufficient exercise. Therefore, adherent exercise should be urgently promoted to improve senior adults' muscle strength, preventing falls and conditions caused by physical and cognitive decline. However, off-the-shelf exercise games, so-called exergames, are mainly targeted at the younger generation or children, while senior adults are neglected, when this age group strongly needs exercise. Exergames could serve as a health intervention for promoting exercise.

Objective: This study aimed to investigate senior adults' experience, perceptions, and acceptance of game technology to promote exercise in order to suggest game design guidelines.

Methods: In this usability study, participants engaged in playing Nintendo Switch and Xbox Kinect games, after which semistructured interviews were conducted. Before the gameplay, the participants provided their background information, exercise habits, and use of technology products. Next, all participants completed a workshop including 3 activities (brief instructions on how to play the games: 20 minutes; playing the selected exergames: 80 minutes; semistructured interviews: 20 minutes) for 2 hours a day for 3 days each. The participants played the latest Nintendo Switch games (eg, Just Dance, Boxing, Ring Fit Adventure) and Xbox Kinect games (eg, Kinect Adventures!, Mini Games). Just Dance, Zumba, and Boxing were played in activity 1; Ring Fit Adventure and Mini Games in activity 2; and Kinect Adventures! in activity 3. Reflexive thematic analysis was applied to identify the relative themes generated from the interviews.

Results: In total, 22 participants (mean age 70.4, SD 6.1 years) were enrolled in the workshop in May 2021. The results of the generated themes included incomprehension of game instructions, psychological perception of game technology, and game art preferences. The subthemes generated from game art preferences included favorite game genres, characters, and scenes.

Conclusions: There is a significant need for customized game tutorials considering senior adults' cognitive and physical aging. Furthermore, the adventure game genre is preferable to other games. Humanlike game characters are preferable, especially those with a fit and healthy body shape. Nature scenes are more enjoyable than indoor stages or rooms. Furthermore, the game intensity design and playing time should be carefully planned to meet the World Health Organization's criteria for physical activity in older adults. Intelligent recommendation systems might be helpful to support older adults with various health conditions. The guidelines suggested in this study might be beneficial for game design, exercise training, and game technology adoption of exergames for older adults to improve health.

(JMIR Serious Games 2024;12:e36154) doi:10.2196/36154

KEYWORDS

exergame; senior user experience; senior technology acceptance; game technology; psychological perception; serious games; exercise; aging; older adults; physical activity

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Introduction

Background

The rapid growth of the aging population has drastically increased the need for medical and health care services. The life expectancy is increasing; however, the average life in a state of good health, the so-called healthy life expectancy, is almost 8-10 years less than the life expectancy [1,2]. It is important to increase the healthy life expectancy for active aging and reduce the financial burden on health systems caused by incapacitation, bedridden patients, and chronic physical or mental health conditions. The World Health Organization (WHO) [3] has suggested that adults 65 years and older perform 150-300 minutes of moderate-intensity or 75-150 minutes of strenuous-intensity aerobic physical activity in a week in order to improve physical and functional health and lower the risk of noninfectious chronic illness and mental health conditions. However, it has been reported that in Taiwan, 33.8% of older adults in the age group of 65-74 years and about 36% of 55-64-year-old "graying" adults do not exercise at all [4]. Many "graying" adults in Taiwan are at risk of mental and physical disorders due to a lack of sufficient exercise. Therefore, providing preventive health care and promoting adherent exercise are urgent issues to be considered in order to improve senior adults' muscle strength and physical fitness to prevent falls and conditions caused by physical and cognitive decline.

Studies on Exergames for Health

Several studies have highlighted the benefits and positive impact of exercise games, so-called exergames, on overall health. The term "exergame" is most frequently used by health-related researchers to refer to video games that use strength training, balance, or flexibility [5]. Exergaming has gained public and commercial interest due to its combination of fun and fitness together and is particularly popular for obesity-related interventions [6]. Furthermore, it is regarded as the future of fitness to maintain regular activity as it is a healthy, appealing alternative to other physical activities, as seen especially during the COVID-19 quarantine [7]. In addition to increasing physical exercise, exergaming could also be beneficial for psychological, cognitive, or psychosocial issues [8]. Exergames have been gradually applied in psychological treatment or physical rehabilitation for senior adults. For example, some studies have adopted exergames in psychological treatment for cognition [9], dementia [10], and depression [11]. Exergames have also been adapted for physical treatment to improve physical skills or fitness [12,13], balance [14,15], fall prevention [16], and rehabilitation [17-19]. Although many studies have applied off-the-shelf exergames for mental and physical health, with proof of their benefits and effectiveness, older adults' perceptions, experiences, and expectations are rarely discussed. Therefore, it is important to investigate older adults' experiences and expectations of playing exergames as a preventive approach to promote exercise habits.

Exergame Technology

Exergames require players to interact with the virtual gameplay by means of their physical movements and gestures in the real world [20]. Exergames generally use motion-sensing technology, which tracks and monitors players' movements while they perform game tasks using sensory devices, such as Nintendo's Joy-Con or Microsoft's Xbox Kinect. Motion-sensing technology differs between Nintendo and Xbox consoles. The Joy-Con contains an accelerometer and a gyroscope built into the device to track a player's motion. Additionally, the Joy-Con also contains 3D touch technology, which provides subtle vibration feedback to the player. In contrast, Xbox Kinect, which is a camera-based and infrared depth-scanning-approach device, enables a player to interact with the game with body movements. Various types of game consoles with different underlying body motion technologies offer different user experiences, but the amount of physical effort and energy required to play exergames remain similar [21]. Accessibility and entertainability are the 2 distinguishing factors of exergames in promoting exercise and activity [22]. This study explored which interactive technology is preferred by older adults.

Technology Acceptance of Older Adults

For decades, many studies have researched how people adopt technology [23-26]. Davis [23] first developed the technology acceptance model to explain user behavior and the intention to use technology. Chen and Chan [26] further modified the technology acceptance model, calling their modified version the senior technology acceptance model, to learn about senior users' adoption of technology. The term "older adults" generally refers to people whose chronological age is 60 years or older [27]. Researchers suggest that older adults' attitude toward using and their intention to use technology are particularly affected by their self-efficacy, anxiety, health conditions, cognitive ability, social relationships, attitude toward life and satisfaction, physical functioning, and the support of technology use they receive around them. The senior technology acceptance model has been applied to understand older adults' behavior with regard to technology in Hong Kong [26], Sweden [28], and Taiwan [29].

According to a statistic survey by the American Association of Retired Persons (AARP), in 2019, in the United States, 44% of older adults enjoyed playing video games compared to 38% in 2016 [30]. The growing population of older adults in the game market shows that their needs should be considered in game design. However, many older adults may not have had much experience playing video games during their childhood, as computer-based video games became popular around the 1980s [31]. The target users of these exergames are mostly younger adults or children. The aging population is neglected in the market, when this age group strongly needs exercise. Therefore, this study investigated older adults' experience, perceptions, and acceptance of game technology to promote routine exercise.

Methods

Study Design and Recruitment

The workshop was conducted in a spacious classroom that was transformed to accommodate exergame testing. The classroom was large enough to ensure there were no obstacles to the participants performing their movements and gestures while playing the games. Four Sanlux 55-inch 4K Ultra HD televisions with Nintendo consoles and Xbox Kinect consoles were set up

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in the classroom, and each television equipped with the consoles was shared by 2 participants while playing the selected exergames. The participants had sufficient space to move around and had full range of motion with the whole body. The classroom accommodated 6-8 participants in each workshop, and 3 workshops were conducted in total.

The inclusion criteria for the workshop and interview were participants aged 60 years and older who could exercise and understand the instructions provided. A total of 22 senior adults (≥60 years old) were enrolled in this study.

Gameplay

Each of the 3 workshops included 3 activities (Figure 1). Every activity was conducted for 2 hours a day for 3 days. Before playing the games, a questionnaire was administered, in which the participants provided their background information, exercise habits, and use of technology products. The following games were selected for this study: the latest Nintendo Switch games *Just Dance*, *Boxing*, *Mini-Games*, and *Ring Fit Adventure* and the Xbox Kinect game *KinectAdventures!* Before each activity, the participants were provided with brief instructions for 20 minutes on how to play the games. Next, they played the selected exergames for 80 minutes, and finally, a 20-minute semistructured interview was conducted. The participants played *Just Dance* and *Boxing* in activity 1, *Ring Fit Adventure* and *Mini-Games* in activity 2, and *Kinect Adventures!* in activity 3.

Figure 1. Participants played Boxing (left) and Ring Fit Adventure (right).

Data Analysis

Data were collected from the semistructured interviews using audio recordings and transcribed verbatim. Qualitative data were analyzed using thematic analysis, a qualitative data analytics method proposed by Braun and Clarke [32,33] and further clarified and defined as reflexive thematic analysis. Reflexive thematic analysis is a common approach to identify, analyze, and report themes from qualitative data sets in content analysis and grounded theory [34]. Braun and Clarke [35] have provided a 6-phase process of thematic analysis for researchers to conduct qualitative studies: (1) familiarizing with the data, (2) generating initial codes, (3) searching for themes, (4) reviewing potential themes, (5) defining and naming themes, and (6) producing a report. The 6-phase process is not linear but an iteratively developing process that is flexible enough to be tailored for qualitative data [36]:

- Phase 1 (familiarizing with the data): In phase 1, the researcher read and reread the data and made notes on a manual transcript. The researcher also identified connections between participants, data, and existing studies.
- Phase 2 (generating initial codes): The interview transcript was systematically analyzed through coding. Some codes matched the participants' concepts, while others had to be interpreted by the researcher.
- Phase 3 (searching for themes): All the coded data were identified and clustered into broader topics or themes based on their similarities and overlaps.
- Phase 4 (reviewing potential themes): All the generated themes were reviewed to check whether they worked meaningfully and relevantly with the coded data.
- Phase 5 (defining and naming themes): After reviewing possible themes, the identified themes were subsequently defined and labeled.
- Phase 6 (producing a report): The generated themes answered the research questions about senior adults' experience, perceptions, and acceptance of adopting exergames for exercise.

Ethical Considerations

This study was approved by the Central Regional Research Ethics Committee China Medical University Taiwan (review number: CRREC-109-090). All participants were informed of the procedures involved in the study. They agreed to participate in the study and signed the consent form. The data in this study is anonymized. This study offered non-monetary incentives to participants as compensation.

Results

Participant Details

In total, 22 participants (n=16, 73% female; n=6, 27% male) were enrolled in the study. Their ages ranged from 60 to 82 years (Table 1).

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Table 1. Participants' general information (N=22).

Characteristics	Value
Age (years), mean (SD)	70.4 (6.1)
Male	68.7 (5.4)
Female	71.0 (6.4)
Sex, n (%)	
Male	6 (27)
Female	16 (73)
Education (years), mean (SD)	11.5 (4.5)
BMI (kg/m^2), mean (SD)	
Male	23.3 (4.5)
Female	22.4 (2.8)
Exercise routine, n (%)[a]	
Everyday	6 (27)
3-5 days a week	12 (55)
1-2 days a week	3 (14)
1-3 days a month	1 (5)
Exercise time (minutes/day), n (%)	
>30	16 (73)
20-30	4 (18)
10-20	1 (5)
<10	1 (5)
Exercise intensity, n (%)	
Barely there	11 (50)
Moderate	10 (46)
Harder	1 (5)
Technology products use habits (possession of smartphones/tablets/computers), n (%)	
I do not have any of them.	1 (5)
I have 1 of them.	8 (36)
I feel comfortable using them.	13 (59)
Frequency of using the technology products, n (%)	
Never	1 (5)
1 time a week	3 (14)
2-3 times a week	0 (0)
Many times a week	1 (5)
1 time a day	2 (9)
Many times a day	15 (68)
Experience of playing videogames/digital games (arcade, home console, handheld game console, computer game, or online game), n (%)	12 (55)

[a]The percentages might add up to more than 100 because of rounding.

The background information of the 22 participants showed that only 7 (32%) met the WHO criteria for weekly exercise. The participants were familiar with phone technology and often used it for social media, photography, Google searching, or online shopping. Some of them had previous experience of playing video games. These results showed that the participants were less active and were comfortable using technology products.

Most participants performed regular or mild light-intensity exercise; however, only a few participants met the WHO criteria

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for senior adult exercise. WHO recommends multicomponent physical activity at a moderate or high intensity [3]; however, the results showed that the exercise intensity of older adults and the time they spend are not enough.

Thematic Analysis

The semistructured interviews raised topics relating to user experience, psychological perceptions, and the adoption of game technology. In phase 2 of the thematic analysis, the manual transcript was systematically analyzed through coding. For example, "The tutorials in the game were not clear and not easy to understand. It is better to have instructors to teach me how to operate the game" was coded as the game tutorials not being supportive, being difficult to understand, and causing the participant to lose the motivation to play. In phase 3, the coded data was grouped into larger themes based on how they were connected. For example, coded data such as "do not know how to play," "not understanding," and "forgot tutorials" were clustered into "incomprehension of game instructions." In phase 4, the identified themes were carefully reviewed to ensure they accurately and meaningfully represented the coded data. In phase 5, the themes were defined and named as (1) incomprehension of game instructions, (2) confusion caused by a complicated interface, (3) frustration caused by the fast game speed, (4) a sense of control and freedom, (5) psychological perception of game technology, (6) social interaction, and (7) preference of game art. These 7 themes could answer the research questions about older adults' experience, perceptions, and acceptance of exergaming. The first 6 themes and the participants' feedback are shown in Table 2.

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Table 2. Themes 1-6 generated from the interviews.

Theme and example quotes	Sex (male/female), age (years), game experience (yes/no)
1. Incomprehension of game instructions (n=8, 36%)	
"It is very critical that someone could guide us before playing games [*Just Dance*]. Knowing how to play motivates me to play the game."	Female, 74, no
"I need someone next to me and tell me how to play.	Female, 67, yes
"I don't know how to play the game because I don't understand the game mechanics and rules."	Male, 68, yes
"I need a detailed game tutorial of the game to support me when playing the game."	Female, 75, no
"The tutorial in the game is not clear and not easy to understand. It is better to have instructors to teach me how to operate the game [*Ring Fit Adventure*]."	Male, 62, yes
"By the game instructions, I cannot fully understand what it means and how to play. I prefer someone (instructors) to teach me for better understanding."	Male, 72, yes
"I can't remember things well. So, I forgot tutorials while playing. I might remember how to play after many times gameplay."	Female, 79, yes
"I need more practice to remember how to play."	Male, 76, yes
2. Confusion caused by a complicated interface (n=5, 23%)	
"At the beginning, it was difficult to understand the game interface, but after practicing, I got used to controlling it."	Female, 66, no
"I don't know the meanings of the icons in the game interface."	Female, 74, no; male, 76, yes
"There is too much information on the screen; I don't know what to look at while playing [*Ring Fit Adventure*]."	Female, 75, no
"The game interface was very complicated and difficult to use. I guess it is also difficult to control machines for most of the older adults [*Just Dance*]."	Female, 63, no
3. Frustration caused by the fast game speed (n=8, 36%)	
"I would give up and feel frustrated when I cannot keep up with the speed of the games."	Female, 82, yes
"I wish I could control the speed of the game from slow to fast so that I could participate in the game, not be excluded since the very beginning."	Female, 63, no
"I was too slow in the response in the playing. For example, I wanted to jump and get the golden coin, but when I jumped, the golden coin disappeared [*Kinect Adventures!*]."	Female, 78, yes; female, 75, no
"It is very difficult and complicated to do more than 2 actions at the same time. I have to avoid getting bombed and to get golden coins [*Ring Fit Adventure*]."	Female, 74, no
"I feel I am not as agile as I was. The game should provide different levels of difficulty for different ages."	Female, 79, yes
"After seeing the boxing icon showing up from the bottom of the screen, I need to punch at the right tempo. But I was always too late to react. I need some time to think and then do the action [*Boxing*]."	Female, 66, no
"The speed in the game was too fast for me. I think the game should provide different levels of difficulty or provide different levels according to different age groups [*Boxing*]."	Female, 79, yes
4. A sense of control and freedom (n=4, 18%)	
"I like to use joystick to control games because of the tactile responses, although I feel free when I don't need to hold anything to control the game. However, I don't receive tactile sensation feedback to know whether I did the correct movement or not [*Kinect Adventures!*]."	Female, 60, yes
"I like to use my body motion to control the game because I don't like to hold anything on hands. I don't know how to use joystick, and I feel it is quite complicated. It is easy, free, and intuitive to control the game by my body."	Female, 63, no
"I prefer the realistic feeling of pressing and dragging the Ring-Con. It gives me real feedback and is easy to use."	Male, 71, no
"The vibration of the joystick gives me feedback of correct movement, and I like to receive the feedback [*Boxing*]."	Female, 74, no
5. Psychological perception of game technology (n=9, 41%)	
"Playing the games could make me keep focus, train my brain and coordination."	Female, 66, no

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Theme and example quotes	Sex (male/female), age (years), game experience (yes/no)
"It is so much fun to do exercise by playing games. I didn't expect myself to enjoy doing exercises [*Boxing*, *Kinect Adventures!*]."	Male, 68, yes
"I prefer to play *Boxing* game because it is very challenging."	Male, 62, yes
"I feel it is fashionable to play state-of-the-art games, which could connect me and the younger generations."	Female, 82, yes
"I feel I am keeping up with trends because I can operate game technology device and share with my grandchildren."	Female, 74, no
"I didn't know games could so charming and interesting. It is a fresh experience, and it is quite fashion and trendy to play games for me."	Female, 79, yes
"I would like to try new things, and I wish I could keep up with the times."	Female, 74, no
"I was afraid of new technology in general. I don't know how to use them. But if I have a chance to approach it and someone could teach me, I will be happy to learn."	Female, 60, yes
I feel video games are not for us; it is for the youth.	Female, 82, yes
6. Social interaction (n=5, 23%)	
"It has become a common interest between me and my grandchildren. We can play together, and we have common topics to talk about."	Female, 75, no
"Collaborating with other players is very fun, and it attracts me to continue using exergames."	Female, 69, yes
"I am feeling that I don't want to lose against my friends. I will make every effort to win."	Male, 68, yes
"I felt lonely when I did exercise alone, so I like exergames, which allow me to do exercise with people."	Female, 68, no
"I enjoyed playing with friends who are the same age as me. It's much more fun to play games or do exercise with friends than by myself."	Male, 63, yes

Additionally, the subthemes of game art preference were generated from the "preference of game art" theme. The qualitative data related to game art were collated and coded into game genres, characters, and scenes (Table 3). In the interviews, participants talked about their favorite games from among *Just Dance*, *Zumba*, *Boxing*, *Kinect Adventures!*, *Mini Games*, and *Ring Fit Adventure*. Adventure games were constantly mentioned as participants' favorite games (n=16, 73%, participants): 11 (69%) participants preferred *Kinect Adventures!*, and 5 (31%) participants liked *Ring Fit Adventure*. Only 3 (14%) participants liked the *Zumba* dance game and 3 (14%) liked *Boxing*. Thus, most participants were fond of the adventure game genre compared to the sports genre, such boxing or dance. Most participants (n=13, 59%) preferred true-to-scale 3D human models as game characters instead of cartoons. Some participants (n=8, 36%) preferred to see a real man on the screen to lead them in exercise, that is, the participants preferred the game characters to be real-scale humans or virtual models. Nearly all participants (n=21, 95%) mentioned that they enjoyed and immersed themselves in outdoor or natural scenes in the games, while only 1 (5%) participant preferred a static virtual stage.

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Table 3. Subthemes generated from theme 7 (preference of game art; n=8, 36%, participants).

Subtheme and example quotes	Sex (male/female), age (years), game experience (yes/no)
7.1. Favorite game genre	
"My favorite game is adventure games. It made me focus and immersed myself in the gameplay. The adventure game is very exciting, which could also train my brain and improve my coordination. I don't usually have the experience in my daily life [*Kinect Adventures!*]."	Female, 74, no
"The *Ring Fit Adventure* provides a more intense and challenging exercise for me. I love to take the challenge."	Male, 76, yes
7.2. Preference of game character	
"I like the game character is made by 3D humanlike model with a realistic ratio, such as the character in *Ring Fit Adventure*. The character looks fit, muscular, and powerful."	Female, 75, no
"I prefer a real man in the game, such as the coaches in *Zumba*. They are real people, who make it easier to understand and learn their dancing."	Female, 69, yes
7.3. Preference of game scene	
"I like the game with outdoor natural scenes. I feel like I was doing exercise outdoor rather than in an indoor room."	Female, 69, yes
"I was very excited and fully immersed in the game with a natural scene, such as *Xbox Adventure!* or *Ring Fit Adventure*."	Male, 63, yes
"The natural background made me feel comfortable, and I wanted to go forward to see what shows up next. It also keeps me focus on the gameplay [*Kinect Adventures!*]."	Female, 69, yes
"I prefer static stages in the background because then I can focus on my game tasks [*Boxing*]."	Female, 60, yes

Themes Generated From the Interviews

A total of 7 themes were generated from the semistructured interviews. Of these themes, 3 (43%; themes 1, 5, and 7) were initially identified in the study. The remaining 4 themes (57%; themes 2, 3, 4, and 6) aligned with prior research findings and are discussed in the *Comparison With Prior Work* section.

Theme 1: Incomprehension of Game Instructions

Lacking gaming experience in their youth might result in senior adults not understanding the game mechanics, the meaning of visual effects or reward icons, health points (HPs), or experience points (EPs). The instructions in the gameplay were not easy to understand, so most of the participants perceived them negatively. Moreover, although some participants had game experience, it did not seem to support their learning in exergames. They still needed appropriate instructions for gameplay learning.

As the game instructions were not helpful to the participants, they needed instructors to explain and teach them again to learn how to play. However, although the participants were taught how to play before the gameplay, they forgot how to play when playing. It was not easy for some participants to understand and memorize the given information. These findings showed that age-related visual and hearing loss might also contribute to increasing the barriers to understanding the gameplay. Thus, repetitive and real-time tutorials in games might be helpful to support memory, learning, and thinking. Therefore, simple visual instructions and oral guidance using plain language might support senior adults' game learning.

Theme 2: Confusion Caused by a Complicated Interface

In general, younger adults tend to find game interfaces more intuitive and user friendly compared to senior adults with regard to playing digital games. Senior adults often encounter significant challenges when attempting to engage with game interfaces. For instance, *Ring Fit Adventure* integrates a diverse range of physical tasks within its exercise regimen. Players are required to perform actions such as pressing or dragging the ring with their hands while simultaneously engaging in activities such as jumping, squatting, or running with their feet. The information and tasks presented in the game interface pose a complexity that senior adults may find challenging to comprehend. For instance, 1 (5%) participant (female, age 75 years, nonexperienced player) said:

> *There is too much information on the screen, I do not know what to look at while playing.*

Another participant (female, age 63 years, nonexperienced player) said:

> *The game interface is very complicated and difficult to use.*

Furthermore, senior adults often struggle to grasp the meaning of icons or virtual objects displayed in the game interface. For instance, they may not be aware that collecting golden coins in *Ring Fit Adventure* can lead to earning additional points. Two participants expressed:

> *I do not know the meanings of the icons in the game interface.*

Theme 3: Frustration Caused by the Fast Game Speed

One participant expressed frustration and a sense of exclusion when unable to keep up with the game's pace. They desired the

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ability to control the game's speed, allowing for a more inclusive gaming experience. The participant (female, age 66 years, nonexperienced player) playing *Boxing* noted that her ability to perform actions effectively was affected by slower response times. She explained:

> *After seeing the boxing icon showing up from the bottom of the screen, I need to punch at the right tempo. But I was always too late to react. I need some time to think and then do the action.*

Another participant (female, age 82 years, experienced player) said:

> *I would give up and feel frustrated when I cannot keep up with the speed of the games.*

In addition, participants perceived a decrease in agility compared to their previous exercise experiences, which could be attributed to the natural decline associated with aging. Thus, an inappropriate game speed could result in senior adults feeling frustrated and avoiding playing exergames.

The American College of Sports Medicine [37] has classified the characteristics of physical fitness into health-related and skill-related components. The skill-related components of physical fitness include agility, coordination, balance, power, reaction time, and speed, which can be adjusted in-game to meet individual conditions. The results in this study showed that game speed levels should be adjustable according to given skill-related health conditions. Senior adults need more time to understand what is going on and how to react accordingly. Therefore, games should provide a range of difficulty levels specifically designed to accommodate different age groups, thereby ensuring an enjoyable gaming experience for senior adult players.

Theme 4: A Sense of Control and Freedom

Participants shared diverse preferences regarding their choice of gaming controls. Some appreciated the tactile responses provided by a joystick (n=3, 14%) or the Ring-Con (n=7, 32%), while others found freedom in not having to hold anything when controlling the game, such as Kinect motion-sensing interaction (n=12, 55%). Alongside their appreciation for the sense of freedom, 7 (32%) participants favored the Ring-Con because it resembles holding a steering wheel, thus enhancing their perception of control.

However, the absence of tactile feedback in some games left participants uncertain about the accuracy of their movements. For example, 1 (5%) participant said:

> *Although I feel free when I do not need to hold anything to control the game...I do not receive tactile sensation feedback to know whether I did the correct movement or not.*

Theme 5: Psychological Perception of Game Technology

Playing exergames was perceived to relate to enjoyment, socializing, achievement, frustration, defeat, and keeping up with trends. Generally, participants enjoyed playing and socializing with people. In addition, playing exergames and operating technological devices made them feel trendy.

> *I feel I am keeping up with trends because I can operate [a] game technology device and share with my grandchildren.* [Female, 74 years]

Some participants felt frustrated when they could not follow the game speed or obtained lower scores due to their longer reaction time and lack of coordination.

> *I want to have a feeling of achievement, rather than being defeated.*

Therefore, the game design should consider senior adults' psychological perceptions to meet their emotional needs.

Theme 6: Social Interaction

The use of exergames fostered a sense of connection and engagement, both within the family and among peers.

> *I enjoyed playing with friends.* [Male, age 63 years, experienced player]
>
> *I like to play with my family, and it is the biggest motivation to play.*

Some participants enjoyed the collaboration and competition with team players. For instance, 1 (5%) participant (female, age 69 years, experienced player) expressed:

> *Collaborating with other players is fun, and it attracts me to continue using exergames.*

These findings showed that playing exergames serves as a common interest that allows for enjoyable collaborative experiences, providing shared topics for discussion, and enhancing the motivation to continue using exergames.

Theme 7: Preference of Game Art

The game preference for game art and game genres was investigated. The exergames in the workshop included the latest Nintendo Switch games, such as *Just Dance* and *Ring Fit Adventure*, and Xbox Kinect games, such as *Kinect Adventures!* Among these games, 16 (73%) participants were fond of adventure games, including *Ring Fit Adventure* and *Kinect Adventures!* Interestingly, the results showed that younger senior adults (6/16, 37.5%, participants; average age 65.8, SD 5.7 years) preferred *Ring Fit Adventure*, which is a resistance exercise and a high-intensity training game, more than older senior adults (10/16, 62.5%, participants; average age 71.4, SD 5.3 years). Other participants (n=6, 27%) preferred less intensive exercise games, such as *Boxing* and *Zumba*. Of these 6 participants, 5 (83%) had no previous game experience, and the average age was 73.2 (SD 6.2) years. Therefore, younger senior adults might prefer a more intensive resistance exercise, while older senior adults might prefer a gentle exercise with less leg work.

For game characters, most of the participants preferred a human or humanlike character because it was easier to understand their movements. The participants also could reflect themselves as the avatar if the game character looked like a human. Of the 22 participants, 21 (96%) preferred human or humanlike characters, of which 13 (62%) participants preferred a humanlike game character and 8 (38%) preferred real humans as game characters. One participant did not show her preference. These findings showed that among the cute animal characters and human

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(humanlike) characters, senior adults prefer human or humanlike avatars, which allows them to easily reflect themselves in games and observe exercise movements more clearly.

For game scenes, outdoor nature scenes were the most preferable, such as scenes in *Kinect Adventures!* and *Ring Fit Adventure*. Of the 22 participants, 20 (91%) preferred nature scenes, followed by static scenes. The participants felt the nature scenes made them feel comfortable and helped them focus. Two participants preferred simple and clean colored indoor scenes rather than a sophisticated background, which allowed them to focus on the game mission and not be distracted by the background.

Therefore, adventure games, humanlike characters, and nature scenes could create a sense of reality and players might be more easily immersed in the gameplay.

Discussion

Principal Findings

In this study, most of the participants had no or little experience of playing exergames. However, after playing exergames in the workshop, they found them interesting and appealing. The results of this study reflect factors of the senior technology acceptance model [26]. Most of the participants referenced a positive attitude, perceived usefulness, and social relationships regarding using game technology. However, the participants provided negative feedback for the perceived ease of use and support of technology use. Lacking experience of playing video games might have also resulted in the participants not having the knowledge and skills needed to adopt game technology.

The supports for technology use, such as understandable tutorials or game mechanics, to help senior adult players are not sufficient. Thus, there is a significant need for customized instructions for senior adults. Overall, the reasons the participants did not have the intention to play could be because they thought video games are for younger people, not for them. Therefore, exergames should also meet senior adults' psychological needs to increase their adoption of game technology.

The results of this study present older adults' experience, perceptions, and acceptance of commercial exergames. In total, 7 themes were generated from the semistructured interviews; 4 of these are in line with previous studies, but 3 were identified in this study.

Three distinguished themes generated from this study are incomprehension of game instructions, psychological perception of game technology, and preferences of game art. These themes have rarely been discussed in prior studies. The psychological perception toward exergames that the participants expressed was that it is fashionable and trendy to play the latest digital games, which belong to the youth. They also enjoyed the gameplay by collaborating and competing with their peers. Among the exergames, the participants preferred adventure games much more than other genres. In this study, the adventure games were *Kinect Adventures!* and *Ring-Fit Adventure*, both of which focus on players' action tasks. These types of games typically emphasize storytelling and character development, as players assume the role of a principal character who must overcome various challenges and obstacles to reach their objectives. The exciting experience of outdoor sports motivated them to continue to play, and the virtual environment provided a safe place to perform thrilling activities.

The game characters and scenes are also critical visual elements to immerse senior adult players in games. In this study, senior adults preferred humanlike characters who looked healthy, fit, and muscular. The game character with a healthy outlook inspired senior adult players to reflect themselves as energetic people exercising in the gameplay. The nature scenes in the game also gave the senior adult players feelings of comfort and relaxation during the gameplay. WHO recommends that adjustable intensity and game levels should be carefully designed to support senior adults perform a sufficient amount of physical activity.

However, if senior adults cannot understand how to play a game or react in time, they feel defeated and frustrated. They may give up playing straight away. Therefore, there is a significant need for game tutorials that are easy to understand for senior adults and game levels that are suitable for their mobile ability.

Comparison With Prior Work

Four themes generated from the qualitative data demonstrated similar issues as in previous studies. First, "confusion caused by a complicated interface" (theme 2) and "frustration caused by the fast game speed" (theme 3) are in line with the results of Aarhus et al [38], who found that simultaneously increasing information, speed, and colors would more likely increase cognitive challenges. Although Aarhus et al [38] adopted Nintendo Wii in a physical rehabilitation context, the issue remains in the current Nintendo Switch. Second, the game speed was too fast to follow for most of the participants, which is in line with the results of Brox et al [39]. From the cognitive ability perspective, an age-related decrease in working memory causes a reduction in the amount and speed of information processing [35]. Third, the participants in this study highlighted "a sense of control and freedom" (theme 4) in the gameplay, similar to the results of Thin et al [21], who found that the game experience of motion-sensing games is preferrable due to its greater freedom and holistic movement experience. Fourth, "social interaction" (theme 6) is a prominent motivation for senior adults to adopt exergames, which is in line with previous studies [38]. Therefore, social interactions with peers, friends, the family, and society formed through playing exergames are appreciated.

Previous studies have also discussed the aforementioned themes, although most of the commercial games tested in previous studies were Nintendo Wii, Wii Fit, Wii Balance Board, and Wii Sports. Compared to prior studies, this study adopted the latest Nintendo Switch and Xbox Kinect to investigate the player experience. However, obstacles, such as game speed, interface, and tasks, remained, indicating that the latest games still do not consider the needs of senior adults.

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Evaluation of This Study

According to the criteria for scientific rigor (credibility, dependability, confirmability, and transferability), in the qualitative research proposed by Lincoln and Guba [40], consistent outcomes are expected when replicating the research process within the same setting. To enhance credibility in this study, continuous interaction was maintained with each participant throughout the data collection process. Furthermore, the participants were encouraged to provide examples while discussing their gaming behavior and experiences, with the interviewer posing follow-up questions. This approach facilitated the participants' familiarity with both the research setting and the content, thereby ensuring an accurate interpretation of their original perspectives. Regarding transferability, which pertains to applicability, the researcher provided detailed descriptive data, such as participants' demographics, exercise characteristics, technology use habits, inclusion criteria of recruitment, workshop and interview procedures, and the iterative research process. The information helped the researcher explain the participants' behavior and experience within a gaming context, potentially making them meaningful and transferable to an external observer. To ensure dependability, which is related to consistency, a detailed analysis process was used throughout this study [41], thereby establishing the potential for reproducing the outcomes across similar participant cohorts and settings. Given the constraints, concerning confirmability, which relates to maintaining neutrality, although the absence of an external review was recognized, diligent steps were taken to compensate for this limitation by implementing a rigorous process of self-evaluation and critical reflection on the research process and outcomes. This included a careful examination of the data, consistent cross-referencing with established literature, and self-awareness regarding potential biases.

Strengths and Limitations

This study makes a noteworthy contribution by emphasizing the importance of game tutorials, preferences of game art and genres, and the perception of trendiness in the game design for older adults. However, the study does have limitations. First, it is essential to acknowledge that the sample size was restricted to 22 participants, consequently impacting the precision of estimates for main outcomes. Second, evaluating the qualitative study's confirmability would ideally involve external researchers. The advantage of having a single researcher code the content is that it ensures consistency and stability in the use of codes; however, confirmation bias can be manifest during various stages of the research process, such as data coding or interpretation [42]. As previously stated, a single researcher may hold preconceived ideas or preferences about the outcomes they anticipate or desire, and these biases can inadvertently impact their scholarly work. Although this study was conducted by a single author, the inherent limitations associated with solo authorship are recognized. The absence of external researchers in this study could limit the diversity of perspectives during data coding and interpretation. This limitation may result in a narrower scope of interpretation and analysis, potentially overlooking valuable insights. By acknowledging potential biases and preconceptions, steps have been taken to minimize their impact on the study's findings. Although collaborative research may not have been feasible in this study, the research process involved continuous cross-referencing with established literature and a sustained awareness of potential biases. It is hoped that this study will contribute valuable insights to the field of digital exergames for senior adults, despite its single authorship limitations. Additionally, it is anticipated that future research will build upon the study's findings to further enhance our understanding of senior adults' experiences in engaging with exergames.

Conclusion

Exergames could serve as an engaging approach to promote exercise and a healthy life among senior adults. Most of the prior studies have focused on usability and facilities, but senior adults' psychological perception toward the exergame experience is highlighted in this study. The findings of this study have some important practical and research implications for adoption of game technology, as well as for research with senior adults' gameplay experience for future work. First, tailored game tutorials for senior adults could be beneficial for increasing the adoption of exergames to promote physical health. Because of insufficient game experience in their youth and cognitive decline due to aging, there is a significant need for understandable and age-friendly tutorials of exergames to equip senior adults with affordable information and skills to get into the game scenario and mechanics. Second, preferences of game art and genres reveal that adventure games are the most favorable game genre and humanlike avatars in nature scenes are most liked among senior adults. Moreover, evidence from this study and the literature shows that the exercise time and intensity of senior adults in Taiwan are clearly not sufficient according to WHO criteria. Thus, game design should plan appropriate game times and intensities for senior adults, which could support them in gradually performing moderate- or high-intensity exercise to promote their health. In addition to game intensity, the game speed of current off-the-shelf exergames is still not suitable for senior adults. Therefore, intelligent recommended systems of game intensity, speed, or difficulty might be helpful for senior adults with various health conditions. Finally, senior adults also want to be fashionable and keep up with trends, not to be excluded by the market, so exergame developers may consider including senior adults' physical and psychological needs to create age-friendly exergames that are more accessible. Future research could focus on investigating age-friendly game tutorials, developing approachable adventure games, creating adjustable game intensity levels, and designing game artwork for senior adults to enhance their exercise for better health.

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Data Availability

All data generated and analyzed during this study are included in this published paper.

Authors' Contributions

YHW is the sole author of this manuscript, responsible for conducting the research, analyses, and data verifications. She successfully secured research funding from the Ministry of Science and Technology. Her contributions encompass interpreting the results and approving the latest version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

WHO: World Health Organization

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Original Paper

Examining and Comparing the Energy Expenditure of Two Modes of a Virtual Reality Fitness Game (Supernatural): Indirect Calorimetry Study

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Abstract

Background: The effectiveness of virtual reality (VR) fitness games as a form of moderate to vigorous physical activity has yet to be thoroughly quantified through gold standard energy expenditure measures.

Objective: The purpose of this study was to examine the energy expenditure of 2 medium-intensity modes (“Flow and “Boxing”) of a VR fitness game, Supernatural, using indirect calorimetry.

Methods: Indirect calorimetry was used to examine relative and objective maximal oxygen consumption (VO_2 max), metabolic equivalents of task (METs), and calories burned during medium-intensity bouts of both Flow and Boxing gameplay modes in young (mean age 25.42, SD 3.25 years), active individuals (n=12 female and n=11 male). METs and calories were also compared using a triaxial waist-worn accelerometer, an Apple smartwatch, and a VR headset. Mood states were assessed pre- and postbout using the shortened Profile of Mood States Questionnaire. Paired 2-tailed *t* tests were used to examine differences in game modes, between sexes, and pre-post exercise sessions.

Results: Objective and relative VO_2 max averaged 1.93 (SD 0.44) L/min and 27.61 (SD 5.60) mL/kg/min, respectively, between modes. Flow (mean 8.2, SD 1.54 METs) and Boxing (mean 7.6, SD 1.66 METs) are both classified as high energy expenditure, vigorous activities. Calorie expenditure data of the accelerometer and VR headset differed significantly from the metabolic cart. Mood changes pre- to post exercise were consistent with expected values for moderate- to vigorous-intensity physical activity, with participants reporting that they felt more “active,” “full of pep,” “vigorous,” and “lively” ($P<.05$) following bouts. Male individuals reported higher objective oxygen consumption (VO_2) for both Flow and Boxing modes; no other sex-specific differences were observed.

Conclusions: Both Flow and Boxing gameplay modes of Supernatural classify as vigorous physical activity and demonstrate the potential to promote mental and physical health benefits. Supernatural may be an effective exercise modality in a VO_2 training program.

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KEYWORDS

energy expenditure; exergaming; indirect calorimetry; virtual reality; VR; VR fitness; VR gaming

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Introduction

Regular physical activity (PA), described as a movement-driven increase in energy expenditure [1], is an important health behavior that has well-established mental and physical benefits [2]. Evidence suggests that individuals who partake in regular PA of 150 minutes of moderate-intensity PA or 75-150 minutes of moderate- to vigorous-intensity PA (MVPA) each week [3] have a lower risk of cancer, type 2 diabetes mellitus, ischemic heart disease, and ischemic stroke [4].

While there are diverse modes in which individuals can engage in regular PA, at-home exercise options have increased in popularity recently [5]. Before the COVID-19 pandemic, at-home PA may have been chosen due to the ease of access, high levels of autonomy in modifying both workouts and equipment, and the increased feeling of comfort provided by exercising in a familiar environment [6]. Due to COVID-19–related shutdowns of traditionally frequented centers for PA (eg, gyms, recreation centers, and organized sports leagues), individuals had to develop new routines to stay active. Many turned to home fitness workouts and exergames, including virtual reality (VR) fitness options, to maintain their PA levels [7,8]. Even beyond the pandemic, home workout options, such as VR gaming and internet-based fitness workouts, continue to appeal to individuals, in part due to their convenience and accessibility.

VR can be described as a head-mounted amalgamation of the human perception of sensation into an interactive virtual environment [9]. Contemporary iterations of VR, specifically immersive VR (such as the Oculus Quest 2 or HTC Vive), involve a head-mounted device inlaid with cameras that track the wearer's environment, in order to project a virtual environment within the headset. VR gaming (also known as VR exercising, VR game exercising, or active VR games) refers to the use of a VR headset (and often handheld controllers) to engage in a single immersive, digital fitness experience consisting of both video game and exercise elements [10]. VR gaming differs from traditional exergaming (eg, Wii Fit and Just Dance) in that the gaming environment is visually immersive and interactive, rather than having visuals confined to a screen and movements or interactivity restricted by the fidelity of an external camera. These limitations of exergaming may contribute to their variability in energy expenditure [11]. Popular VR games include Beat Saber (Beat Games), Fruit Ninja VR (Halfbrick Studios), HOLOFIT (Holodia Holofit), Dance Central (Harmonix Music Systems), and BOXVR (FitXR). VR fitness demonstrated both mental and physical health during the COVID-19 lockdown [12]. Thus, VR fitness continues to remain popular as we emerge from the era of COVID-19 lockdowns, in part due to its enjoyable, flexible, and motivating nature [13].

While VR is gaining in popularity as a form of PA, there are, unfortunately, several factors that currently limit our understanding of whether it can serve as an effective means of achieving MVPA intensity. There is a tremendous amount of variance in the equipment involved within a VR gaming setup. Many studies use specialized equipment (eg, cycle ergometer [14], bespoke machinery [15], or sport-specific VR setups [16]), which would be unrealistic or inaccessible for most users to acquire or comfortably use. Among studies that examined a "regular" VR gaming setup, other confounding factors may also be at play. For example, some studies examine the use of additional accessories to existing VR setups, such as hand weights [17], which further obfuscate the energy expenditure of VR games.

Even in previous research that has used more consumer-friendly VR (eg, Oculus Quest and HTC Vive), the VR games themselves are quite variable in what they demand from the user. For example, Beat Saber, a popular VR rhythm game, requires users to hit targets in a virtual space with either one or both of their handheld controllers. However, the intensity with which these targets must be hit to register as a valid hit can be quite low. Additionally, the movements facilitated by VR games can vary, leading to a change in energy expenditure. Stewart [18] compared the energy expenditure from 3 different VR games, including Beat Saber, and found that each game demonstrated a significantly different energy expenditure for a similar playtime. Given the nature of VR setups and the range of movement they require [19], few studies have used the gold-standard measures of energy expenditure (eg, indirect calorimetry) within VR gaming studies. Furthermore, the presence of sex and gender differences within the field of VR gaming remains a controversial topic, with mixed evidence supporting a higher rate of physical discomfort and symptoms for female individuals [20,21]. Combined with the tendency for male individuals to demonstrate higher maximal oxygen consumption (VO_2 max) values when controlling for age [22], investigating the presence of any sex-specific differences within VR gaming is of importance.

Supernatural is a VR fitness service that is available on the Oculus Quest (Meta) headsets, a popular consumer VR headset. Supernatural was chosen due to its specificity as a fitness service [23]. Other contemporary titles, like Beat Saber and Fruit Ninja VR, play closer to rhythm or arcade games in that the goal of the game is to achieve a high score, which can be done by hitting more targets. Supernatural is similar in that target accuracy is a metric; however, the key difference is that Supernatural records a metric of movement power (ie, power for the "Flow" mode and speed for the "Boxing" mode). In this way, Supernatural provides a means to compare effort, not just accuracy. Hence, limiting our study to just Supernatural was deemed appropriate. Thus, the primary purpose of this study was to examine and compare the energy expenditure of a bout of the VR fitness game Supernatural through indirect calorimetry; specifically, we examined the energy expenditure of both the Flow and Boxing modes, selecting workout durations and intensities (ie, medium intensity) based on the game's average workout data. Comparisons between sexes (ie, male and female) were also examined as part of this primary objective.

The emerging popularity and novelty of VR gaming presents a further point of interest insofar as how accurate traditional PA monitoring devices are when applied to VR contexts. Traditional devices, such as waist-worn accelerometers and wrist-worn

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accelerometers (eg, smartwatches), demonstrate reasonable validity for capturing walking and running behaviors [24]; however, whether this extends to the more space-restricted, calisthenic-focused movements of VR gaming is unclear [25,26]. The inclusion of an onboard accelerometer in many consumer VR headsets is also a noteworthy activity monitor that is worth comparing to gold-standard energy expenditure measures [23]. Thus, the secondary purpose of this study was to examine the energy expenditure of the VR game as measured by accelerometry, consumer activity monitor (ie, Apple Watch 2), and the built-in accelerometer in the VR headset to provide a comparison to the gold-standard measure of indirect calorimetry.

The tertiary purpose of this study was to examine any changes to mood as a result of engagement in Flow and Boxing, as compared to the contemporary literature on VR exercise and mood [27,28].

Methods

Participants

Inclusion criteria for participants were (1) being 19-40 years of age; (2) self-reporting a minimum of 150 minutes of MPVA per week; (3) self-identifying as not being at increased risk for contracting COVID-19 or being a part of an immunocompromised population; and (4) being considered to have a minimal risk of an exercise-induced adverse outcome. To ensure participants with a broad range of VR experiences were recruited, recruitment documentation described the study as a “digital fitness experience” to avoid confounding any measurements collected. Participants became aware of the use of VR technology upon their receipt of the informed consent documentation before their first visit. Participants were recruited between September 2022 and December 2022 using a combination of social media postings, physical postings on the host university’s campus, and word of mouth.

VR Headset and Game

Participants engaged with the VR fitness game Supernatural [29], which was played using the Oculus Quest 2 VR headset [30]. The Oculus Quest 2 uses a head-mounted display and 2 handheld controllers to provide an immersive VR experience for users. For this study, a 5-foot (1.5 m) by 5-foot space was marked onto the floor with tape to calibrate the in-headset play area boundaries (Multimedia Appendix 1). For each participant, the floor level was calibrated, and headset straps were adjusted to fit comfortably.

The Supernatural game has 2 exercise modes: Flow and Boxing. Both modalities cue participants to arm movements with color-coordinated orbs that have directional arrows to indicate movements to participants. There are also horizontal bars and triangles to encourage squatting, lunging, and the dodging of obstacles. During their first session, participants engaged in the workout mode Flow. Flow is an aerobic workout that involves both the upper and lower body and footwork in 360 degrees (Figure 1). Participants wield a virtual bat in each hand, striking targets in a variety of patterns and intensities. Lower-body movements are incorporated into each sequence, requiring participants to squat or lunge to hit some targets. During the second session, participants challenged a Boxing workout. Boxing requires participants to punch, uppercut, or swing through color-coordinated orbs and has horizontal and diagonal bars that participants have to maneuver their head and torso under and around (Figure 2). Note that still captures of Supernatural provide only an approximate impression of the actual, first-person in-app perspective of a Supernatural user on modern Meta Quest hardware.

Figure 1. Supernatural Flow game mode.

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Figure 2. Supernatural Boxing game mode.

Experimental Overview

Overview

Interested participants contacted the researcher by email to arrange the initial session. Participants attended 2 sessions at the host institution which occurred a minimum of 24 hours apart. The first visit centered around the Supernatural Flow session, and the second visit was around the Supernatural Boxing session. This order was maintained for all participants. Participants were asked to abstain from engaging in MVPA for 12 hours before each session. During the first study visit, participants signed the informed consent document, completed a Get Active Questionnaire (GAQ [31]), had their anthropometric data collected, and completed a baseline survey assessing previous knowledge and exposure to VR. Before and after each session, participants' mood states using the shortened version of the Profile of Mood States (POMS-SF [32]) were assessed. After initial surveys, participants were fitted with a heart rate (HR) monitor and the Oculus Quest 2 VR headset and then followed a standardized progression up to the measurement intensity workout until meeting the predetermined threshold for competency (see Zones of Competency section). Upon meeting the zone of competency, participants were fitted with the indirect calorimetry mask and headpiece, Apple Watch, and waist-worn accelerometer and completed the measurement session.

VR Game Stage Progression

Following initial surveys at each visit, participants watched a series of tutorial videos for the respective mode of the session (ie, Flow for session 1 and Boxing for session 2) which are available on Supernatural's YouTube page. Participants then engaged in an in-game tutorial (approximately 5 minutes). Participants then proceeded to a low-intensity "Quick Hits" workout and a medium-intensity "Quick Hits" ramp-up workout, both approximately 5 minutes long, to further familiarize them with the mode. Participants who were able to meet the minimum zones of competency for each mode (as detailed in Zones of Competency section) proceeded to the measurement workout. Participants could repeat the "Quick Hits" workouts until the zones of competency were obtained. The measurement session was a medium-intensity workout between 14 and 17 minutes in length. All workouts were selected from a predetermined list of relatively similar-intensity workouts. In correspondence with Supernatural, the makeup of the different workouts within the same intensity is generally similar to one another in the range of motion, target origination, pace, and number of targets delivered. Participants chose the genre of music (eg, pop, rock, hip-hop, and electronic) they preferred, and a researcher would select a workout matching the description.

Zones of Competency

To advance to the measurement session, participants had to meet the predetermined zones of competency for each mode. Flow measures participant competency in accuracy (ie, percentage of targets hit) and power (ie, how fast targets were hit). Participants had to obtain a minimum of 92% accuracy to participate in the measurement session. Power was not used in the determination of participant readiness. Boxing measures participant competency in accuracy (ie, percentage of targets hit) and speed (ie, how fast targets were hit). Participants had to achieve a minimum of 94% accuracy in Boxing to progress to the measurement round. During preliminary testing, it was also determined that a minimum speed goal should be achieved to ensure participants were all working out at a similar intensity. Hence, a minimum score of 70% speed was determined to be sufficient, as this best reflected the lower end of the speed an average user would hit the targets at, according to correspondence with Supernatural.

Instrumentation and Measurement

Primary Outcome: Energy Expenditure (Breath-by-Breath Oxygen Consumption)

A Parvo Medics TrueOne 2400 metabolic cart was used to assess oxygen consumption (VO_2; ie, volume of oxygen) during both measurement sessions [33]. A 2-meter hose and a 3-meter hose were joined together using a polyvinyl chloride elbow joint and hose clamps to allow the hose to reach from the metabolic cart to loop suspended above the participant, then down to the participant to allow VO_2 to be assessed with minimal interference during the testing (Multimedia Appendices 1 and 2). The metabolic cart was calibrated to room air and known gas concentrations before testing, followed by individual setup according to participants' height, weight, age, and sex. Both objective VO_2 max and relative VO_2 max were collected. Relative VO_2 max was also compared to age-predicted VO_2 max. VO_2 averages were recorded in 30-second intervals.

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Secondary Outcomes

Energy Expenditure (Metabolic Equivalents and Caloric Expenditure)

Metabolic equivalents of task (METs) and caloric expenditure were assessed using the metabolic cart, an ActiGraph GTX3 triaxial waist-worn accelerometer, a Series 7 Apple Watch, and the built-in accelerometer on board the Oculus Quest 2 headset (as displayed through the Oculus Move in-headset app). Time spent in low-, moderate-, and high-intensity exercise was recorded by the waist-worn accelerometer. The waist-worn accelerometer was calibrated according to each participant's age, height, weight, and sex. The Apple Watch and Oculus Move accounts were calibrated to a reference individual (female, height 181 cm, weight 78 kg) to avoid the need for an individual Apple and Oculus Move account for each participant. The Oculus Quest 2 boundaries were standardized to a 1.5 meter by 1.5 meter square.

Heart Rate

A Polar H10 HR monitor was used to measure average and maximum beats per minute (bpm) and the percentage of time spent in HR zones. Polar classifies HR into 5 zones by both levels of intensity and percentage of age-predicted maximum HR (HRmax). Specifically, these zones are categorized as zone 1: very light, 50%-60% HRmax; zone 2: light, 60%-70% HRmax; zone 3: moderate, 70%-80% HRmax; zone 4: hard, 80%-90% HRmax; and zone 5: maximum, 90%-100% HRmax [34]. The Polar H10 HR monitor was calibrated to a reference individual (female, height 181 cm, weight 78 kg) to avoid the need for an individual Polar account for each participant.

Tertiary Outcomes

Demographics

Participants' age, sex, height, weight, waist circumference, and PA levels were recorded during the initial visit. Age, sex, and PA level were self-reported using a single item. Height, weight, and waist circumference were measured by a researcher.

Mood States

Participants completed surveys at the beginning and end of each session to assess potential changes in mood states, which were assessed with the POMS-SF [32]. Our specific subscales of interest were vigor (ie, lively, active, energetic, full of pep, and vigorous) and fatigue (ie, worn out, fatigued, exhausted, weary, and bushed), as these were thought to be the most receptive to participants' exertion within our acute aerobic intervention and nonclinical sample [35,36]; however, the entire POMS-SF was completed by each participant.

Data Handling and Analysis

Energy Expenditure Outcomes

Energy expenditure outcomes were analyzed descriptively (mean and SD) and assessed for normality. Winsorization [37] of any outliers was planned. An average of the objective VO_2 max and relative VO_2 max for Flow and Boxing sessions was calculated. The relative VO_2 max was also calculated as a percentage of the age-predicted VO_2 max. Accelerometer data were analyzed using the Freedson Adult MV3 cut points [38]. The accelerometer, Apple Watch, and Oculus Move data were compared to the metabolic cart data to determine the percentage difference between the measurement tools. Comparisons between modes (Flow and Boxing) and measurement modalities (ie, metabolic cart, waist-worn accelerometer, Apple Watch, and Oculus Move) were compared for the 21 complete data sets (n=11, 52% male individuals) using paired sample 2-tailed *t* tests using a Bonferroni correction (ie, α=.0125). Missing data were excluded case-wise.

Psychological Outcomes

Changes in mood state (ie, vigor and fatigue subscales) from pre- to postsession for both Flow and Boxing modalities were assessed using paired 2-tailed *t* tests.

Sample Size Determination

To be sufficiently powered to do a sex-specific subanalysis, we aimed to collect at least 20 full data sets (ie, 10 male and 10 female individuals). This number was determined based on an investigation of previous energy expenditure and VR fitness publication recruitment numbers and was deemed appropriate to capture sex-specific differences in energy expenditure outcomes [39-41]. Sex-specific subanalyses were only performed for the energy expenditure outcomes, as the sample was deemed to be too small to capture small-to-medium–sized effects on psychological outcomes.

Ethical Considerations

This prospective, single-group experimental study was approved by the host University of Victoria's research ethics board (22-0213), and all participants provided written, informed consent before their involvement in the study and for inclusion in the publication of any research findings, as indicated by the Declaration of Helsinki.

Results

A CONSORT (Consolidated Standards of Reporting Trials)-eHealth checklist for this study can be found in Multimedia Appendix 3.

Participant Characteristics

A total of 12 male and 12 female individuals who met inclusion criteria and provided informed consent were recruited for this study. One male participant dropped out before beginning the Flow data collection due to issues with the VR environment. Overall, 2 female participants completed the Flow session but not the Boxing session due to factors unrelated to the study. A total of 23 (n=11, 48% male) participants completed the Flow session, and a total of 21 participants (n=11, 52% male) completed the Boxing session.

Participant demographics are presented in Table 1. The average age of participants was 25.42 (SD 3.25) years. Participants reported participating in MVPA 4.71 (SD 1.62) days a week for an average of 72.38 (SD 39.04) minutes per session, classifying our participants as active [3]. Our participant pool was very naive to VR and VR fitness, however, with 96% (n=23)

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reporting no previous familiarity with VR fitness products before study participation. There were no outliers in the data set.

Table 1. Participant demographics.

Characteristic	Male participants (n=12), mean (SD)	Female participants (n=12), mean (SD)
Age (years)	25.5 (3.1)	25.2 (3.0)
Height (cm)	178.1 (9.9)	166.6 (7.9)
Weight (kg)	76.7 (14.1)	64.36 (7.9)
Waist circumference (cm)	85.5 (6.2)	76.0 (5.1)

Workout Characteristics

The average Flow workout was 15.48 (SD 1.31) minutes in duration and was completed with 94.57% (SD 2.35%) accuracy and 85.52% (SD 5.27%) power. The average Boxing workout was slightly longer than Flow at 16.91 (SD 1.51) minutes in length, with 96.67% (SD 1.77%) accuracy and 78.86% (SD 7.89%) speed.

Energy Expenditure

Oxygen Consumption

Objective VO_2 max, as measured by the metabolic cart, was 1.98 (SD 0.44) L/min for Flow, 1.88 (SD 0.45) L/min for Boxing, and 1.93 (SD 0.44) L/min overall. Relative VO_2 max was 28.52 (SD 5.39) mL/kg/min for Flow, 26.70 (SD 5.79) mL/kg/min for Boxing, and 27.61 (SD 5.60) mL/kg/min overall. There was a significant difference between Flow and Boxing for both objective (mean difference [M_{diff}]=0.14, 95% CI 0.05-0.24; *P*=.006) and relative VO_2 max (M_{diff}=2.05, 95% CI 0.53-3.56; *P*=.01). The percentage of age-predicted VO_2 max was 59.39% (SD 11.75%) for Flow, 55.42% (SD 12.45%) for Boxing, and 57.41% (SD 12.12%) overall. There was no difference between Flow and Boxing with respect to the percentage of age-predicted VO_2 max (M_{diff}=4.20%, 95% CI 1.34%-7.05%; *P*=.006).

With respect to sex-specific differences, a significant difference was observed for objective VO_2, with male individuals demonstrating a significantly higher objective VO_2 for Flow than female individuals (M_{diff}=0.46, 95% CI 0.13-0.78; *P*=.009). Sex differences for objective VO_2 for Boxing were not statistically significant (M_{diff}=0.36, 95% CI –0.02 to 0.74; *P*=.06). No significant differences between sexes were revealed for any other VO_2 outcome (*P*>.05).

Outcomes for METs

METs were collected by both the metabolic cart and the waist-worn accelerometer. The metabolic cart recorded average METs to be 8.15 (SD 1.54) for Flow, 7.63 (SD 1.66) for Boxing, and 7.89 (SD 1.60) overall, while the waist-worn accelerometer recorded averages as 4.31 (SD 0.56) for Flow, 4.78 (SD 0.57) for Boxing, and 4.55 (SD 0.65) overall. For data recorded by the metabolic cart, there was a significant difference between Flow and Boxing modes (M_{diff}=0.58, 95% CI 0.15-1.02; *P*=.01). There was a significant difference between the values recorded by the metabolic cart and the waist-worn accelerometer for both Flow (M_{diff}=3.69, 95% CI 3.12-4.25; *P*<.001) and Boxing (M_{diff}=2.84, 95% CI 2.21-3.47; *P*<.001), with the accelerometer reporting a percent of metabolic cart reading of 45.26% (SD 14.55%) for Flow, 56.03% (SD 13.80%) for Boxing, and 50.64% (SD 15.05%) overall.

With respect to sex-specific differences, no significant differences were revealed for METs as assessed by either the metabolic cart or waist-worn accelerometer (*P*>.05). Oxygen consumption and metabolic equivalent data are given in Table 2.

Table 2. Oxygen consumption (VO2) and metabolic equivalent of task (MET) data.

Energy expenditure outcome	Flow, mean (SD)	Boxing, mean (SD)	Overall, mean (SD)
Objective VO_2 (L/min)	1.98 (0.44)[a]	1.88 (0.45)[a]	1.93 (0.44)
Relative VO_2 (mL/kg/min)	28.52 (5.39)	26.70 (5.79)	27.61 (5.60)
Age-predicted VO_2 max[b] (%)	59.39 (11.75)	55.42 (12.45)	57.41 (12.12)
METs (metabolic cart)	8.15 (1.54)[a]	7.63 (1.66)[a]	7.89 (1.60)
METs (accelerometer)	4.31 (0.56)	4.78 (0.57)	4.55 (0.65)

[a]Values represent a significant difference between modes (ie, Flow and Boxing).

[b]VO_2 max: maximal oxygen consumption.

Calories

The estimated caloric expenditure of the metabolic cart, waist-worn accelerometer, Apple Watch, and Oculus are presented in Table 3. For Flow, both the accelerometer (M_{diff}=79.25, 95% CI 68.30-90.20; *P*<.001) and Oculus Move (M_{diff}=30.79, 95% CI 12.84-48.74; *P*=.002) were found to be significantly different from the metabolic cart, while the Apple Watch (M_{diff}=–4.83, 95% CI –18.30 to 8.66; *P*=.47) was not.

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Similarly, for Boxing, both the accelerometer (M_{diff}=70.56, 95% CI 56.59-84.53; *P*<.001) and Oculus Move (M_{diff}=62.89, 95% CI 45.52-80.26; *P*<.001) were found to be significantly different from the metabolic cart, while the Apple Watch (M_{diff}=–14.24, 95% CI –32.22 to 3.73; *P*=.11) was not.

Table 3. Caloric expenditure data.

Device	Flow (kcal)		Boxing (kcal)		Overall (kcal)	
	Mean (SD)	% Metabolic cart	Mean (SD)	% Metabolic cart	Mean (SD)	% Metabolic cart
Metabolic cart	151.22 (35.52)	N/A[a]	159.76 (38.829)	N/A	155.49 (36.95)	N/A
Accelerometer	70.60 (22.34)[b]	45.26[b]	89.20 (28.892)[b]	56.03[b]	79.90 (27.12)[b]	50.46[b]
Apple Watch	155.41 (24.87)	107.56	174.00 (39.607)	112.34	164.71 (33.59)	109.95
Oculus Move	121.27 (21.98)[b]	82.88[b]	102.00 (17.914)[b]	63.75[b]	111.63 (22.06)[b]	73.32[b]

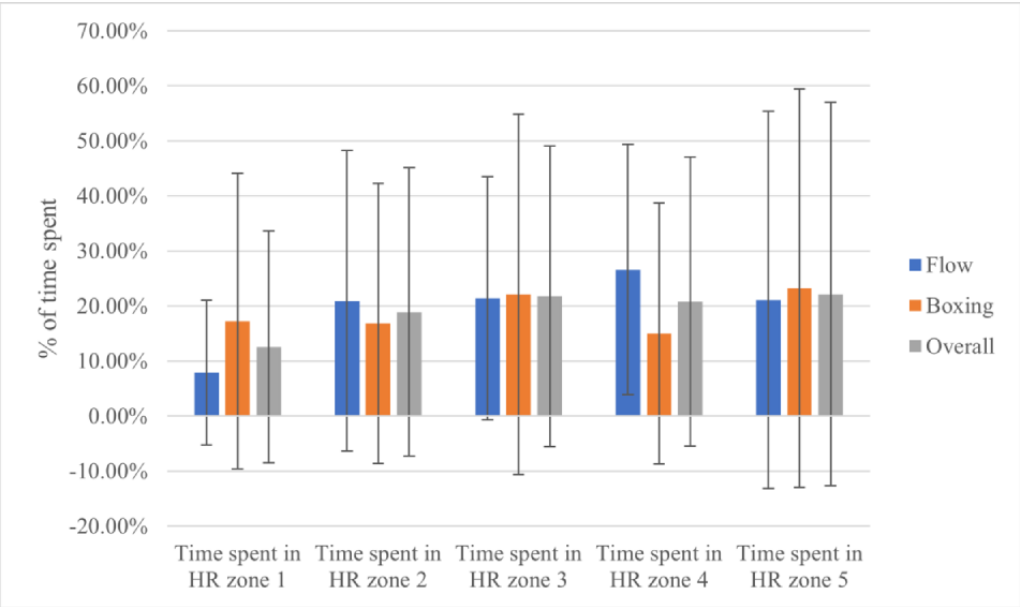
[a]N/A: not applicable.

[b]Values represent a significant difference from the metabolic cart (*P*≤.0125).

Heart Rate

The average HR for Flow was 151.13 (SD 23.12) bpm, and HRmax was 169.39 (SD 20.04) bpm. The average HR for Boxing was 143.29 (SD 26.36) bpm, with an HRmax of 161.43 (SD 26.36) bpm. Flow demonstrated a significantly higher average HR (M_{diff}=8.43, 95% CI 3.45-13.40; *P*=.002) and HRmax (M_{diff}=8.38, 95% CI 3.12-13.64; *P*=.003) when compared to Boxing. The overall average HR across both modalities was 147.21 (SD 23.12) bpm, and the average overall HRmax was 165.41 (SD 20.04). Sex-specific differences in HR were observed for Boxing average HR (M_{diff}=25.61, 95% CI 1.99-49.23; *P*=.04) and HRmax (M_{diff}=25.53, 95% CI 4.04-47.01; *P*=.02), with male individuals demonstrating a higher HR during Boxing. Time spent in HR zones is presented in Figure 3.

Figure 3. Time spent in heart rate zones. Error bars represent the SD. HR: heart rate.



Changes in Mood States

Between baseline and postsession 1, on average, participants reported that they felt more "lively" (M_{diff}=0.46, 95% CI 0.50-0.86; *P*=.03), more "active" (M_{diff}=0.67, 95% CI 0.32-1.07; *P*<.001), more "full of pep" (M_{diff}=0.57, 95% CI 0.14-0.99; *P*=.01), and more "vigorous" (M_{diff}=0.48, 95% CI 0.90-0.87; *P*=.02). Between presession 2 and postsession 2, on average, participants reported feeling more "active" (M_{diff}=0.76, 95% CI 0.36-1.17; *P*<.001), more "full of pep" (M_{diff}=0.38, 95% CI 0.02-0.75; *P*=.04), and more "vigorous" (M_{diff}=0.52, 95% CI 0.18-0.87; *P*=.004). No item on the fatigue subscale of the POMS-SF changed significantly for either session 1 or 2.

Discussion

VR fitness games have seen an increase in popularity as a mode of PA in recent years [7]. However, variability among game demands and objectives, along with difficulties in measuring energy expenditure with gold standard assessments (ie, indirect calorimetry), have limited our understanding of the intensity of these games [19], in turn limiting recommendations involving this mode of PA with respect to MVPA guidelines. Hence, the primary aim of this study was to examine the energy expenditure

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of one of the most popular VR fitness games, Supernatural. Specifically, we assessed the energy expenditure of a session of medium intensity for both the Flow and Boxing modes of Supernatural using indirect calorimetry. We also examined how other popular measures of energy expenditure compared relative to indirect calorimetry.

For Flow, average relative VO_2 max was 28.52 (SD 5.39) mL/kg/min, which translated to approximately 8.2 (SD 1.54) METs, classifying it as vigorous intensity (ie, >6 METs) [42]. Compared to other forms of PA, Flow was akin to climbing stairs (8.0 METs) or general circuit training (8.0 METs) [43]. Moreover, the percent of age-predicted VO_2 max (mean 59.39%, SD 11.75%) points to the potential use of this mode of Supernatural within a VO_2 training program [44]. Notably, only objective VO_2 was found to be significantly different between male and female participants, which suggests that this mode of PA demonstrates a significant sex difference in objective energy expenditure. This finding is likely due to the body weight nature of the game (ie, movements were relative to participants' own body weight), as this significant difference was not evident when examining the relative VO_2 values or METs (ie, accounting for participants' weight). This is encouraging, suggesting that young, active individuals engaging in a bout of Supernatural Flow should receive a relatively similar aerobic workout, independent of sex. This indicates that during a flow session, participants were averaging a high enough percentage of VO_2 to potentially improve maximum oxygen uptake.

For Boxing, average relative VO_2 max was 26.70 (SD 5.79) mL/kg/min, which translated to approximately 7.6 (SD 1.66) METs, also classifying it as vigorous intensity (ie, >6 METs) [42]. Compared to other modes of PA, Boxing was higher than high-impact aerobics (7.3 METs) and close to sparring while boxing (7.8 METs) [43]. Interestingly, both the Flow and Boxing modes demonstrated a higher energy expenditure than "activity-promoting video or arcade game (eg, Exergaming and Dance Dance Revolution), vigorous effort" (7.2 METs), which further speaks to the heterogeneity in demands among available VR fitness games [45]. For example, the lower average energy expenditure of the Boxing mode may be due to the difference in physical demands between modes, with Flow incorporating more frequent multimuscle group movements (eg, squats and arm swings) than Boxing, which consists primarily of slips and punches. Similar to Flow, there was a trend in objective VO_2 between sexes (P=.06) favoring male individuals but no significant differences in any other VO_2 outcome or METs, for the Boxing session. Furthermore, while the objective VO_2 max and METs were significantly lower for Boxing than Flow, the data suggests that individuals were still exercising at a high enough percentage of VO_2 to improve maximal oxygen uptake [46]. Hence, Boxing also has implications as a candidate for use in aerobic training programs, independent of sex.

Given the lack of research comparing indirect calorimetry to device-based measures when examining VR fitness, we also aimed to compare the findings from the metabolic cart to that of a triaxial waist-worn accelerometer, an Apple Watch, and the Oculus Move. On average, the accelerometers underestimated the energy expenditure of the metabolic cart by approximately 65% (SD 14.55%) for Flow and approximately 45% (SD 13.8%) for Boxing. This discrepancy and variability were somewhat surprising, given the relative reliability and validity of this particular accelerometer in assessing aerobic PA (eg, running and walking) [47]. However, this underestimation is likely due to the placement of the accelerometer (ie, waist-worn), which is unlikely to capture the full range of dynamic upper and lower body movements characteristic of a VR fitness game. Notably, several other studies have used waist-worn accelerometers within VR research [25,26], though these studies have examined time spent in MVPA rather than an energy expenditure outcome (eg, METs). Despite this, an underrepresentation of MVPA as captured by accelerometry still appears to be evident; Sousa et al [26] reported an average of 4.10 (SD 4.93) minutes of MVPA for a 20-minute VR fitness session (approximately 21%), while Giakoni-Ramirez and colleagues [25] reported an average of 3.57 minutes of MVPA for a 9-minute "intermediate" VR fitness session (approximately 40%). Hence, our findings suggest that the use of accelerometers during this form of PA be used cautiously.

Compared to the accelerometer, the Apple Watch was relatively more accurate, estimating approximately 108% (SD 24.88%) and approximately 112% (SD 25.41%) of the metabolic cart for Flow and Boxing, respectively. This may be due to the wrist-worn placement of the Apple Watch, which makes it more sensitive to the movements of the VR fitness games. Notably, there was a considerable degree of variability within the Apple Watch measures, ranging from a 28% underestimation to a 56% overestimation of caloric expenditure. Our findings are consistent with previous validation work using the Apple Watch to measure MVPA and energy expenditure [48]. Work by Bai and colleagues [49] does support the validity of the Apple Watch as a measure of MVPA; importantly, however, their work uses a waist-worn accelerometer as the criterion measure, which limits the interpretability of their findings in a VR fitness context. Hence, while our results support the relative accuracy of the Apple Watch, its usefulness as a precise measure of energy expenditure during VR fitness is limited.

On average, the Oculus Move accelerometer underestimated the energy expenditure of the VR fitness games measured by the metabolic cart by 27% (SD 23.1%) and 44% (SD 12.48%) for Flow and Boxing, respectively. Like the waist-worn accelerometer, the placement of the accelerometer within the Oculus headset may have impacted the accuracy of its measurements. Similar to the other measures of energy expenditure, the use of this outcome as a measure of energy expenditure is limited.

Lastly, preliminary comparisons of pre-post VR fitness measurement session mood states revealed reported changes in mood that are consistent with the beneficial changes we would expect from a bout of moderate-intensity PA [36] and with previous VR exergaming research [28,35]. These changes provide preliminary evidence for the positive mental health benefits of even single sessions of VR fitness, which is encouraging given the relationship between positive affect and adherence to PA [50].

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Though our study contained many strengths, such as a gold-standard measure of energy expenditure (ie, indirect calorimetry) and a relatively homogeneous sample, there are limitations to our work. One limitation of this study is that all participants were naive to VR fitness. This may have resulted in a variable amount of energy expended compared to someone who regularly engages in VR fitness. Although we implemented a strict threshold for inclusion in the measurement session, discrepancies in the final accuracy and power scores, along with direct observation of participants, suggest that some participants spent more or less energy adjusting to the difficulty of the measurement session workout. In other words, the final score across participants suggests that some struggled more than others in acclimating to the difficulty of the measurement session. Further, all participants were active individuals (ie, meeting the weekly PA guidelines). As a result, the measured metabolic and cardiorespiratory responses to the measurement session may not be reflective of the average new user.

Both the Flow and Boxing medium-intensity modes of Supernatural demonstrated relatively high energy expenditures (8.2, SD 1.54 METs, and 7.6, SD 1.66 METs, respectively), classifying as vigorous-intensity PA (ie, >6.0 METs) [42]. Device-based measures of energy expenditure varied considerably both between participants and when compared to the metabolic cart results. Hence, caution should be used when using and interpreting device-based measures of energy expenditure within VR fitness games, including Supernatural. This study also provides preliminary evidence to support the physical and mental health benefits of engaging in VR fitness games like Supernatural. These findings are encouraging, given the increasing popularity and accessibility of VR fitness games as a means of achieving MVPA. For individuals who are interested in being physically active at home or are unable to access traditional forms of exercise, VR fitness presents a potential supplement or alternative to achieving the recommended levels of MVPA.

Acknowledgments

This research was funded by Supernatural.

Data Availability

The data sets generated and analyzed during this study are not publicly available due to privacy restrictions in accordance with the study sponsor but are available from the corresponding author on reasonable request.

Conflicts of Interest

This research was commissioned and funded by Supernatural. Supernatural was involved in the design and development of the protocol but was not involved in the conduction, analysis, or publication of the study or study data.

Multimedia Appendix 1
Experimental setup in action detailing the Oculus Quest 2 VR headset, metabolic cart apparatus, Apple Watch 2, and ActiGraph waist-worn accelerometer (located beneath model's shirt).
[PNG File , 3761 KB - games_v12i1e53999_app1.png]

Multimedia Appendix 2
Experimental setup including Oculus Quest 2 VR headset and metabolic cart headgear and mouthpiece.
[PNG File , 4287 KB - games_v12i1e53999_app2.png]

Multimedia Appendix 3
CONSORT (Consolidated Standards of Reporting Trials)-eHealth Checklist.
[PDF File (Adobe PDF File), 8798 KB - games_v12i1e53999_app3.pdf]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
GAQ: Get Active Questionnaire
HR: heart rate
HRmax: maximum heart rate
Mdiff: mean difference
MET: metabolic equivalent of task
MVPA: moderate to vigorous intensity physical activity
PA: physical activity
POMS-SF: shortened version of Profile of Mood States
VO2 max: maximal oxygen consumption.
VO2: oxygen consumption.
VR: virtual reality

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Original Paper

Design of Virtual Reality Exergames for Upper Limb Stroke Rehabilitation Following Iterative Design Methods: Usability Study

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Abstract

Background: Since the early 2000s, there has been a growing interest in using exercise video games (exergames) and virtual reality (VR)–based interventions as innovative methods to enhance physical rehabilitation for individuals with multiple disabilities. Over the past decade, researchers and exercise professionals have focused on developing specialized immersive exercise video games for various populations, including those who have experienced a stroke, revealing tangible benefits for upper limb rehabilitation. However, it is necessary to develop highly engaging, personalized games that can facilitate the creation of experiences aligned with the preferences, motivations, and challenges communicated by people who have had an episode of stroke.

Objective: This study seeks to explore the customization potential of an exergame for individuals who have undergone a stroke, concurrently evaluating its usability as a technological tool in the realm of physical therapy and rehabilitation.

Methods: We introduce a playtest methodology to enhance the design of a VR exergame developed using a user-centered approach for upper limb rehabilitation in stroke survivors. Over 4 playtesting sessions, stroke survivors interacted with initial game versions using VR headsets, providing essential feedback for refining game content and mechanics. Additionally, a pilot study involving 10 stroke survivors collected data through VR-related questionnaires to assess game design aspects such as mechanics, assistance, experience, motion sickness, and immersion.

Results: The playtest methodology was beneficial for improving the exergame to align with user needs, consistently incorporating their perspectives and achieving noteworthy results. The pilot study revealed that users had a positive response. In the first scenario, a carpenter presents a game based on the flexion-extension movement of the elbow; the second scenario includes a *tejo* game (a traditional Colombian throwing game) designed around game mechanics related to the flexion-extension movement of the shoulder; and in the third scenario, a farmer challenges the player to perform a movement combining elbow flexion and extension with internal and external rotation of the shoulder. These findings suggest the potential of the studied exergame as a tool for the upper limb rehabilitation of individuals who have experienced a stroke.

Conclusions: The inclusion of exergames in rehabilitation for stroke-induced hemiparesis has significantly benefited the recovery process by focusing on essential shoulder and elbow movements. These interactive games play a crucial role in helping users regain mobility and restore practical use of affected limbs. They also serve as valuable data sources for researchers, improving the system's responsiveness. This iterative approach enhances game design and markedly boosts user satisfaction, suggesting exergames have promising potential as adjunctive elements in traditional therapeutic approaches.

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KEYWORDS

stroke; user-centered design; exergame; design; virtual reality; playtest; upper limb rehabilitation

Introduction

Background

In recent years, technological advances have influenced motor rehabilitation interventions for survivors of stroke, with the introduction of exergames, known as "serious games for health," which help motivate individuals in their rehabilitation [1-4]. However, the development of such exergames needs to consider users' needs and rehabilitation goals [5].

Virtual reality (VR) immersive [6] systems have become increasingly popular in rehabilitation, as they offer immersive and engaging activities, improving motivation and skill acquisition [7]. Nevertheless, systematic reviews have noted that most VR apps primarily focus on balance and gait, with limited attention to upper extremity rehabilitation [8,9].

Efforts have been made to design exergames tailored for survivors of stroke, but challenges remain, including limited user involvement and lack of immersive VR integration [10,11].

This study aims to address these challenges by designing a VR-based upper limb rehabilitation exergame using a user-centered approach, involving survivors of stroke in the design process and conducting playtests with an immersive VR setup [12]. The methodology aims to improve interdisciplinary collaboration and facilitate the involvement of clinicians in the design process [13,14]. The primary objectives are to provide personalized upper arm physiotherapy for survivors of stroke through an improved VR exergame and to assess its usability through user feedback [15]. This work encourages collaboration among clinicians, researchers, and designers to create an engaging rehabilitation exercise that complements the recovery process for survivors of stroke, ultimately enhancing their quality of life.

Related Work

VR-Based Physical Rehabilitation for Stroke

Experts in rehabilitation, kinesiology, and neuroscience are integrating VR systems with exergames to enhance the appeal and effectiveness of rehabilitation processes [16]. Early studies, such as those by Henrique et al [17] and Burke et al [18], demonstrated the positive impact of exergames on balance, gait, and upper limb motor function in patients with stroke, highlighting improved therapy adherence [14,16-20]. However, systematic reviews have indicated that most VR apps for after-stroke therapy primarily focus on balance and gait, with limited attention to upper extremity rehabilitation [3,21,22]. To address this gap, we aim to evaluate the potential of an exergame for upper limb rehabilitation using immersive VR systems [22].

In addition, prior research has shown that complementing or replacing standard rehabilitation with VR-based rehabilitation can result in significant improvements in gait speed, balance, and mobility in patients with stroke [3,17,21-23]. Our work aims to contribute to the development of guidelines for using VR-based rehabilitation in conjunction with conventional therapy, with a focus on upper limb rehabilitation.

Although some researchers, such as Reis et al [10], Leung et al [11], and Horsham et al [24], have proposed methodologies for developing specific exergames for stroke rehabilitation, there is still limited knowledge regarding immersive VR-based designs targeting upper limb rehabilitation [10,11,24]. Therefore, we intend to involve survivors of stroke in an iterative playtesting process to develop an upper limb VR-based rehabilitation system and bridge this gap.

Playtesting as an Iterative Design for Stroke

This section covers research related to the use of playtesting as an iterative user-centered design (UCD) methodology. UCD has played a significant role in the development of games for rehabilitation and overall health [25,26], as it is a methodology that allows active participation of the target population in the system's prototyping process. UCD, applied in game design, often advocates for an interactive and participative methodology that includes multiple playtests with end players. Playtesting is an activity carried out with potential users or players who interact with game prototypes developed in the early stages, making it easier to gather individual opinions and ideas that contribute to improving the gameplay aspects of exergames during their development [27,28]. Playtesting is a key and standardized methodology used in game studios to iterate and systematically improve games before they are released to the public [29].

A relevant example is the work of Duval et al [30], who conducted a collaborative study with 14 clinicians, focusing on therapeutically validating the game based on their opinions rather than those of users. Duval et al [30] obtained significant findings by addressing the adoption of therapy and personalizing it according to the characteristics valued by medical professionals. In contrast, other UCD works, such as the study by Aguilar et al [31], have not used playtesting but have used usability tests involving scales and flow state questionnaires. Findings from 3 years of experience with exergames developed for older adults using UCD methods concluded that devoting the key to engaging with end users and considering feedback and opinions can be considered the best practice guide for the development of therapeutic games [32]. We believe that playtesting can be beneficial for the design process of games for health, as it is strongly recommended to involve the target audience during the game design and development processes. By doing so, developers increase the likelihood of creating games that consider the specific preferences, motives, and characteristics of survivors of stroke in need of physical therapy [21]. By including survivors of stroke in interactive playtesting and, consequently, in enhancing a VR exergame, we begin to understand how this design methodology affects the subsequent use of the exergame as a therapeutic tool.

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Methods

In this section, we introduce the interdisciplinary team that worked on the improvement of the VR exergame we used in the playtesting session and the pilot study, as well as the description of the VR exergame. Furthermore, we present the playtesting methodology and the pilot study methodology.

Interdisciplinary Team

The structured design team was composed of an expert clinical physiatrist who advised the movements that users with stroke are likely to perform from a clinical viewpoint; a physiotherapist who provided permanent follow-up in all sessions with the users; a designer of exergames who helped implement the UCD methodology to have clear game mechanics; an expert in biomechanics who analyzed ranges of movement, postures, and gestures; a user experience researcher who organized all sessions with the users; 2 professional game programmers who created the game prototypes; and 2 users who experienced stroke episodes and interacted with the system and based on the answers they gave us an improved exergame. For 2 months, this group convened weekly to discuss the exergames' requirements, technologies, and overall scope of the project. The discussions were centered on defining the activities in the internet-based environment and strategies for the recruitment of potential users. At the end of the design process, the group of game developers with programming experience used the Unity game engine (Unity Technologies) to materialize the ideas.

The main topics addressed by the interdisciplinary team were (1) the definition of the main objectives and roles of the project; for example, project management was assumed by the exergames designer, and the user experience researcher assumed the role of project manager and conducted most of the fieldwork; (2) socialization of playtesting activities, including user recruitment and experimental protocol; and (3) reconsideration and further adjustment of game design elements, such as game mechanics and their mapping with therapeutic objectives.

Design of the VR Exergame

Prior Design of the VR Exergame

We performed a rapid contextual design based on a previous study, where user profiles were defined using user personas [33]. In this study, we characterized 4 persona roles that distinguish them as gamers: apathetic, empathetic, beginner, and experienced. Specifically, we used the results of the user modeling process to define certain game elements. For example, we found that users showed interest in sports games. Hence, body interaction familiar with certain sports games was an important requirement to be integrated into the exergames. In addition, users were comfortable with game content related to their daily lives. Therefore, incorporating cultural activities into the exergames could be a promising approach. In addition, in this prior study, we considered the following clinical requirements when developing the VR exergame [34,35].

Population specificity: according to previous studies [36], most users who have experienced a stroke are older than 40 years, and few are younger than 30. These studies also showed that the older population has little experience with VR. In contrast, therapist experience suggested that ranges of motion vary across users who have experienced a stroke. Therefore, designers should be careful when adapting internet-based therapy to a wide range of capabilities [37].

Motor learning: different principles of motor recovery should be considered in the creation of the activities to be performed within the exergames, such as a meaningful task, intensive and repetitive practice, movements close to the normal range, muscle activation that drives the practice of movement, and variability and progression of training [10,38,39].

Rehabilitation movements: the movements suggested by clinicians to perform upper limb physical therapy in paretic users are listed in Table 1. These are shoulder flexion and extension, elbow flexion and extension, and Kabat diagonals. Kabat diagonals are internal and external rotation movements of the shoulder. According to Della Tommasina et al [40], a repetitive process of these movements is necessary to perform physiotherapy, from which a more effective range of motion recovery will be obtained [41]. The elbow and shoulder are the upper limbs' main joints, articulating the arm's largest segments. These joints require a greater range of motion in flexion and extension and often affect and limit arm motion when a stroke episode occurs. Hence, we decided that users in a seated position should perform different arm movements while playing the VR-based rehabilitation exergame, targeting multiple possible physical rehabilitation needs in the upper limbs of people with stroke.

Table 1. Rehabilitation movements proposed for the exergame.

	Movement	Application	Action in the exergame
Elbow	Flexion and extension	Improvement in the width of movement in daily life activities	Destroying blocks with a hammer
Shoulder	Flexion and extension	Improvement in the width of movement in daily life activities	Throwing *tejos*
Elbow	Interior and exterior extension	Improved range of motion in the daily life activities	Cutting grass with a machete

Complementary therapy: we propose a therapy that uses the VR-based rehabilitation exergame to complement the rehabilitation process instead of replacing the traditional one, such as the one proposed by Goncalves et al [42]. We are confident that users who have experienced a stroke will play an exergame with engaging activities because they are developed based on their needs and motivations. Therefore, the exergames will allow a disruptive experience different from conventional therapies, generating interest, excitement, and willingness to carry out their rehabilitation process without neglecting the conventional therapy recommended by clinical specialists [38]. Considering the rapid contextual design and the clinical

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requirements named in this study, in a prior study, we developed a VR exergame following the well-known game design methodologies by Schell [29], as we contextualize in the following subsection.

Motion Health VR: VR Exergame for Stroke Rehabilitation

In a prior study, we established a game design concept and game mechanics using the methodology proposed by Schell [29] and a complete contextual design conducted with users with stroke. This study covers a more systematic and complete description of the playtesting sessions conducted with players with stroke to iterate and improve the game based on the initial concept. Knowing the preferences, ages, and profiles of potential users, we decided to explore a design concept for the cultural regions of Colombia (the Caribbean, Pacific, Andean, Orinoco, and Amazon). We discovered that older adults are inclined to engage in activities in the countryside and typical and authentic Colombian games. We discussed this exergame concept with the clinicians of our design team, gathering feedback regarding the potential movements to be performed, particularly in the context of mapping them for stroke rehabilitation therapies. Considering the scope of the project and previous research conducted with local users, development capabilities, and timelines, we decided to start by developing a game design concept related to the activities of the Colombian Andean region. The Andean region is the central region of Colombia and has crosscutting activities that are representative of the entire country and run throughout the central Andes. The population of this region practices sports, such as *sapo* and *tejo* (throwing games), rowing, and other more well-known sports, such as basketball and boxing. They also engage in other daily activities, such as fruit picking, horseback riding, and bush cutting [43]. Aligned with these cultural activities, we designed game scenarios that focused on a local setting using Colombian games. The design team analyzed existing VR games to establish game mechanics that could involve desired rehabilitation movements, always considering the player's motivators and needs. This analysis facilitated communication between the team of clinicians and specialists and the design and development team while also helping to specify the activities that would be familiar and engaging to the users. Therefore, we called the VR exergame "Motion Health VR." The exergame comprises 3 main scenes in which players must develop 3 different activities: hammering, throwing a metal disk (a traditional Colombian game called *tejo*), and cutting bushes while riding a horse.

The exergame presents 3 meticulously crafted scenarios, each aligned with its unique reference to Figure 1. In the "carpenter" scenario (Figure 1A), players engage in a dynamic elbow flexion and extension challenge, wielding a hammer to systematically crush boxes that vary in color and size, demanding specific ranges of motion. Players must skillfully adjust their proximity to the boxes to adapt to this diverse challenge, seamlessly weaving in back-and-forth and crossbody-reaching motions. Between the box-smashing activity, a captivating puzzle gradually unveils itself, featuring distinct Andean wildlife. Upon completing the activity, players earn the gratifying experience of visualizing the completed animal puzzle. As players enhance their hammering skills, the game dynamically escalates in difficulty either by increasing hammering frequency or by reducing box sizes. In the second scenario, inspired by Colombia's traditional *tejo* game (Figure 1B), players embark on a shoulder-focused flexion and extension adventure, mirroring the popular sport played nationwide. Throwing a metal disk toward an explosive target known as a *mecha* on a clay court, players must adjust their shoulder movements according to the target's distance, finetuning their range of motion for precise throws and aiming to maximize target hits with minimal repetitions. In the third scenario, the "farmer" (Figure 1C), players are challenged with a multifaceted movement that combines elbow flexion, extension, and internal and external rotation of the shoulder, akin to Kabat diagonals. In this rural setting, players ride an internet-based horse while wielding a machete, a staple tool in the Colombian countryside, tasked with clearing the obstructive bushes that appear on both sides of the road. With one arm gripping the machete and the other resting on the horse's rein, players face escalating challenges as the game progresses.

Figure 1. The presented scenarios of the Motion Health VR exergame with (A) a carpenter, (B) a throwing activity, and (C) a farmer, based on the movement of the Kabat diagonals.

Playtesting Sessions

Iterative game design involves playtesting sessions with end users, who will shape the game features before its final deployment. The main objective of playtesting sessions is to iterate different playable prototypes to improve the overall playability of the game, thus increasing the likelihood of adoption. In addition, playtesting allows the researcher to assess the ability of potential players to perform the proposed activities and understand game feedback. We developed playtesting sessions using the VR exergame designed in a prior work.

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The playtest sessions were guided by a researcher accompanied by a clinical specialist who helped contact different users who had experienced a stroke. Owing to the COVID-19 pandemic, visits to each user were scheduled in such a way that biosafety protocols were maintained (eg, distancing, constant use of masks, and hand and footwear disinfection). Upon arrival at the agreed location, stakeholders performed the recommended distancing protocols. Then, the researcher prepared the experimental protocol, which consisted of setting up a table, a chair without a hand rest, and verifying the internet connection. Prototypes of the exergames were developed before the playtesting sessions and ported to the VR headsets (Oculus Rift in the first 4 iterations and Oculus Quest in the final version). Disposable headset protectors and cleaners were used to maintain biosafety measures. Table 2 presents the structure of the playtest sessions.

Table 2. Protocol for conducting playtests.

Actions	Considerations	Time (min)
Brief introduction of the dynamics of the session and interaction between the researcher and the user with stroke to obtain informed consent	__[a]	10
A quick explanation of how the VR[b] system works and what to expect from the activity	Preparation and arrangement	5
System implementation (HMD[c], headphones, and controls)	—	—
Free play or natural interaction with the system	Manifestation of difficulties, in real time if necessary	5
Receive feedback or explore ideas while users play	Formulate the questions established for the session	10
Conclude the session with questions about the experience	Questions	10

[a]Not available.

[b]VR: virtual reality.

[c]HMD: head-mounted display.

A total of 4 playtesting sessions involving 9 end users who had experienced a stroke were conducted. Each session was performed with a minimum of 2 users chosen considering their availability (Multimedia Appendix 1 lists the users who participated in each session and their demographic information). After playtesting, we recorded a video summarizing the session and documented a brief analysis that was subsequently discussed with the research and design teams. After each playtest, the team held a general meeting where all the discussions were presented. The subsequent playtest was scheduled after the implementation of the suggested game changes.

Pilot Study: Evaluation of the Game Experience and Usability of the Exergames

After conducting game playtests and completing a playable prototype of the VR exergame (4 iterations), we decided to carry out a pilot study to evaluate the usability of the game with a group of users who had experienced a stroke, in which 2 users who participated in one of the 4 iterations were part of the pilot study group.

We conducted a 20-minute session that was part of the rehabilitation therapy in which users who had experienced a stroke played the iterated version of the Motion Health VR exergame. We ported the final version of the game to the standalone VR headset, Oculus Quest 2, as it has several advantages, such as being wireless, comfortable, and having a high image resolution.

Users

This usability study was developed with 10 users who had experienced a stroke contacted through the clinician and therapist of the design team. We chose this sample size conveniently, considering the availability of users, which was very limited. In contrast, the small sample size allowed us to follow the biosafety protocols required for the COVID-19 pandemic, which was still ongoing in Colombia at the time of the study. The inclusion criteria for the study were being aged >50 years, having experienced a stroke and having hemiparesis or monoparesis, being able to read and write, not having serious vision problems (eg, strabismus), and not having diagnosed cognitive disabilities (eg, dementia).

Ethical Considerations

The bioethics committee of the local university approved this study, which was also approved by the bioethics committee of a local rehabilitation center (52–050623). Users volunteered for this study and agreed to participate by signing an informed consent form.

Usability Study

Two questionnaires (instruments) were used to assess the game user experience immediately after interacting with the immersive game.

Virtual Reality Neuroscience Questionnaire

The Virtual Reality Neuroscientific Questionnaire (VRNQ) measures the quality of user experience, game mechanics, and in-game assistance. It comprises 20 questions, each scored on a Likert-type scale ranging from 0 to 5 [44]. The advantage of using this questionnaire is that it provides the limits to assess the suitability of the software in VR [44]. VRNQ produces a total score that reflects the overall quality of the VR software and 4 categories as follows: (1) game experience, where the level of immersion and pleasure of the experience are evaluated; (2) game mechanics, where user interaction in the internet-based

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environment is evaluated; (3) game assistance, where the exergame instructions, indications, arrows, and labels are evaluated; and (4) motion sickness, which evaluates whether you experience nausea, disorientation, fatigue, and instability.

Immersive Tendencies Questionnaire

The Immersive Tendencies Questionnaire (ITQ) determines the differences in an individual's tendencies to experience immersion and presence after interacting with a VR scenario. ITQ comprises 18 questions rated on a Likert scale from 1 to 7, resulting in a possible score ranging from 18 to 126. In the original study, the mean score of the samples was 76.66 [45]. This questionnaire is considered a standard in VR research and has been widely used in different applications [22]. A user with a positive immersive tendency based on the ITQ score is likely to experience higher levels of VR presence, which has been associated with better task performance [22,41,46]. This questionnaire is useful because it allows the evaluation of immersion in a way that does not depend on the specific internet-based environment, making it possible to determine independently if an internet-based environment performs poorly or if the statistical sample has low immersion trends. Some ITQ questions are as follows:

- Does it often happen that while daydreaming, you forget what is happening around you?
- Does it happen to you that you are so engrossed in a movie that you forget what is happening around you?
- Do you identify with television characters?
- When you use an exergame, does it occur to you that you feel like you are inside the game instead of sitting down using the controller?
- Do you stay scared for a while after watching a scary movie?

Experimental Setup

The researcher and the physical therapist held the interaction session at each participant's home, where they chose a comfortable space to set up the VR system. The setup consisted of a chair in which the user with stroke was seated with the Oculus Quest 2 wearable headset and its respective wireless controllers. The researchers were able to see what the players were doing via the official Meta Quest app using an electronic tablet in real time.

Protocol

The users began the pilot study session seated, using the headset and holding the controllers. We conducted the session in the following order. The user who had experienced a stroke performed an upper body warm up for 5 minutes, guided by the physical therapist. The researcher and physical therapist prepared the user for the game by helping them put on the VR system. The researcher started the exergame, which was presented throughout the session, accompanied by a physiotherapist. After the interaction, the user who had experienced a stroke completed the 2 proposed questionnaires. Given the biosafety regulations established by the Colombian government because of the COVID-19 pandemic, all those involved in the sessions always wore masks. In addition, the researcher cleaned all VR and mounting elements each time they were used.

Data Analysis

The questionnaires were scored following the instructions of previous works. Descriptive statistics, such as mean and SD, were calculated and reported [47,48].

Results

Overview

The results are presented in 2 subsections. The first subsection details the transformation process of the game after conducting 3 playtesting sessions and iterations involving the end users and the interdisciplinary design team. The second subsection presents the preliminary results of a pilot study evaluating the user experience of the final game with a group of 10 players with stroke.

Playtesting

The following subsections detail the results of the iterative design process of the Motion Health VR exergame, reporting the details of the playtesting sessions and the modifications made to each iteration. The overall objectives of the playtest were to validate the acceptance and playability of users with stroke and to explore whether they were able to perform the activities proposed in the VR scenarios and game mechanics. In addition, analysis of errors and optimization of game mechanics were crucial to improve playability. A total of 9 users with stroke were involved throughout the 4 playtesting sessions conducted (Multimedia Appendix 2), focusing on certain game elements (eg, mechanics and esthetics) via playable prototypes and reporting back to the design team.

Analysis of Playtest 1

This version of the exergame was created to test the first 2 scenarios. Players 1 and 2 (U1 and U2) participated in this session following the protocol in Table 2. We used a VR-ready laptop and an Oculus Rift headset with controllers. The playtesting goals were to evaluate the appropriateness of the proposed range of movement for hammering and throwing the disk and to explore button combinations for performing the activity using the controllers. We found that (1) the game should consider different scales of spasticity to provide a more adaptive experience [49]; (2) the buttons should be suspended from their functions to avoid triggering involuntary functions; and (3) a rest period should be granted to the user because, as recommended by the physiotherapist, long periods of exercise generate symptoms of fatigue.

Analysis of Playtest 2

The objective of these playtests was to test the modifications introduced in the first 2 scenarios based on the considerations in the Analysis of Playtest 1 subsection. Players U3, U4, and U5 participated in this playtest following the protocol in Table 2. A VR-ready laptop and an Oculus Rift headset with controllers were used. Figure 2 shows the evolution of the 2 scenarios after the first playtest, showing the improvement in

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content according to the real scenarios where these activities were performed.

Figure 2. The final version of each scenario of the Motion Health VR exergame: (A), the carpenter scenario, (B) the tejo scenario, and (C) the farmer scenario.

Users with stroke reported an improvement in the simplicity of the interaction, as they found it much easier to perform the movement owing to an initial calibration of the position added to the 2 scenarios, which adjusts the player's position concerning the internet-based surroundings, ensuring objects are at a reachable distance. In addition, we found that (1) the objects in each scenario should be in a static position; thus, people can avoid unnecessary displacements within the internet-based space that can generate dizziness; (2) we need to improve the auditory feedback of scenarios to create an immersive experience; and (3) we need to improve the calibration scene to allow players with low mobility to perform the tasks.

Analysis of Playtest 3

The third scenario was prototyped, and the game mechanics were ready for playtesting. The objective of this playtest was to test whether players could easily understand and interact in the farmer scenario by performing the proposed movements, that is, riding the horse while holding the rein with the unaffected arm and cutting bunches with the machete using the affected arm. Players U6 and U7 (Multimedia Appendix 3) participated in this test following the protocol in Table 2. We used a VR-ready laptop and an Oculus Rift headset with controllers. We found that (1) it would be useful to place the avatar on the horse from the beginning and (2) the game should allow cutting bushes to be performed using both arms and provide adequate time to switch the game controller between hands because the players become tired after certain repetitions.

Analysis of Playtest 4

After iterating each scenario and exploring potential pitfalls and interaction errors, a final playtesting session was scheduled to test the overall functioning of the integrated system. This prototype of the exergame presented an embellishment of the contents (Figure 2), which was an improvement in the overall esthetics of the game. In addition, a structured exercise session was recommended by the clinical rehabilitation experts, following a 15-minute session (similar to other studies of the same nature [50]). Therefore, the 3 scenarios were presented in sequence and switched after 5 minutes (approximately). Players U3, U4, and U5 participated in this test following the protocol in Table 2. We used a VR-ready laptop and an Oculus Rift headset with controllers.

We found that (1) scene transitions should be smoothed and (2) the game should implement rest periods between each scenario, as users still manifested mild fatigue from performing so many repetitions while preparing for the next mechanic.

Finally, we integrated the above recommendations into the scenarios and developed the final prototype of the Motion Health VR exergame.

Evaluation of Game User Experience

This section presents the results of evaluating the game user experience of the co-designed Motion Health VR exergame involving 10 users with stroke (Multimedia Appendix 4). For this part, the game was modified to a more portable, standalone, and easy-to-use headset, the Oculus Quest 2. Only the final deployment platform was changed (from wired to wireless VR), and no other changes were made. The questionnaires were administered at the end of the session, asking users to rate their experience in a wide range of aspects following the ITQ and VRNQ.

Virtual Reality Neuroscientific Questionnaire

The results of administering VRNQ are reported as average values with SD (Table 3). Each category had a maximum of 35 points. Gaming experience was rated at a mean of 24.8 (SD 4.5), game mechanics mean 23.8 (SD 5.5), game assistance mean 23.9 (SD 5.5), and motion sickness (inversely proportional), mean 31.1 (SD 5.6). Consequently, the maximum possible general score for this test was 140, in which the exergame Motion Health VR obtained a mean of 103.6 (SD 19.4). This level of quality is considered more than adequate as it exceeded 100 points. From this, it can be concluded that the users experienced a high level of immersion during their video game experience, and the quality of the Motion Health VR exergame obtained a general average of mean 103.6 (SD 19.4), which is considered an adequate quality because it exceeded 100 points [47]. On the basis of this result, we observed that users had a high immersion index; the experience with the exergames was very pleasant; and the quality of the graphics, sound, and technology, in general, was perceived as very positive. Finally, the system showed the best results in the motion sickness index, which shows that exergames did not cause major side effects associated with cybersickness or nausea [47,51].

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Table 3. Virtual Reality Neuroscientific Questionnaire (VRNQ) categories.

VRNQ categories	Score, mean (SD)
Game experience	24.8 (4.5)
Game mechanics	23.8 (5.5)
Game attendance	23.9 (5.5)
Motion sickness	31.1 (5.6)

Immersive Tendencies Questionnaire

ITQ was used to evaluate users' immersion experience and presence following their engagement with the exercise. The overall ITQ score averaged 60.8 (SD 11.6), signifying that participants with a history of stroke perceived relatively low to moderate levels of immersion and enjoyment (Table 4). In terms of concentration (mean 22.3, SD 2.9, with a maximum score of 35), users consistently achieved high scores, indicating that the game effectively captured their attention.

Regarding immersion (mean 17.9, SD 4.7, with a maximum score of 35), users reported a sense of engagement with the game. In terms of emotions (mean 14.6, SD 5.1, with a maximum score of 28), the findings suggest that users developed a strong emotional connection with the game [33,51,52].

Table 4. Immersive Tendencies Questionnaire (ITQ) categories.

ITQ categories	Score, mean (SD)
Concentration	22.3 (2.9)
Immersion	17.9 (4.7)
Emotion	14.6 (5.1)
Enjoyment	6.1 (2.2)

Discussion

Principal Findings

This study summarizes our efforts to report methodological approaches extensively used in game design that have a significant value when used to design VR exergames for stroke. We also showed the results of a preliminary usability test conducted involving 10 users with stroke who played the Motion Health VR exergame after completing 4 iterations using playtesting sessions. Overall, the VR exergame exhibited medium-to-high levels of game user experience and low levels of perceived symptoms associated with VR, such as nausea and dizziness. Moreover, regarding enjoyment, users expressed a high willingness to participate in therapies and continue with the sessions. The user experience questionnaires showed that users experienced increased immersion, emotional connection, and enjoyment with the VR exergame, although the concentration remained consistent. These results are consistent with previous research using immersive VR in older adults [53] and people with stroke [54,55]. Furthermore, we have carefully reported the methodological aspects related to playtesting sessions with users with stroke and specific procedures to conduct such sessions. From the playtesting sessions, we can extract the value of evaluating prototypes in the early stages of the game design process because this prevents researchers from struggling with complex interactivity and usability issues later during the trials. As reported in the study by Toro et al [56], early involvement of end users in VR systems for exercise promotion is a desired practice, and it is not commonly used among those creating custom-made exergames for older adults [57-59].

Playtesting as a Tool for Iterative Design

Playtesting is a part of the iterative design methodology used in different UCD approaches [51,60]. In our case, we performed playtest with several users who had experienced a stroke, which allowed us to improve the content, playability index, and game mechanics from an ergonomic approach to provide greater user comfort. Although prior designs of physical rehabilitation games for stroke have involved UCD [61], involving users with stroke in playtesting and follow-up sessions is not common [50]. We suggest that designers consider including playtesting with users with stroke because, in terms of rehabilitation therapy performance, playtesting revealed important details, such as the importance of performing a calibration stage or removing the buttons and other interactions with the VR equipment. We found that this stage provides exergames with the characteristics to adapt to the physical needs of each user, such as the range of motion and spasticity scale of each user [62]. In the context of serious games, the importance of adaptive games has increased, as every user has different requirements [62].

Furthermore, the playtesting methodology allowed us to strengthen relationships with all stakeholders, from developers to clinicians. This aligns with the findings of previous studies that have emphasized how involving multiple stakeholders in the design process leads to a more suitable and user-centered prototype [63]. The importance of maintaining close relationships with stakeholders has also been underscored, and this study reaffirms the relevance of this challenge in the successful implementation of playtesting. Effective collaboration between developers and clinicians, driven by the willingness and availability of both parties, has been a recurring theme in the literature [62]. Previous studies have pointed out the pivotal

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role of this relationship in the success of VR rehabilitation programs following stroke.

In particular, we noticed that playtesting allowed a stronger relationship with patients with stroke, increasing their willingness to participate in future studies. Although other researchers have reported difficulty finding specific populations to be involved in studies [64,65], considering our final results, we highly recommend that research teams plan to conduct multiple playtests before conducting studies.

Finally, we consider that after performing 4 playtests, based on the observations of the users who had experienced a stroke and the recommendations of the clinicians, an optimal version of the exergame was obtained, which could also be used by designers to facilitate piloting and prevent errors during data collection. As mentioned in this study, the inclusion of playtests and the collaboration of specialized professionals in programming and design align with the best practices recommended by previous research [66].

Usability of UCD VR Games in Patients With Stroke

We observed that ITQ and VRNQ scores were below the expected mean, as reported in the Results section. Similar results have been reported previously because there were some concerns about the usability of VR in older adults, including those who have had strokes. A systematic review of clinical and research applications of VR in older people identified usability issues, such as discomfort, cybersickness, and difficulty with the equipment [67]. Therefore, based on the current results, the design team must improve the gameplay mechanics and usability of the VR exergame to achieve better results in gameplay experience metrics before the subsequent trial. Nevertheless, the system scored high in usability, as its overall score was higher than expected (100 points). Furthermore, as our results showed that the VRNQ category with the highest score was motion sickness, meaning that users who experienced a stroke felt little nausea, our work aligns with studies using similar VR apps [8,20,47]. These usability results can guide other exergame designers to adjust their apps to suit older adults.

Use of Interactive Technology for Telehealth Care

The use of portable and autonomous technologies, such as the Oculus Quest 2 headset, during the pandemic has been an innovative response supported by this research [68]. This reinforces the notion that virtualization of health care, driven by technology, is becoming increasingly important. A recent review describing the promising landscape of telerehabilitation tools aided by serious games for upper limb stroke rehabilitation highlights the evidence of efficacy, the need for further research in this area, and the promise of digitally connected games to complement conventional rehabilitation [69]. Nevertheless, although VR has never been more accessible before, the reality is that the cost-effectiveness of its use in telehealth programs in both rural and urban areas in Latin America is still very limited [70]. In summary, our study contributes to emerging efforts in which interdisciplinary collaboration and the use of innovative technology during times of crisis, such as the pandemic, continue to draw a research pathway in this continually evolving field [63,71,72].

Limitations

We developed this study between August 2020 and June 2021, when most rehabilitation centers were closed owing to COVID-19 pandemic restrictions. Therefore, accessing users with stroke was a difficult task that we overcame with the help of the therapists. They provided us with the contact list of their former users, and we contacted them personally. Notably, although we took all safety precautions, people with stroke feared contagion and only a couple of them participated in the playtesting sessions. We acknowledge the lack of homogeneity in the sample of users who participated in the playtesting because stroke is a condition caused by several factors and affects both sexes, and users who have experienced a stroke tend to have a wide range of ages and ethnicities. The small sample size may limit the generalizability of our findings. Moreover, this limitation was difficult to address because of the COVID-19 pandemic restrictions that were under regulation when we developed this study. That is why, for the pilot study, we limited the users' age to >50 years. VR is a technology that is constantly changing and improving, in the sense that we started playtesting with the Oculus Rift headset and then moved on to using the Oculus Quest 2 for the pilot study because of its portability advantages. We overcame these technological changes because of the cross-platform features offered by the game engine used (Unity).

However, VR content development is a challenge when designing deployable solutions. Nonetheless, despite the pandemic situations in which this study was developed, the iterative design and preliminary study were carried out owing to the implementation of portable and autonomous tools, such as the Oculus Quest 2 VR headset, which are becoming increasingly important in the virtualization of health care delivery.

The duration of the usability study was very short, and users only interacted with the final game in a single session lasting approximately 15 minutes. A short-term study may not adequately capture the long-term benefits or challenges of using VR exergames for stroke rehabilitation. We plan to extend this initial pilot study and conduct a single-arm longitudinal study involving a similar group of users for 12 sessions for 3 months. Furthermore, this study did not include a control group for comparison. Without a control group undergoing traditional rehabilitation methods, it is challenging to conclusively attribute improvements to the VR exergame alone. Finally, although the study emphasizes the iterative design process and user feedback, it is difficult to know how these design changes directly affect the rehabilitation outcomes. Future studies with this game should include rehabilitation outcomes such as upper limb range of motion and spasticity levels.

Conclusions

Our research has conclusively demonstrated that creating VR exergames for stroke rehabilitation by involving end users early in the design stages brings advantages such as reducing interaction errors and unnecessary game design elements that do not contribute to the therapy. UCD is highly recommended as a design methodology for creating games specifically tailored to the rehabilitation of users who have experienced strokes. The

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results of this study support the effectiveness of multiple playtesting in producing therapeutic games that align with the needs and abilities of users with stroke, such as creating familiar internet-based environments and activities and removing unnecessary motion that could lead to motion sickness. This conclusion underscores the importance of adopting a patient-centered approach in the development of medical apps and technologies for rehabilitation. Our findings have yielded promising results regarding the use of immersive VR in the context of upper limb stroke rehabilitation. Users who immersed themselves in internet-based environments using custom-built exergames showed good levels of immersion and enjoyment and reduced levels of perceived nausea or dizziness. These results suggest that VR technology holds potential as a therapeutic tool for the treatment of users with stroke-related impairments, especially for at-home therapies. However, further research and long-term follow-up are required to fully understand the scope and limitations of this technology in the rehabilitation of this user group. The use of playtesting as an iterative tool for enhancing video game design enables comprehensive interaction with the user. This interaction allows for genuine customization of the therapy, leading to the development of a video game tailored specifically for users who have experienced stroke.

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Data Availability

The data sets generated during or analyzed during this study are available from the corresponding author upon request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Users in the playtests.
[DOCX File , 15 KB - games_v12i1e48900_app1.docx]

Multimedia Appendix 2
Demographic data of the user's study pilot.
[DOCX File , 15 KB - games_v12i1e48900_app2.docx]

Multimedia Appendix 3
Changes made throughout the iteration process of the playtests.
[DOCX File , 16 KB - games_v12i1e48900_app3.docx]

Multimedia Appendix 4
Scenario sketches.
[DOCX File , 60 KB - games_v12i1e48900_app4.docx]

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Abbreviations

ITQ: Immersive Tendencies Questionnaire
UCD: user-centered design
VR: virtual reality
VRNQ: Virtual Reality Neuroscientific Questionnaire

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Original Paper

Comparing Walking-Related Everyday Life Tasks of Children with Gait Disorders in a Virtual Reality Setup With a Physical Setup: Cross-Sectional Noninferiority Study

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Abstract

Background: A frequent rehabilitation goal for children with gait disorders is to practice daily-life walking activities. Unfortunately, these are often difficult to practice in a conventional therapeutic setting. Virtual reality (VR) with head-mounted displays (HMDs) could be a promising approach in neurorehabilitation to train such activities in a safe environment. First, however, we must know whether obstacles in VR are indeed mastered as obstacles.

Objective: This study aimed to provide information on whether VR is feasible and motivating to induce and practice movements needed to master real obstacles in children and adolescents with gait disorders. Furthermore, this project aims to evaluate which kinds of everyday walking activities are appropriate to be practiced in VR.

Methods: In this cross-sectional study, participants stepped over a bar, crossed a gap, balanced over a beam, and circumvented stationary obstructions arranged in a course under real physical and virtual conditions wearing a VR HMD. We recorded the respective primary outcomes (step height, step length, step width, and minimal shoulder-obstacle distance) with motion capture. We then calculated the mean differences and 95% CI of the spatiotemporal parameters between the VR and physical setup and later compared them using noninferiority analysis with margins defined a priori by a clinical expert panel. Additionally, the participants responded to a standardized questionnaire while the therapists observed and evaluated their movement performance.

Results: We recruited 20 participants (mean age 12.0, range 6.6-17.8 years) with various diagnoses affecting their walking ability. At 3.77 (95% CI 1.28 to 6.26) cm, the mean difference in step height of the leading foot in the overstepping task did not exceed the predefined margin of –2 cm, thus signifying noninferiority of the VR condition compared to mastering the physical obstacles. The same was true for step length (–1.75, 95% CI –4.91 to 1.41 cm; margin –10 cm), step width (1.05, 95% CI 0.20 to –1.90 cm; margin 3 cm), and the minimal shoulder-obstacle distance (0.25, 95% CI –0.85 to 0.35 cm; margin –2 cm) in the other tasks. Only the trailing foot in the overstepping task yielded inconclusive results.

Conclusions: Children with gait disorders perform everyday walking tasks like overstepping, crossing, balancing, or circumventing similarly in physical and VR environments, suggesting that VR could be a feasible therapeutic tool to practice everyday walking tasks.

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KEYWORDS

adolescent; child; gait; head-mounted display; motion capture; neurological rehabilitation; noninferiority trial; physical therapy; virtual reality; walking

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Introduction

In pediatric neurorehabilitation, children and adolescents with congenital or acquired lesions of the sensorimotor system often experience impairments in gait [1,2]. Consequently, recovery of walking ability is a frequent rehabilitation goal in pediatric neurorehabilitation [3]. Thereby, the focus is on promoting everyday life activities and ensuring meaningful participation for the child and their family [4]. Therapies targeting gait encompass a wide variety of therapeutic approaches. In our clinic, Swiss Children's Rehab, these therapies include, for example, conventional physical therapy, including task- and everyday life–oriented training, rehabilitation robots, and sports therapy. Normally, these therapies occur in a conventional therapeutic setting. However, within this setting, many everyday walking tasks, such as, for example, crossing a wide gap to board public transportation or avoiding contact with people or obstacles while navigating through crowded places, cannot be reasonably practiced.

In recent years, immersive virtual reality (VR) has become increasingly popular. Since companies have made the technology more accessible to the community through more affordable and easy-to-use devices, the use of VR has increased, as have the areas of its use [5]. Accordingly, this upswing in VR could be promising for its implementation in neurorehabilitation. Immersive VR puts users directly into virtual scenarios and gives the illusion of a full physical presence, providing rich sensory fidelity (high degree of reliability) [6,7]. To experience immersive VR, head-mounted displays (HMDs) are most suitable and can convey many of the abovementioned impressions [8]. A potential goal of using VR in pediatric neurorehabilitation could be to enhance children's abilities in their daily lives by practicing task-specific activities relevant to their everyday lives while still being in a safe therapeutic environment. Furthermore, its game-like attributes and animations can increase children's motivation and enhance their active participation by minimizing their focus on task repetitions [9,10]. Additionally, as VR is an accessible and affordable technology, it could enable home training. Moreover, a significant advantage of using VR in children aged between 6 and 18 years could be that they experience higher levels of presence and "realness" within a virtual environment compared to adults [11].

Recent studies have already investigated the effectiveness of acquiring different cognitive and motor tasks with VR. In the pediatric field, VR has been mainly used for pain management [6] or educational purposes [12,13], as well as to create relaxing and learning opportunities for children diagnosed with autism spectrum disorder [14,15] or attention deficit hyperactivity disorder [16]. However, the long-term effects of VR on developing children are unknown, and cybersickness or fatigue of the eyes and brain are potential disadvantages [6,17,18]. According to the authors' best knowledge, no evidence exists of using immersive VR as a gait therapy intervention in children with gait disorders. When including results from augmented reality studies, a systematic review showed moderate evidence for improved gait-related outcomes when gait training was enhanced with commercially available videogame systems, such as the Nintendo Wii or Microsoft Xbox Kinect, in children with cerebral palsy (CP) [19]. Furthermore, a systematic review and meta-analysis from Chen et al [20] showed a large effect size of d=0.861 for improved motor function in children with CP when comparing commercially available game systems with conventional therapy or controls (eg, no intervention). However, such systems lack essential aspects of VR since they are usually presented on a 2D screen or as floor projections [8] and, therefore, do not transmit the entire concept of VR, including full physical presence and immersion.

Immersive VR offers many advantages regarding task-specific training, motivation, "realness," and costs [5-7]. Still, it remains uncertain whether the use of VR in children with gait disorders is a feasible approach to inducing and practicing the movements required to perform everyday gait activities. Reasons to assume that VR in children with gait disorders might not be feasible are the lack of visual information of the lower extremities and the difference in the perception of virtual obstacles by the children [6,11,21]. Therefore, a prerequisite for the meaningful use of VR in training everyday gait activities would be that the children master obstacles presented in VR like they master physical obstacles. Thus, this project aims to provide information on whether a VR setup is feasible and motivating to induce and practice movements that are needed to master real obstacles in children and adolescents with gait disorders. Furthermore, this project aims to evaluate which kinds of everyday walking activities are appropriate to be practiced in such a VR setup. To evaluate this, we compare the spatiotemporal parameters of performing certain everyday walking tasks in a virtual and a physical environment using a noninferiority analysis. The noninferiority analysis should indicate that the virtual setup is not unacceptably worse than the physical setup.

Methods

Ethical Considerations

This cross-sectional study took place at the gait laboratory of Swiss Children's Rehab, University Children's Hospital Zurich, during a single 60-minute session. The ethics committee of the Canton of Zurich confirmed through a clarification of responsibility that no approval was needed for this study (Req-2021-00364).

Participants

We included children and adolescents aged between 6 and 18 years with gait disorders undergoing inpatient or outpatient rehabilitation at Swiss Children's Rehab. In line with recommendations for comparative studies, which propose 8 to 25 participants [22], we aimed to include 20 participants. All children who were receiving physiotherapy at the time of recruitment were screened according to the inclusion and exclusion criteria and recruited consecutively within 3 months. To be eligible to participate, they had to be able to walk short indoor distances without assistive devices or with crutches. Additionally, they had to be able to follow simple verbal instructions. Exclusion criteria were a history of seizures, epilepsy, blindness, or inability to use the HMD (eg, cybersickness, open wounds on the head).

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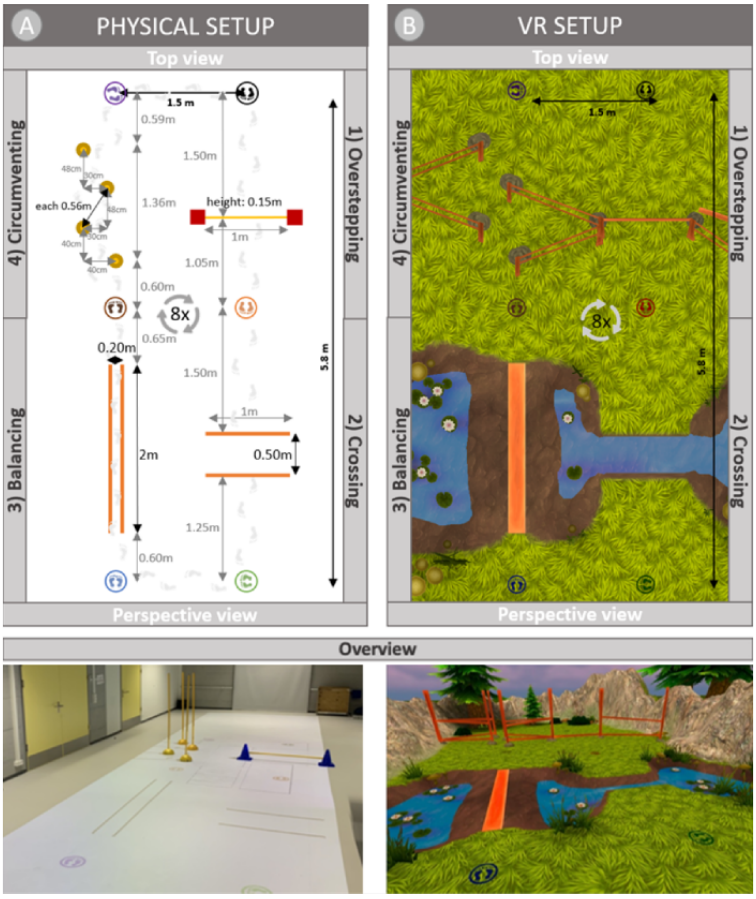
Participants' characteristics were collected from the patient records. The physiotherapist rated the functional mobility level using 2 performance measures: the Functional Mobility Scale (FMS) and the Gillette Functional Assessment Questionnaire (FAQ) walking scale [23]. The FMS describes the participant's level of functional mobility by assessing the assistive device used in everyday life over 5 m, 50 m, and 500 m on a scale from 1 (uses a wheelchair) to 6 (independent on any terrain). The FAQ assesses functional walking abilities on a scale from 1 (can not make any steps at all) to 10 (walks, runs, and climbs on even and uneven terrain). Finally, the lower extremity proprioceptive impairments of the participants were rated with the percentage score of the proprioception subsection of the Fugl-Meyer (FM) assessment for the lower extremities [24]. We assessed proprioception at the hip, knee, ankle, and toe joints while the participant was supine and barefoot.

According to good clinical practice standards, we obtained written informed consent from the participants and their legal representatives before participation.

Experimental Setup

The participants had to perform everyday walking tasks in 2 different conditions: physical setup and VR setup. In the physical setup, the participants had to master real (physical) obstacles (Figure 1A). The 4 obstacles, including overstepping, crossing, balancing, and circumventing, were arranged in a course. In the VR setup, the participants had to master the same 4 obstacles virtually. The obstacles were incorporated into an everyday environment (Figure 1B). The VR setup matched the locations and dimensions, but not the appearance of the physical obstacles. This discrepancy was chosen intentionally since we wanted to incorporate the obstacles into an everyday environment as they would appear in future applications. During the development process, it was ensured that the environment was designed as stimulatingly as possible, since interaction and sensorimotor contingencies are crucial contributors to a full VR experience [8]. Nevertheless, to compare the 2 conditions, we also had to keep the VR environment simple to avoid the participants being distracted from their tasks.

Figure 1. (A) Scheme of physical setup, and (B) the appearance of the VR setup when wearing the HMD.



For this setup, the commercially available VR HMD Meta Quest 2 (Meta Platforms) was used. We aligned the coordinate systems of the physical and the virtual world, using the hand-tracking function of the Meta Quest, and scaled and rotated the virtual world based on 2 points. To test the alignment between the 2 conditions, we checked that the scaling coefficient was near 1.0.

To minimize the influence of fatigue, we randomized the sequence of the conditions and the starting position within the obstacle course. We used a minimization method (randomization factor 1), including the factors of gender, age, and functional walking ability defined by the FAQ. During the session, the physiotherapist accompanied the participants to ensure their safety and provide assistance if necessary.

Task Description

For the overstepping task, the participants had to step over a 15-cm-high obstacle, which consisted of a plastic bar mounted

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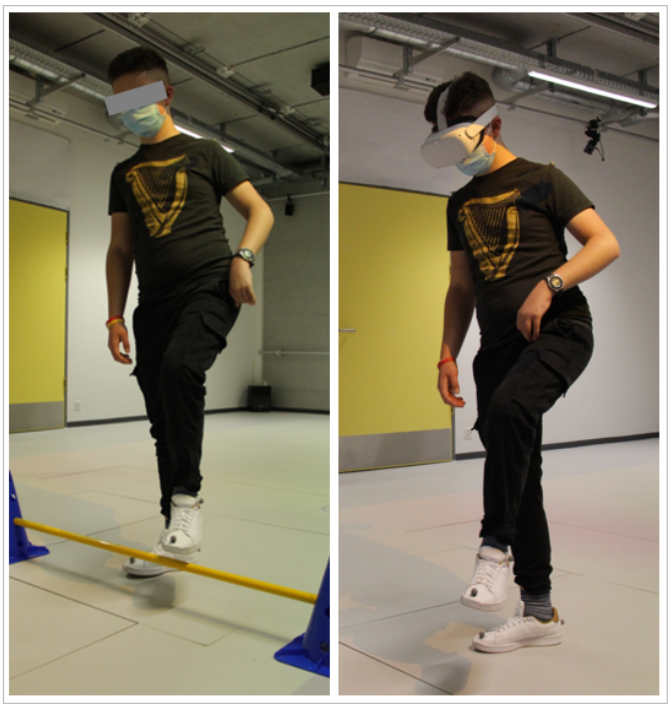
on 2 cones (physical setup) or the lower part of a fence (VR setup; Figure 2). In the physical setup, participants had to cross two 3-cm-wide lines projected on the ground with a beamer, whereas they had to cross a small stream in the VR setup. In both setups, the gap was 50 cm, thus exceeding the average step length of children with CP aged between 7 and 14 years (Gross Motor Function Classification System [GMFCS] levels I and II) or traumatic brain injury (TBI) [25-27]. For the balancing task, we instructed the participants to walk between two 2-cm-wide lines projected 20 cm apart on the floor in the physical setup and a 20-cm-wide wooden panel over a pond in the VR setup. Circumventing was performed by walking around 4 plastic poles (physical setup) or fence posts (VR setup). The distance of the poles was 56 cm, corresponding to approximately 1.7 times the average shoulder width of children aged between 6 and 18 years [28,29]. With an estimated protective zone of 30 cm around the obstacle [30], even smaller participants would sidestep, while taller participants could still pass through the obstacles, even when relying on crutches. In addition to the 4 tasks, the participants walked 6.5 m in a straight line without any obstacles, both with the HMD (walking on green grass) and without the HMD.

Figure 2. Execution of the overstepping tasks in the physical and virtual reality setups.



Measurement Procedure

Task execution was recorded with a total of 12 Vicon Vero 2.2 high-speed cameras (Vicon Motion Systems). We placed 9 infrared reflective markers of 16 mm diameter on specific anatomical landmarks at both feet (3 markers each) and shoulders (3 markers). The markers were attached to the shoes as the participants performed the tasks with shoes and orthotics (if needed) as in everyday life.

After measuring the participants' height and shoulder width and attaching the 9 reflective markers to the defined positions, the measurements started with either the physical or the VR condition. The participants first walked 4 times along the 6.5-meter walkway at self-selected walking speeds. Afterward, they performed 2 accommodation rounds of the obstacle course to familiarize themselves with the condition and the tasks. The physiotherapist could provide physical support if the participants had difficulties with any obstacle. Finally, we instructed the participants to always step over the obstacle and cross the gap with the leg they had spontaneously used in the first round.

According to Redekop et al [31], reliability with an interclass correlation coefficient of 0.90 is given for an average of 6 strides when examining discrete gait parameters in children with CP. Therefore, 8 trials per condition were recorded to have 2 spare measurements if any unexpected errors arose while reviewing the recordings. Once the 8 valid attempts per task were recorded, the participants had a short break, during which they answered the first part of the questionnaire. Subsequently, the same procedure was repeated with the second condition, followed by the second part of the participants' questionnaire and the proprioception subsection of the FM assessment performed by the investigator. Meanwhile, the physiotherapist completed the therapist's questionnaire and rated the participant's FMS and FAQ.

Data Processing

Vicon data were processed using Nexus Motion Capture Software (version 7.2; Vicon Inc). Processing of the raw data included visual determination and defining gait events like foot strike, foot off, etc. We analyzed the data from the first 6 valid trials for each condition and task. Then, the data were exported to MATLAB R2021a (version 9.10; MathWorks) to calculate the spatiotemporal parameters. For the spatiotemporal parameters, we calculated the mean of the 6 valid trials per task for each participant and condition individually. A negative mean difference between the VR and physical setup indicated a smaller value in the VR setup.

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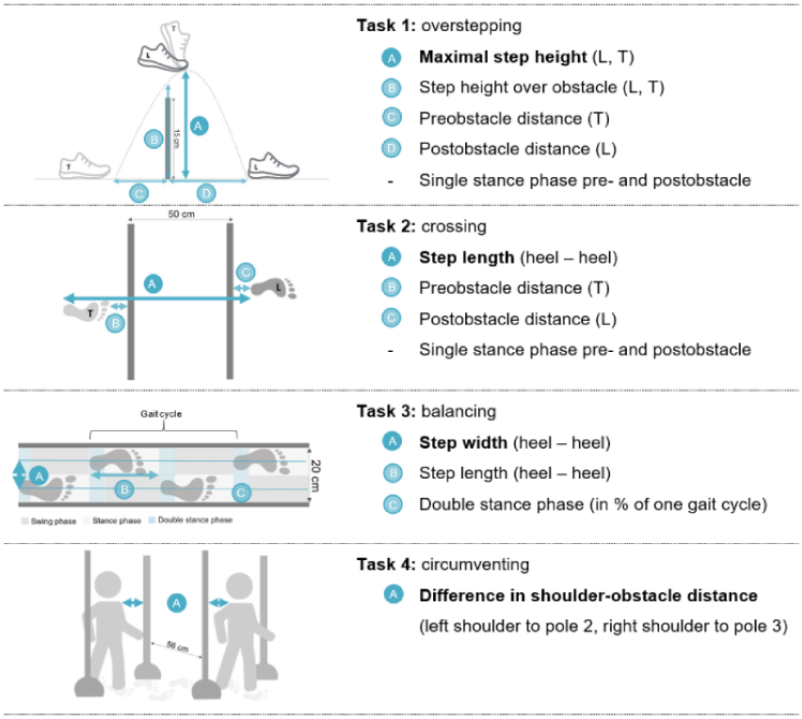
Outcome Measures

For the 4 tasks, we selected spatiotemporal parameters (Figure 3) in line with the literature [27,32-35]. We calculated the walking speed, step length and width, and double-stance phase during normal walking with and without the VR HMD. Additionally, we recorded the time to master each task and the number of failures, indicating unsuccessful obstacle negotiations.

Figure 3. Investigated spatiotemporal parameters for each task. (A) represents the respective primary outcomes. L: leading foot; T: trailing foot.



The participants answered standardized questions covering their movement ability, spatial presence, and enjoyment during task execution on a visual analog scale (VAS). In addition, the physiotherapists rated the participants' movement execution, level of engagement, and meaningful use on a 5-point Likert scale.

Statistical Analysis

Participants' clinical and functional characteristics are presented using descriptive statistics. A normal distribution could be assumed for the differences between the primary outcomes (Shapiro-Wilk test; $P>.05$). Therefore, the mean differences and their SDs were subsequently calculated. Additionally, the primary spatiotemporal parameters were analyzed using noninferiority testing with 95% CIs and a priori defined margins of noninferiority [36]. The noninferiority margins, which served as boundaries for the 95% CI of the mean differences, were defined for each task by a panel of 15 expert physiotherapists (n=14 women; n=1 men). These margins represent the maximum difference between the VR and the physical setup defined as acceptable while still considering the conditions to be equal [37]. To determine the maximum tolerated deviation, the physiotherapists compared the tasks with everyday life tasks and considered what deviation they would accept in conventional therapy for the respective task. A normal distribution could not be assumed with 15 responses; therefore, we described the margins using nonparametric parameters such as the median and IQR. Descriptive statistics are used to present the participants' and therapists' questionnaire responses. Additionally, to analyze the difference in fun between the 2 conditions, we used the Wilcoxon signed rank test with continuity correction.

Results

Participants

All patients that were examined for eligibility within the recruitment agreed to participate. In total, 7 girls and 13 boys with different gait disorders participated in this study. Their mean age was 12.0 (SD 3.5) years, and their mean height was 1.46 (SD 0.21) meters. All participants were able to follow the instructions and remained compliant during the measurements. None of the participants reported cybersickness. The spectrum of functional mobility was broad, including FMS levels 3-6 for 5 m and 50 m and 1-6 for 500 m, as well as levels 6-10 of the FAQ. However, most participants could walk independently on all surfaces without any walking device, for at least short to medium distances (FMS 5 m and FMS 50 m ≥5 each). Participants' lower extremity proprioception (FM score) ranged from normal to mildly impaired. A total of 9 of the 20 participants had already used a VR HMD at least once before this study. Participants' clinical and functional characteristics are presented in Table 1.

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Table 1. Clinical and functional characteristics of the participants.

ID	Sex	Age (years)	Height (cm)	Diagnosis[a]	FMS[b]	FAQ[c]	FM[d]	Mobility aid[e]
1	Male	13.4	155	Unilateral spastic cerebral palsy (I)	6/5/5	9	93%[f]	None
2	Male	13.4	157	Unilateral spastic cerebral palsy (I)	6/6/6	9	100%[f]	None
3	Female	17.0	165	Vasomotor dysregulation with neurological involvement	5/3/3	9	93%[f]	Forearm crutches
4	Male	9.3	135	Brain tumor	6/6/6	9	94%	None[g]
5	Male	14.2	166	Polytrauma	6/6/5	9	94%	None
6	Male	17.8	176	Spinal tumor with neurological involvement	6/5/5	8	94%	None[g]
7	Male	8.0	141	Stroke	6/6/6	10	100%	None
8	Female	16.8	163	Myasthenia gravis	6/6/5	9	94%	None
9	Female	8.0	121	Rhabdomyolysis	6/6/5	9	94%	None
10	Male	6.6	110	Brain tumor	6/6/6	9	88%	None
11	Male	13.6	148	Myelomeningocele	5/3/1	7	100% [f]	Forearm crutches
12	Female	10.9	147	Stroke	6/6/6	9	100%	None
13	Male	15.1	160	Myelomeningocele	3/3/1	6	100%	Forearm crutches
14	Male	14.5	165	Stroke	6/6/6	9	100%	None
15	Female	13.4	171	Ataxia	6/6/5	9	100%	None
16	Male	11.6	145	Bilateral spastic cerebral palsy (I)	6/6/5	9	100%	None
17	Male	7.0	112	Arthrogryposis Multiplex Congenita	5/5/2	7	94%	None[g]
18	Male	9.7	118	Myelomeningocele	5/5/1	9	88%	None
19	Female	8.3	121	Unilateral spastic cerebral palsy (I)	6/6/6	10	100%	None
20	Female	10.9	142	Brain tumor	6/5/5	8	94%	None[g]

[a]In children and adolescents diagnosed with cerebral palsy, the Gross Motor Function Classification System Level is given in parentheses.

[b]FMS: Functional Mobility Scale 5/50/500 m.

[c]FAQ: Gillette Functional Assessment Questionnaire-walking scale.

[d]FM: Fugel-Meyer assessment.

[e]Mobility aid used in both conditions.

[f]Due to restricted movements in certain joints or due to pain, not all movements of the FM could be performed by these participants. Therefore, for these participants, the relative value is not calculated from the maximum score (16 points), but from the individual maximum score (8-14 points).

[g]Did not need a mobility aid, but needed close supervision of their physiotherapist.

The participants had to walk the obstacle course from 8 to 16 times to obtain 6 valid trials per task. This resulted in 25-39 recordings per participant for the entire measurement. The most frequent reason why a trial was considered invalid was crossing the obstacle with the wrong leading foot. Furthermore, some attempts were declared invalid when the instructions were not followed or the recording of the markers failed. There were no missing data, except for participant 9 (only 5 valid crossing task trials in the physical setup) and participant 10 (only 5 valid overstepping task trials in the physical setup).

Spatiotemporal Parameters

The differences between the VR and the physical condition varied widely between the participants and tasks (Figure 4).

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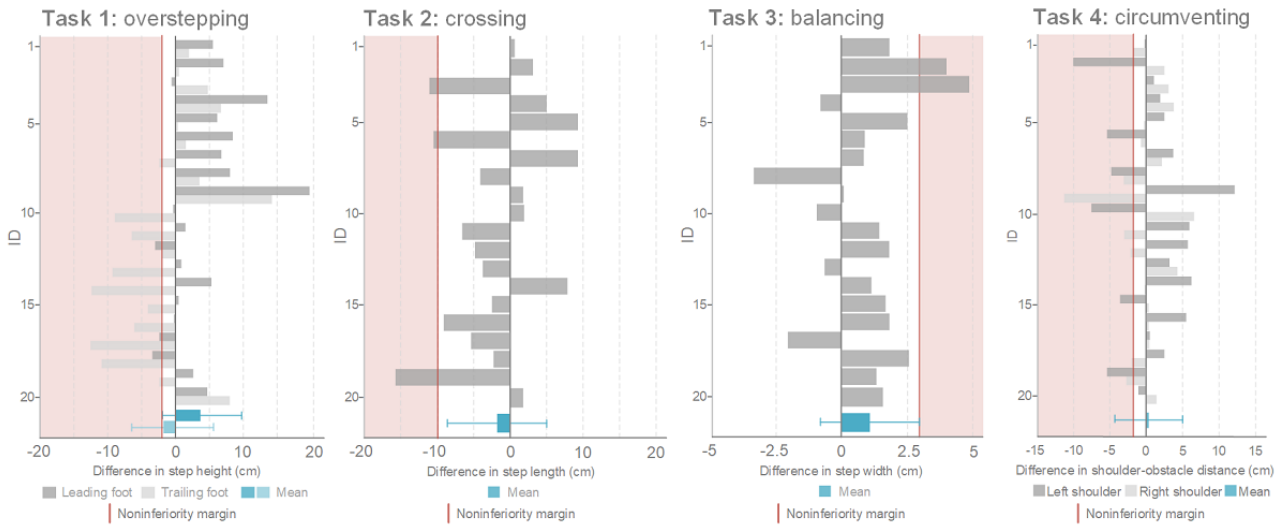
Figure 4. Differences per participant and task for the primary outcomes. The blue bars represent the mean differences and SD over all participants.



During normal walking, step length and gait speed decreased, and step width slightly increased in the VR condition compared to the physical setup (Table 2). In task 1, participants lifted the leading foot 3.77 cm higher and the trailing foot 1.75 cm lower in the VR setup when overstepping the obstacle. In task 2, they decreased the step length by 1.75 cm in the VR setup. As in normal walking, step width and the double stance phase increased, while step length decreased in the VR setup of the balancing task. For task 4, the distance from the shoulder to the obstacle did not differ between the 2 conditions.

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Table 2. Spatiotemporal parameters for the conditions and tasks.

Task and parameter	Physical setup	Virtual reality setup	Difference[a]
Task 0: normal walking, mean (SD)			
Step length (cm)	60.44 (10.22)	54.91 (7.11)	–5.53 (7.14)
Step width (cm)	9.29 (3.92)	9.48 (3.07)	0.19 (2.07)
Gait speed (m/second)	1.10 (0.23)	0.95 (0.20)	–0.15 (0.24)
Double stance phase (%)	24.75 (4.41)	27.48 (3.82)	2.72 (4.21)
Task 1: overstepping			
Max step height (L[b]; cm)[c], mean (SD)	27.53 (4.74)	31.31 (7.21)	3.77 (5.69)
Max step height (T[d]; cm)[c], mean (SD)	28.30 (6.27)	26.55 (8.47)	–1.75 (7.07)
Step height over obstacle (L; cm), mean (SD)	24.77 (5.18)	25.30 (8.29)	0.53 (5.64)
Step height over obstacle (T; cm), mean (SD)	25.32 (5.61)	18.80 (9.06)	–6.52 (8.28)
Preobstacle distance (T; cm), mean (SD)	16.45 (7.66)	10.17 (9.01)	–6.28 (5.60)
Postobstacle distance (L; cm), mean (SD)	19.60 (5.67)	24.45 (6.97)	4.85 (5.58)
Single stance preobstacle (T; seconds), mean (SD)	0.70 (0.17)	0.75 (0.16)	0.05 (0.10)
Single stance postobstacle (L; seconds), mean (SD)	0.62 (0.14)	0.60 (0.10)	–0.01 (0.12)
Total time (seconds), mean (SD)	3.64 (1.49)	4.03 (1.16)	0.39 (0.84)
Total failures max step height <16 cm (L), n (number of children)	1 (1)[e]	4 (2)[e]	3 (1)[e]
Total failures max step height <16 cm (T), n (number of children)	1 (1)[e]	15 (3)[e]	14 (2)[e]
Task 2: crossing			
Step length (cm)[c], mean (SD)	83.81 (7.11)	82.06 (9.32)	–1.75 (7.22)
Preobstacle distance (T; cm), mean (SD)	6.36 (4.55)	–5.91 (8.27)	–12.27 (8.87)
Postobstacle distance (L; cm), mean (SD)	3.29 (5.99)	13.82 (7.50)	10.53 (6.96)
Single stance preobstacle (T; seconds), mean (SD)	0.61 (0.14)	0.69 (0.17)	0.08 (0.15)
Single stance postobstacle (L; seconds), mean (SD)	0.54 (0.08)	0.54 (0.09)	0.00 (0.07)
Total time (seconds), mean (SD)	4.05 (1.26)	4.69 (1.11)	0.64 (0.79)
Total failures step length <51 cm, n (number of children)	14 (7)[e]	31 (10)[e]	17 (3)[e]
Task 3: balancing			
Step width (cm)[c], mean (SD)	5.36 (2.92)	6.41 (2.69)	1.05 (1.93)
Step length (cm), mean (SD)	52.73 (8.51)	47.31 (11.56)	–5.41 (8.45)
Double stance phase (%), mean (SD)	28.58 (5.35)	32.55 (6.05)	3.97 (6.39)
Total time (seconds), mean (SD)	4.44 (1.43)	5.31 (1.72)	0.87 (1.88)
Total failures step width >19 cm, n (number of children)	6 (3)[e]	5 (3)[e]	–1 (0)[e]
Task 4: circumventing			
Minimal shoulder-obstacle distance (cm)[c], mean (SD)	10.66 (3.36)	10.41 (3.77)	0.25 (4.44)
Total time (seconds), mean (SD)	5.25 (2.48)	5.76 (1.98)	0.50 (1.51)
Total failures minimal distance <2 cm, n (number of children)	3 (3)[e]	13 (7)[e]	10 (4)[e]

[a]The differences were calculated by subtracting the value of the physical setup from the value of the virtual reality setup. Consequently, negative differences indicate a lower value for the virtual reality setup.

[b]L: leading foot.

[c]Primary outcomes (also used to define the number of fails).

[d]T: trailing foot.

[e]The number of children that made these fails.

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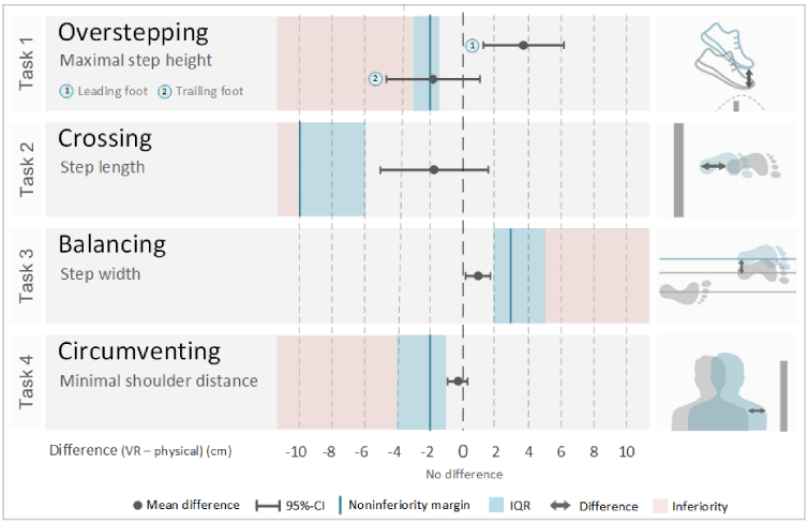
Noninferiority Analysis

We applied noninferiority analyses [37] to compare the differences in the primary outcomes between the VR and physical setups for each task according to the a priori defined noninferiority margins. As depicted in Figure 5, the noninferiority analysis revealed noninferiority for the leading foot and was inconclusive for the trailing foot when overstepping the obstacle. For crossing, balancing, and circumventing, the results of the statistical analysis showed noninferiority in all cases.

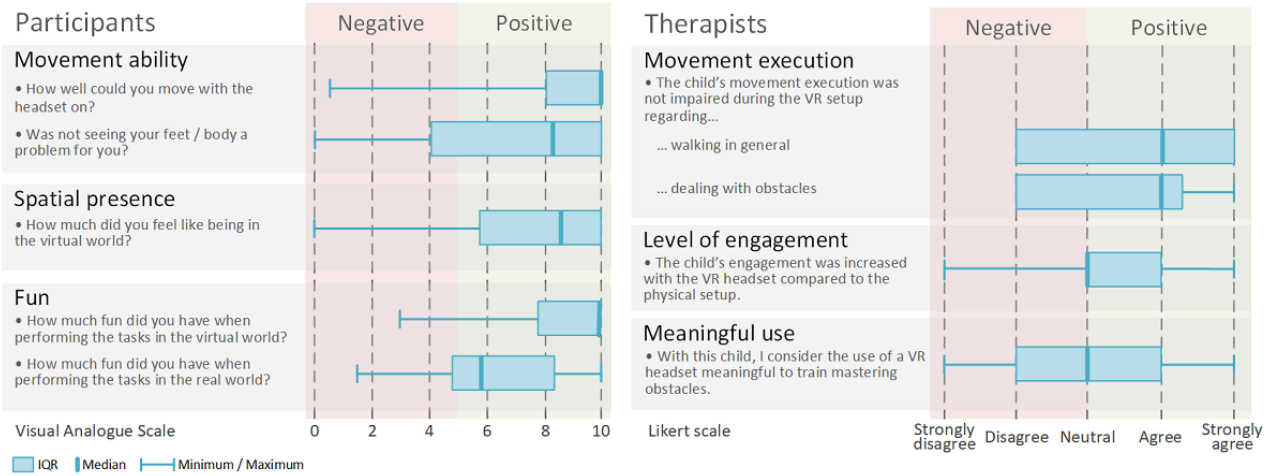
Figure 5. Noninferiority analysis for the primary outcomes. A negative mean difference indicates a smaller value in the virtual reality (VR) setup than in the physical setup. The noninferiority margins in blue represent the maximum difference between the two conditions while still considering the conditions to be equal. As long as the 95% CI of the mean difference does not exceed this margin, the VR setup is noninferior to the physical setup. Inferiority of the VR setup is assumed when the 95% CI touches the red inferiority area and, at the same time, does not cross the line of no difference between the two conditions.



Questionnaires

When asked how well the participants could move around using the HMD, 75% (15/20) of the participants scored ≥8 and did not feel restricted in their ability to move around. Not being able to see their body or feet was no problem (score ≥7) for most (14/20, 70%; Figure 6) participants. Most participants (14/20, 70%) felt physically present in the virtual scenario (score ≥7), even if the environment and the objects did not seem entirely realistic to them. The participants had fun in both conditions; however, the VR setup was rated significantly better ($P<.001$).

Figure 6. The participants' and therapists' views on the use of the virtual reality (VR) head mounted display (HMD) in physiotherapy.



According to the therapists, movement execution during the VR setup was not impaired in 65% (13/20) of the participants when walking normally or dealing with obstacles. The most common reason why therapists considered mild impairment in movement execution while wearing the HMD was a more cautious and slower gait pattern. The therapists perceived the level of engagement in the VR setup to be lower in 4 participants, similar in 7 participants, and higher in 9 participants. Therapists had ambivalent views regarding the meaningfulness of using VR to train for mastering obstacles. Reasons for considering the application meaningful included increased enthusiasm for movement, the challenge of altered visual control, and, therefore, the increased awareness of the children's bodies. Reduced speed, reduced focus on the given instructions, lack of feeling the edges of the obstacles, and consequences, such as stumbling when not lifting the foot high

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enough, were reasons against VR being a meaningful application for some participants. The balancing task was the task most often considered meaningful by the therapists.

Discussion

Principal Findings

This study aimed to provide information on whether a VR setup is feasible and motivating to induce and practice movements that are needed to master real obstacles in children and adolescents with gait disorders. Furthermore, this study aimed to evaluate which kinds of everyday walking activities are appropriate to be practiced in such a VR setup. To achieve these goals, a virtual and a physical condition, the latter resembling therapeutic setup, were compared with each other. We chose a noninferiority analysis to quantify the differences between spatiotemporal parameters defined a priori. This noninferiority analysis revealed that for 3 of the 4 walking tasks encountered in everyday life, mastering the virtual obstacles provided by an HMD was noninferior to mastering the physical obstacles. Thus, the results suggest that children and adolescents with gait disorders can practice crossing a wide gap, balancing on a narrow area, and circumventing stationary obstacles appropriately in a virtual setup. Furthermore, overstepping a virtual obstacle with the leading foot was also noninferior; only the results for the trailing foot were inconclusive.

Comparison to Previous Work

Normal Walking

The participants walked slower in the VR compared to the physical setup, which corresponds to the findings of Almajid et al [38] and Horsak et al [39]. Almajid et al [38] found that younger and older adults needed significantly more time to perform the timed up-and-go test when wearing an HMD, even without the projection of a virtual scene. In the study of Horsak et al [39], healthy individuals also demonstrated a slower walking pattern when walking in an overground VR environment compared to a real environment. This effect should be considered when wearing an HMD in rehabilitation. Still, the mean gait speed during normal walking in the VR setup was within the range of self-selected walking speed in children aged between 7 and 14 years with CP (GMFCS levels I and II) and TBI [25-27]. Although the participants' FMS and FAQ values were in the upper range of the scales, their gait speed in the physical setup was still below the average of typically developing youths [40]. The reduced gait speed in the VR setup was accompanied by a decreased step length and a slightly prolonged double stance phase.

The mean step length in both conditions was above the average step length of 50 cm reported for children aged between 7 and 14 years with CP (GMFCS stages I and II) and TBI, but below the average step length of 68 cm reported for typically developing children of the same age [25-27]. The double-stance phase of our participants during normal walking was in both conditions remarkably longer than in typically developing youths aged between 5 and 21 years [40]. Several therapists observed that the movements of their patients were constrained at the beginning of wearing the HMD, especially during normal walking. This could be because more than half of the participants had never worn a VR HMD before participating in this study. However, the difference in double stance time between the VR and physical setup was considerably smaller compared to the difference in double stance time between typically developing individuals and individuals with blindness [41].

Overstepping

First, the noninferiority analysis demonstrated that the maximal step height of the leading foot when stepping over the virtual obstacle was noninferior compared to the physical obstacle. This indicated that participants raised their leading foot to the same height when overstepping the virtual obstacle. However, they lifted their trailing foot considerably less high in the VR condition. This finding is supported by a study by Hagio and Kouzaki [42], in which healthy adults overstepped a virtual and physical obstacle. While the vertical height of the leading foot correlated highly (r=0.77) between the VR and physical condition, the correlation was lower for the trailing foot (r=0.47). As Kim et al [43] describe, an explanation for the difference between the leading and trailing foot in the VR setup could be the missing visual information regarding the height of the foot and, therefore, not being able to correct its height. Further results from Hagio and Kouzaki [42] suggest that visuomotor transformation in the leading leg contributes to a motor plan for trailing limb toe trajectories while stepping over an obstacle.

Crossing

Second, although the primary outcome parameters were mostly comparable between the virtual and physical setups, the movement was slightly displaced when overstepping or crossing the obstacles in the VR setup. Participants stepped too close to the obstacle or even over the edge of the obstacle. In general, however, the steps were almost the same length and height in the VR and physical setups, just at different locations. As the HMD blocks out the physical world, a lack of spatial information about the environment and the body's state relative to the environment could be a reason for the slightly displaced movement execution in the VR condition. However, most participants indicated on the VAS that not seeing their feet or body was not a problem for them. Furthermore, almost half of the participants scored 100% on the FM assessment, which tests the proprioception of the lower extremities. Nevertheless, using a fully immersive VR, Kim et al [43] investigated how visual information about the lower extremities is integrated with information about the environment to facilitate successful obstacle avoidance in healthy young adults. Their study revealed that visual information about the lower extremities promoted more consistent behavior while stepping over an obstacle.

Balancing

Third, in both conditions of the balancing task, the step length was slightly decreased, and the double stance phase increased compared to the corresponding normal walking condition. As reduced step length and prolonged double stance phase are considered indicators of reduced balance [41], we can assume that the participants made a real effort to balance over the physical and virtual obstacles. Although the participants rated

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this task as rather difficult, they produced only a small number of failures. The step width, which we considered crucial for successfully completing the balance task, was, on average, 1 cm larger in the VR than in the physical setup. However, the noninferiority analysis illustrated that the step width in the VR setup was noninferior to that of the physical condition. Therefore, we assume that the participants successfully balanced over the obstacle in VR and in reality.

Circumventing

Fourth, when moving in public areas, it becomes essential to circumvent stable objects or moving people, have a stable base of support, and balance in a narrow space. Several studies have investigated the critical point (the ratio between aperture width and shoulder width at which a shoulder rotation occurs at the time of crossing) and safety margin (the space that is maintained between the shoulders and the obstacles at the time of crossing) for aperture crossing [30,44]. Whenever the participants had to rotate their shoulders, they maintained a larger safety margin when crossing [44]. For example, the critical point for circumventing poles, calculated from the mean shoulder width of the participants and the distance between the poles, was a ratio of 1.3 [44]. The present study's ratio between the aperture width and the mean shoulder width equaled 1.6. Assuming that participants did not rotate their shoulders at such a ratio, the safety margin was slightly less than the 30 cm observed in the study of Hackney et al [30]. However, the safety margins of 10 cm of the VR and physical setup equal those of young, healthy adults who had to avoid poles with an aperture/shoulder width ratio of 1.3 [44]. The results of the noninferiority analysis suggest that participants successfully circumvented the obstacles in the VR setup. In addition, Hackney et al [45] recently showed that individuals who had to avoid obstacles in a virtual scenario wearing an HMD behave similarly with virtual poles and avatars, indicating generalization to a wide range of applications in VR.

Questionnaires

In summary, the participants were very positive toward training walking tasks in a VR setting. Due to its game-like features, the participants experienced significantly more fun in the VR than in the physical setup. How VR-assisted physical therapy might affect a participant's enjoyment and motivation over time needs to be investigated in the future. The physiotherapists did not observe a difference in the participants' engagement level between the VR and physical setup, indicating that the participants made similar efforts in both conditions. Thus, a comparison between the 2 conditions was feasible.

Limitations

This study has several limitations. First, the group size of 20 participants was rather small. However, it is in line with recommendations [22], as the purpose of this study was to provide information on whether a VR setup is feasible and motivating to induce movements that are needed to master real obstacles and which kinds of everyday walking activities are appropriate to be practiced in such a VR setup. To examine the appropriateness and effectiveness of VR training, more participants would have to be included in the next study. Despite the considerable heterogeneity of this study, noninferiority could still be shown in 3 tasks.

Second, even though the dimensions and locations of the obstacles did match in both conditions, the different visualizations of the physical setup and the VR setup could have impacted the participants' gait. However, this limitation was chosen intentionally, as we wanted the obstacles to look like they would appear in future applications.

Third, a panel of experts decided on specific margins to define noninferiority, as no reliable reference values for the noninferiority analyses existed in the literature. In order to minimize this limitation for a further project, additional external experts could be asked and added to the panel.

Fourth, the gait laboratory is frequently used for clinical gait analysis. Therefore, the Vicon cameras pointed to the middle of the room. Since the recording area for this study was slightly broader, some markers disappeared at times from the measurement volume, which is one reason why some participants had to complete more than 8 rounds to record sufficient valid trials. Consequently, the high number of repetitions might have bored and fatigued some participants, which might have decreased their concentration toward the end. With verbal input for the participants and breaks between the trials if needed, we tried to keep the number of trials and the fatigue of the participants as low as possible.

Fifth, a slight misalignment between the real and virtual setups might have introduced an unknown error in calculating the parameters. We calibrated the alignment immediately before putting the HMD on the participant's head to minimize this error.

Sixth, the feet were not visible to the participants in the VR condition. We assume that a lack of spatial information rather than impairments in proprioception might have caused failures such as stepping over the edge, as the FM assessment did not indicate major lower limb proprioception impairments in the participants. A further study investigating the influence of foot projection in VR could provide further information regarding the influence of the visability of the feet.

Conclusions

This is the first study showing that children and adolescents with gait disorders master various obstacle tasks, such as overstepping a bar, crossing a wide gap, balancing on a narrow area, and circumventing stationary obstacles, similarly in VR and physical conditions. Only the results for the trailing foot in the overstepping task were inconclusive. Therefore, we conclude that using a VR setup to practice mastering obstacles with children and adolescents with gait disorders is feasible and motivates them to practice everyday walking tasks. In the long run, the feasibility of using HMDs in a clinical therapy setting, patient motivation over a longer period of time, the appropriateness and effectiveness of such VR interventions, and identifying potential responders to such interventions require further investigations.

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Acknowledgments

The authors would like to thank the participants and their physiotherapists for the time and effort they have dedicated to this project. The project was financially supported by the J&K Wonderland Foundation (Steinhausen, Switzerland) and the Promedica Foundation (Chur, Switzerland).

Data Availability

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

Authors' Contributions

All authors contributed to the conceptualization and methodology of the study. CA-R obtained ethical approval. SR performed participant recruitment. SR, AK, and CA-R assisted with the measurements. SR and AK were involved in the data analysis. SR provided the figures. SR and CA-R were responsible for writing the first draft. All authors critically reviewed the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CP: cerebral palsy
FAQ: Functional Assessment Questionnaire
FM: Fugl-Meyer
FMS: Functional Mobility Scale
GMFCS: Gross Motor Function Classification System
HMD: head-mounted display
TBI: traumatic brain injury
VAS: visual analog scale
VR: virtual reality

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Original Paper

Addressing Data Absenteeism and Technology Chauvinism in the Use of Gamified Wearable Gloves Among Older Adults: Moderated Usability Study

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Abstract

Background: Digital health technologies have the potential to improve health outcomes for older adults, especially for those recovering from stroke. However, there are challenges to developing these technologies, such as *data absenteeism* (where older adults' views are often underrepresented in research and development) and *technology chauvinism* (the belief that sophisticated technology alone is the panacea to addressing health problems), which hinder their effectiveness.

Objective: In this study, we aimed to address these challenges by developing a wearable glove integrated with culturally relevant exergames to motivate older adults to exercise and, for those recovering from stroke, to adhere to rehabilitation.

Methods: We conducted a moderated usability study with 19 older adults, of which 11 (58%) had a history of stroke. Our participants engaged in a 30-minute gameplay session with the wearable glove integrated with exergames, followed by a quantitative survey and an in-depth interview. We used descriptive analysis to compare responses to the System Usability Scale between those who had a history of stroke and those who did not. In addition, we analyzed the qualitative interviews using a bottom-up thematic analysis to identify key themes related to the motivations and barriers regarding the use of wearable gloves for rehabilitation and exercise.

Results: Our study generated several key insights. First, making the exergames exciting and challenging could improve exercise and rehabilitation motivation, but it could also have a boomerang effect, where participants may become demotivated if the games were very challenging. Second, the comfort and ease of use of the wearable gloves were important for older adults, regardless of their stroke history. Third, for older adults with a history of stroke, the functionality and purpose of the wearable glove were important in helping them with specific exercise movements.

Conclusions: Our findings highlight the importance of providing contextual support for the effective use of digital technologies, particularly for older adults recovering from stroke. In addition to technology and usability factors, other contextual factors such as gamification and social support (from occupational therapists or caregivers) should be considered to provide a comprehensive approach to addressing health problems. To overcome data absenteeism and technology chauvinism, it is important to develop digital health technologies that are tailored to the needs of underserved communities. Our study provides valuable insights for the development of digital health technologies that can motivate older adults recovering from stroke to exercise and adhere to rehabilitation.

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KEYWORDS

wearables; exergames; older adults; active aging; rehabilitation; stroke

Introduction

Background

There has been an increasing trend in the development and implementation of digital health technologies for older adults, known as *gerontechnologies*. However, there are challenges to developing these technologies, such as *data absenteeism* (where older adults' views are often underrepresented in research and development) and *technology chauvinism* (the belief that sophisticated technology alone is the panacea to addressing health problems) [1]. Gerontechnologies aim to assist older adults in healthy aging through the promotion of physical exercise and empowering them to maintain a certain level of functional independence throughout their later years and delay the onset of frailty [2,3]. For instance, examples of such technologies are the use of *exergames* to motivate physical activity or virtual reality technology for the purposes of pain management and therapy [4,5]. Other types of health technologies, such as wearables, are also becoming common among older adults. Existing commercial products such as FitBit (Google, Inc) and Apple Watch make it easy for older adults to track and monitor their health [6]. To date, such digital health technologies targeted at older adults have received substantial attention and investments, ranging from US $1.1 billion to US $3.1 billion between 2019 and 2020, and it is expected to grow in the next few years [7,8].

While there are several studies documenting the positive impact of digital health technologies on older adults' physical and mental health, there are 2 key gaps in existing public health literature [9,10]. First, very few studies have explicitly addressed the problems of *data absenteeism* and *technology chauvinism.* Second, as many of the existing health technologies are developed in a clinical setting for data collection, few researchers have examined how to develop technology that is fun, relatable, and equitable for the older adults [11]. The overall objective of the study was to address the problem of data absenteeism and technology chauvinism in the development of digital health technologies—a stretchable wearable glove integrated with exergames—by examining the motivations and barriers of older adults without a history of stroke and those recovering from stroke in the use of such technologies through the lens of equity.

Theoretical Framework: Data Absenteeism and Technology Chauvinism

While the momentum to build and develop different digital health technologies by academia or industry is noteworthy, it is important to adopt the lens of equity in building such technologies for older adults. Older adults are often disadvantaged as compared to the general and younger population in terms of their access, use, attention, and processing of health information from digital health technologies [12]. Not giving attention to the context in which such digital health technologies are developed and introduced may result in the unintentional consequence of exacerbating the health disparities between those who are well resourced and those with less resources [13]. In advocating for technology and big data use through an equitable lens, Lee and Viswanath [1] argued for the need for health communication and informatics scholars and technology developers to pay attention to the 2 perennial problems: data absenteeism and technology chauvinism.

Data absenteeism refers to a situation where data from underserved populations are not represented. For example, recent studies of large-scale national programs that use wearables to boost physical activity, such as Singapore's National Steps Challenge, which offers free wearables and gamified mobile apps to encourage participants to walk 10,000 steps, show that older adults are often underrepresented in the data. This gap aligns with previous findings indicating that users of such technology tend to be younger and more educated and possess a higher degree of eHealth literacy [14,15].

In contrast, *technology chauvinism*, refers to the blind faith in big data systems or technology platforms in addressing health disparities. One of the most infamous cases was the use of Google Flu Trends to predict the outbreak of influenza, where search trends overestimated the prevalence of influenza as compared to official sources [16,17]. To address the problems of data absenteeism and technology chauvinism in the use of digital health technologies to improve physical activity among healthy older adults and those recovering from stroke, it is vital to involve them from the start of the research process and engage them to codevelop wearable gloves and exergames. This is consistent with studies of the principles of user-centered design, where it is crucial to be intentionally inclusive in the process by incorporating the target group as full partners in the decision and design groups as part of the research process. This ensures that their participation and input are not merely symbolic or exploitative, but rather meaningful and beneficial for them as a whole [18].

Context of the Study: Motivating Rehabilitation and Exercise Using Wearable Gloves and Exergames

In recent years, there has been a surge in the exploration and creation of wearable glove technologies aimed at enhancing exercise motivation and aiding stroke recovery. The smart glove industry is projected to reach a value of US $3.9 billion by 2028, with an annual growth rate of 10% [19]. These innovative gloves are developed in 2 main styles: rigid hand exoskeletons and soft assistive gloves. The latest soft rehabilitation gloves are being designed to support bending, straightening, and spreading or closing of each finger to address the difficulties some patients face in performing hand grabbing motion [20].

There are several existing studies that have documented the efficacy of the use of wearable gloves for patients with stroke in improving upper limb movement across several metrics. For instance, Yurkewich et al [21] tested the Hand Extension Robot

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Orthosis (HERO) Grip Glove among 11 participants with difficulty in finger extension in their poststroke journey and found that the glove significantly improved their water bottle grasp and index finger movement and extension and enabled individuals who are lacking grip strength to handle blocks, use a fork, and write with a pen. Wang et al [22] conducted a study where 69 patients with severe upper limb impairment following a stroke were divided into three treatment groups: (1) repetitive transcranial magnetic stimulation, (2) soft robotic glove use, and (3) standard treatment, and the results showed that the group assigned to use the robotic gloves achieved better upper extremity scores compared to those in the standard treatment group.

Given that the use of wearable gloves is comparable to neurostimulation or neuromodulation techniques in improving movements for patients with stroke, other research teams have incorporated the use of other forms of stimulation (ie, tactile sensations) in wearable gloves to improve its efficacy. Seim et al [23] conducted a pilot study involving 16 patients with chronic stroke, where participants were randomly placed into 2 groups for an 8-week period: one group received a vibrotactile stimulation glove, and the other group received a similar glove without vibration (acting as the control condition). The outcomes demonstrated that those using the vibrotactile stimulation glove experienced notable enhancements in finger mobility and improvements in the range of motion of their elbows and shoulders compared to the control group.

While these studies have found improvements in upper limb movements through the use of wearable gloves in their respective sample, it was unclear why or how they were effective. In a systematic review of wearable technology for improving activity in adult patients with stroke, Parker et al [24] found that, overall, very few studies have found evidence for the use of wearable gloves to improve rehabilitation. Thus, a significant oversight in many recent advancements in these state-of-the-art wearable gloves is the lack of consideration for how their target user group might engage with these technologies and the probability of their adoption as consumer products. Examples of these gaps in knowledge would be ideas about what could motivate a potential consumer to purchase the wearable glove product and incorporate it into their daily rehabilitation routine, and ultimately, what could be the barriers that prevent them from making the gloves a staple part of their rehabilitation journey. Examining how specific design features affect the perceived usefulness and perceived ease of use of the product could also affect their decision to adopt these fancy wearable gloves into their routines [25].

Addressing the Gaps in Wearable Gloves Research: Integrating Wearable Gloves With Exergames

One of the ways to improve rehabilitation through wearable gloves among older adults is through the gamification of the rehabilitation process. This is done through the use of specialized video games that simulate exercise, known colloquially as *exergames*. It is an area of health technology that has gained interest in recent years, especially among older adults. According to Harrington et al [26], the use of exergames may address barriers to older adults being physically active and exercising. These video games demand that the player physically moves their body to advance within the game or program [27]. Therefore, the implications surrounding the movement-centric nature of the gaming technology means that it has the potential to be used in rehabilitative health care practices also.

Existing systems such as the Nintendo Wii Fit, a low-cost commercial gaming system, have been found to be effective in improving clinical measures of balance in older adult patients [28,29]. Thus, exergames are able to transform exercise, through the process of gamification, by introducing alternative motivators such as entertainment and encouragement into activities that would otherwise be considered as physically strenuous [30]. A study by Yu et al [31] found that exergames as an intervention using the Xbox Kinect significantly improved the physical activity level, leg strength, and cardiopulmonary endurance of healthy older adults. Although exergames make physical exercise and rehabilitation more accessible, there are still obstacles to the uptake of these innovations in health technology among older adults.

One key aspect in which exergames have been shown to aid the rehabilitation process is adherence to exercise. Research by Oesch et al [32] on the difference between conventional self-regulated exercise and exergames revealed that exergames showed heightened levels of adherence to rehabilitation exercise routines within the first 2 weeks of introduction. However, the same study also showed that the motivation levels reversed after the first 2 weeks.

Understanding the Motivations and Barriers

One of the main goals of using a gamified wearable glove is to further motivate patients and older adults who are undergoing hand rehabilitation by increasing the movement of their hands through gameplay using wearable gloves and, subsequently, reduce the barriers to use of technology through seamless incorporation of the gaming medium. In addition, the hand movement data that the gloves are capable of collecting can further assist health care professionals in providing focused rehabilitation activities to their individual patients.

As such products are aimed to be used by patients and older adults, one must also consider motivations and barriers to adoption. This is because new technologies (ie, the wearable gloves) may present potential problems from the perspective of the consumers (older adults and health care professionals), such as being incompatible with existing products or technologies and individuals' needs [33]. In this regard, health care technology has never really seen the introduction of gloves with the technological capability of collecting vast amounts of data from each exergaming session. Traditionally known as "haptic gloves," these wearable devices offer force feedback and originated in the virtual reality gaming industry. They have the potential for gathering data for video game technology developers, although their application in rehabilitation and health care is quite rare [34]. Thus, to understand older adults' needs, it is paramount to investigate their motivations and barriers regarding the use of wearable gloves and exergames and whether their past experiences with rehabilitation have any effect on their perception of these products.

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Study Objectives

This study aims to answer the following research questions (RQs) regarding the general usability of these wearable gloves in the context of the rehabilitation process:

- RQ1: What are the motivations and barriers toward the use of an integrated wearable glove system with exergames?
- RQ2: What are the differences between older adults without a history of stroke and older adults with a history of stroke regarding their perceptions about an integrated wearable glove system with exergames?

Methods

Wearable Glove and Exergame Development

Before the study, the research team worked with a start-up company that specializes in the development of rehabilitation gloves to develop a wearable data glove that could be integrated with exergames. Figure 1 shows the glove prototype that was developed for both survivors of stroke and older adults, specifically to capture hand motion for gesture recognition and for data visualization with the help of the multiple sensors integrated within the gloves. The bendable and flexible sensors embedded in the glove cover the joints on each individual finger and capture bending data signals from finger movement. This technology supports the training of specific wrist, hand, or finger movement and finger joints mobilization activities that is commonly found in the rehabilitation process, as seen in Figure 2.

The gloves were designed to be integrated with existing in-house exergames developed by the research team at the university. The exergame system consists of exercises and games that could be personalized for each individual user to suit different durations and number of repetitions for a particular exercise [35,36]. These exergames were specifically created to suit older adults to promote successful aging by motivating exercise, where they aim to improve physical and cognitive functional capacity through easy-to-follow actions and interface and culturally relevant game themes [37].

While there were a series of 9 exergames developed to date, the research team integrated the wearable glove with 1 exergame called “Chinatown Race” (Figure 3), where players are required to dodge barriers while aiming to collect coins to score points while running down a road in an online Chinatown setting. The avatar is controlled through rotation of hand and finger movements that would be detected by the wearable glove. As shown in Figure 2, participants had to perform movement 5 and movement 8 to slide the avatar toward left and right, respectively. To catch the lantern power-ups in the game, participants had to flex their pointer finger, as seen in movement 2.

Figure 1. Prototype of the wearable glove.

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Figure 2. Specific hand motions for rehabilitation: (A) idle, (B) finger trigger, (C) up, (D) down, (E) right side, (F) right, (G) left, and (H) left side.

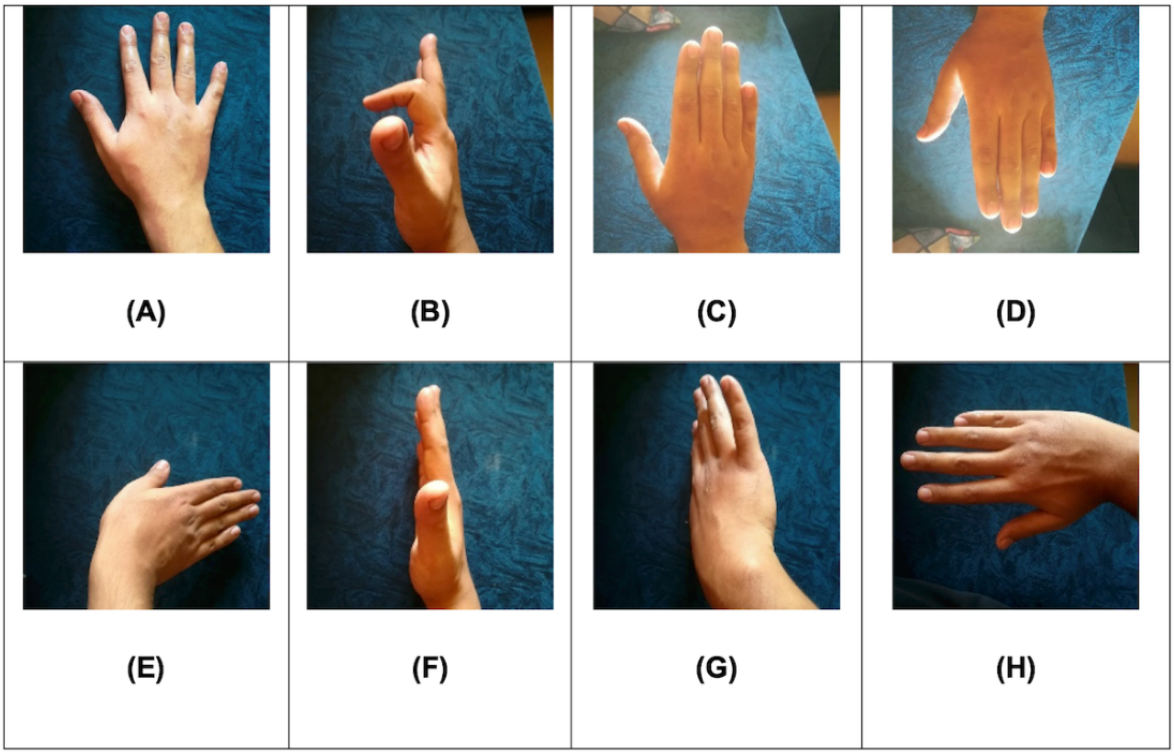

Figure 3. Screenshot of the Chinatown Race gameplay.

Participants and Recruitment

After the development of the wearable glove and integration with the exergame, we conducted a moderated usability study with 19 participants aged ≥50 years, recruited from an older adult activity center with a convenient sample of individuals with and without a history of stroke (n=11, 58% had a history of stroke and n=8, 42% did not). The average age of the participants was 66.8 (SD 4.5) years, and 53% (10/19) were women and 47% (9/19) were men. Of the 19 participants, 13 (68%) belonged to the Chinese ethnic group, while 4 (21%) belonged to the Malay ethnic group. There was also 5% (1/19) Burmese and 5% (1/19) Singh individuals who participated in the study. Overall, 74% (14/19) of the participants were considered to have lower levels of education below an "A-Level" certification. The inclusion criteria for the study were that participants had to be (1) aged at least 50 years and (2) willing and able to use the wearable glove to play the designated

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exergames and participate in a qualitative interview and survey. The moderated usability sessions were conducted in either English or Chinese depending on the language preference of the participants.

Ethical Considerations

Before the study, we obtained approval from the institutional review board of from the institutional review board of Nanyang Technological University, Singapore (IRB-2022-405). Written informed consent was also obtained from the participants. They were briefed about the procedures involved in the use of the wearable glove and exergames; they were also informed that the risks were minimal in the gameplay and that they could exit the study without any penalty. Upon successful completion of all the tasks in the moderated usability study, the participants were given a voucher worth SGD 50 (US $37) as incentive. To safeguard participants' privacy, the data were de-identified before analysis.

Study Design and Procedure

The moderated usability study session was designed to be a 1-hour long session, which consisted of a series of tasks involving participants' use of the wearable glove and exergame, led by 1 moderator and 1 technical specialist. The moderator guided the participants through the required activities and conducted the interview and survey upon the completion of the tasks. The technical specialist ensured that the devices were working as intended and handled all the technical difficulties that arose during the session.

In the session, participants were required to complete the following tasks:

1. Navigation of wearable glove and exergames: Participants were taught the basics about how to use the wearable gloves and control functions on the exergame dashboard.
2. Chinatown Race gameplay: Participants had to use the wearable glove to engage in Chinatown Race gameplay, where they had to move their avatars to avoid barriers and collect lanterns to score points by using hand and finger rotation.
3. Qualitative interview: This is a qualitative interview through which the moderator obtained feedback about participants' attitude and perceptions regarding the wearable glove and exergame.
4. System Usability Scale (SUS) survey: The moderator administered a short SUS scale, which is a 10-item measure of the usability of systems.

Measures of SUS

The SUS scale (Cronbach α=.95) was adapted from Chu et al [37], and participants provided their responses to the following items measured using a 5-point scale (1=strongly disagree and 5=strongly agree): (1) I think that I would like to use the glove frequently, (2) I found the glove unnecessarily complex, (3) I thought the glove was easy to use, (4) I think that I would need the support of a technical person to be able to use the glove, (5) I found the various functions of the glove to be well integrated with the game, (6) I thought there was too much inconsistency with the glove, (7) I would imagine that most people would learn to use the glove very quickly, (8) I found the glove very cumbersome to use, (9) I felt very confident using the glove, and (10) I needed to learn a lot of things before I could get going with the glove.

The qualitative interviews were analyzed using a bottom-up thematic analysis to identify key themes regarding the motivations and barriers toward the use of wearable gloves for rehabilitation and exercise among older adults who had a history of stroke and those who did not. The thematic analysis was performed in accordance with the steps described by Proulx et al [38] regarding usability testing of wearable gloves: (1) the recordings were transcribed, (2) the transcript was first read by a member of the research team to develop the coding frame, and (3) the coding frame was refined to identify different types of motivators and barriers regarding the use of wearable gloves and exergames. Next, descriptive analysis was conducted to compare the differences in responses to SUS items between older adults who had a history of stroke and those who did not. This is consistent with the studies by Tong et al [39] and Casterlé et al [40].

Results

Competition as a Motivation

RQ1 involves the motivations and barriers toward the use of a wearable glove integrated with exergames. Multimedia Appendix 1 shows the summary of the mean scores of participants' responses to SUS items. From the qualitative interview, one of the key motivations identified was that a certain *degree of competition* was required to ensure that the older adults are engaged and motivated. For instance, the inclusion of features such as collectible coins, lanterns, and a scoring system presented a form of incentive for the participants to continue persevering to complete the game. These features made the game fun, as there was a tangible goal associated with each movement that they made within the game. Some even noted that it spurred them to strive to get better at the game, as a participant mentioned the following:

> *To score the highest score, that is very exciting.* [Participant 10; with a history of stroke]

As such, the competitive element of the gameplay objectives plays a key role in motivating older adults to continue playing and, in essence, adhere better to their rehabilitation practices. However, they need to be familiar enough with the game systems and movements for them to attribute poor performance with their own lack of skill rather than an external device, which would otherwise deter them from continuing to play the game.

Helplessness as a Barrier

Regarding RQ1, we found that a significant barrier to using the integrated wearable glove is the feeling of helplessness, particularly if it is in the context of technical difficulties. While the participants mostly agreed that the exergame navigation was easy to understand because of the simple nature of the menu layout and user-friendly, large, and visible buttons, the older adults were not familiar with the movement system of the wearable gloves. Therefore, while they had very clear intentions regarding navigating the menu, the disconnect between intention

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and execution made the process a lot more difficult than intended for the participants. This became even more apparent when participants were asked to describe if anything was confusing about the gameplay movements of Chinatown Race, to which many expressed the following general sentiment:

> *Not confusing, only unfamiliar with the controls [in reference to glove].* [Participant 2; without a history of stroke]

Therefore, it was evident to a certain degree that the overall experience of playing the game was hindered because the gameplay affordances provided by the glove apparatus were not intuitive to the participants. This, in turn, had a demotivating effect on the participants as their ultimately poor gameplay would then be attributed to an external factor such as the glove and the game system, making them feel somewhat helpless as they struggled to competently dodge all the obstacles and collect the harder-to-collect lantern items that required them to hyperextend their thumb. This is exemplified when looking at "necessity of support" (ie, question 4 of the SUS scale), where the participants were asked to rate how much technical support they would require to use the gloves. The patients with a history of stroke were more likely to want to get more help (mean 2.45, SD 1.51) as compared to those who had no history of stroke (mean 3.45, SD 1.37). This could be attributed to how older adults with a history of stroke may have experienced feelings of helplessness using novel rehabilitation technologies in the past and therefore might show an aversion to new technologies.

RQ2 deals with the differences between older adults without a history of stroke and those with a history of stroke regarding their perceptions about the glove integrated with exergame. Our findings indicated that the rehabilitation history influenced the level of critique from user groups when engaging with the integrated glove. The comfort level of the glove was a major theme; in the SUS questions, participants who did not have a history of stroke indicated that comfort level was very important (mean 3.78, SD 0.97) as compared to those with a history of stroke (mean 4.18, SD 0.60).

When asked about what could be improved to make the overall experience of playing Chinatown Race using the wearable gloves better, there was a noticeable difference regarding the category of improvement suggested by both groups. The comments by participants with a history of stroke tended to pertain toward making the controls more intuitive:

> *Improve the controls, like grabbing action for the lantern instead of thumb extension.* [Participant 4; with a history of stroke]

In contrast, comments by participants who did not have a history of stroke were more likely related to areas such as game design and esthetics (collectible items or general color contrast):

> *Barrier needs to be bigger in size and have more contrasting colours so that it can be seen from the distance.* [Participant 19; without a history of stroke]

This difference could suggest that older adults with a history of stroke were more focused on the movements associated with the gloves and what their actual bodies were doing in relation to the game than whether the game was appealing enough to be played effectively. A possible attribution for this difference could be how the older adults with stroke have an acute awareness that the exergame is a tool to be used in a long and tedious process that they have experienced previously, and therefore, they have deeper awareness of what is essentially important in the actual process of rehabilitation. In contrast, the older adults without a history of stroke could be looking at the exergame and the wearable gloves as just another gaming device, and therefore, their criticism would be directed toward the exergames as a game than as a rehabilitation tool.

Finally, for RQ2, our results showed that the valence of anticipation regarding using a new device varies based on their history with stroke. This is seen when looking at "intention to frequently use," which refers to question 1 of the SUS scale used in the survey. It must be noted that the group without a history of stroke indicated more eagerness to use the glove with exergame (mean 4.38, SD 0.71) as compared to those with a history of stroke (mean 3.18, SD 1.47). It could be because participants who have had stroke before maintained a level of cynicism toward such novel methods for stroke rehabilitation as they have been through the rehabilitation process previously. Furthermore, it might be due to barriers related to perceptions of the ease of use. Participants without a history of stroke indicated that the glove was easy to use (mean 4, SD 1.50), and the score was slightly higher than those with a history of stroke (mean 3.64, SD 1.50). It might also be due to the visual esthetics, as there is a "box" attached to the glove that contains the wiring. A participant noted the following:

> *The box is big and is not needed...The extra electronic devices seem delicate and can break.* [Participant 9; with a history of stroke]

While the box itself is safely secured and presents no actual hindrance to the gameplay experience, the apparently excessive amount of gadgetry can scare older adults who are not familiar with the durability that most present-day technology have and, at worst, can incite a certain fear response within them to abstain from handling something they think can break any minute.

Discussion

Principal Findings

Several key findings were generated from this study. First, this study addresses the problem of data absenteeism and technology chauvinism by engaging older adults— those with and those without a history of stroke—to provide insights into the potential motivations and barriers regarding the use of integrated wearable glove with exergame solution for rehabilitation and exercise at the early stages of the development process. Most notably, while technologies such as wearable gloves and exergames play a pivotal role in the rehabilitation process, it is reductionistic to assume that the technology itself would be the panacea to addressing health issues. For instance, although older adults with and those without a history of stroke indicated that the glove and exergames were well integrated, we found that individuals who have a history of stroke were more likely to indicate that they would still require help in operating the wearable glove compared to those who have not experienced stroke, which was perceived to be complicated. This finding is

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supported by the "blind faith" aspect of technology chauvinism research: if technology is offered as a solution in isolation without paying attention to the larger social context of the participants, it would not be effective [13]. This is supported by our findings where older adults with a history of stroke indicated that they would need the support of a technical person to be able to use it effectively and that it could be unnecessarily complex. Thus, solutions that embrace the development and implementation of wearable gloves with exergames need to consider designing the technology such that it can be used in a community setting by tapping into the social and support networks of older adults as co-users to improve adherence and uptake. This is consistent with the study by Proulx et al [38], where they examined occupational therapists' perceived usability and utility of a similar wearable glove for rehabilitation. In their study, while the researchers found that the occupational therapists rated the usability of such gloves ranging from "moderate to good" on the SUS, they shared that the gloves would be challenging for patients if they did not have the assistance of a therapist, owing to the physical and cognitive deficits of patients with stroke. The therapists also suggested that the development of wearable gloves would need to account for different contexts, such as using the gloves with therapists or with the assistance of a caregiver.

Second, it was noted that although older adults indicated that the gloves were relatively easy to use and that they intend to use them frequently, the comfort level while using the glove is an important factor for older adults with a history of stroke. This is corroborated by existing studies of technology acceptance and usability, which suggests that the practicality of use is a fundamental cornerstone in the acceptance and integration of technology into a daily routine. Our finding is consistent with that of the study conducted by Yurkewich et al [21], where they designed the HERO Grip Glove to help patients with stroke to perform activities of daily living and finger movement. While participants reported that they were relatively satisfied with the glove in terms of safety, security, and general ease of use, they had the lowest satisfaction regarding the ease of wearing the glove.

Third, we found that it is crucial to consider how gameplay could motivate or demotivate older adults from using wearable gloves. Existing studies of commercial device-based hand rehabilitation for patients with stroke have shown that game-based training using wearable gloves was generally positive in improving hand function and that they would be received favorably as they would be perceived as entertaining [41]. However, our study showed that the design of gameplay would need to aim for a fine balance in managing the difficulty level for a diverse group of patients and players, such that players would find the game challenging enough to sustain their interest, but it would not be very complex to demotivate them. This is important because our results showed that some older adults could be easily demotivated by some of the gameplay scenarios, especially when they feel that they cannot achieve the objectives (ie, collecting lanterns and points and avoiding barriers) or when their perceived expectations of their personal performance do not match with their scores. This results in some of them being demotivated, not enjoying the gameplay, and feeling helpless as they felt that there was nothing they could do to improve their scores.

Finally, it could be observed that individuals with a history of stroke show a stronger aversion to using rehabilitative technology and would thus require more assistance and technical support. This is an interesting as it suggests that those with previous experience with such novel rehabilitative technology may have a predisposed resignation that they would not be able to fully use these new technological methods in their recovery and would thus rather heavily rely on some form of instruction or expertise in conducting the rehabilitation exercises. Patients with a history of stroke have experienced rehabilitation in the past and thus could experience resistance to new rehabilitation technology due to a bias or preference to use what they are already familiar with [42].

In the case of patients with a history of stroke, they might prefer to use something that worked for them in the past because there is precedence of that working. Thus, getting used to a completely new device in stroke rehabilitation presents a level of psychological uncertainty or risk perception associated with the new method and would thus cause them to feel like they may not be able to adapt or manage it efficiently without proper assistance [43].

Implications

The theoretical implication of the findings from this study has shown that the motivation levels toward new technology among a homogenous group of people can differ depending on their personal experiences related to the purpose of the proposed technology. For instance, in this study, it was demonstrated that even among older adult patients, the mere experience of a stroke altered their perception toward the wearable gloves by a significant degree compared to those who did not have a history of stroke. Therefore, it is crucial that future studies consider medical conditions or individuals' experiences when designing health technologies.

The practical implication of the findings of this study illustrates how future exergames can be properly and suitably designed for an aging audience, for example, ensuring that visual elements can be differentiated from one another in a very clear manner and that the video game's difficulty level is attuned not to be extremely difficult but moderately challenging to both prevent the demotivation of the players and encourage continued gameplay, which basically means that the patients continue the rehabilitation process through the exergame medium. In addition, digital health technologies must be designed to have clear affordances without visibly looking like it would be very difficult or complicated to use, as this has an effect on the users' perception about the apparatus, which would inadvertently affect their motivation to buy and use the product.

Limitations

Similar to all studies, there are several limitations in our research. The first limitation of this study would be the lack of a substantial sample size. The sample size of 19 is very small to draw concrete quantitative conclusions and comparison between the focus groups, and therefore, any findings and results that were gleaned from the study are educated guesses and

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conjecture. However, it should be noted that the opinions shared by the older adults during the study are ideas that people in the target group actually have, but they need to be carefully examined in future studies. Second, our participants only used the wearable gloves and games in 1 session with 2 games. We are cognizant that our participants who willingly participated in our research may be qualitatively different from those who did not join. Third, we are mindful that older adults who did not have a history of stroke might have other health conditions that the research team is not aware of that might influence their perceptions about the wearable glove and gameplay.

Conclusions

In summary, there is tremendous potential in the use of digital health technologies such as wearable gloves and exergames to motivate older adults to exercise and, for patients recovering from stroke, to adhere to rehabilitation exercises. While we recognize the benefits of such digital health technologies, without representation from older adults in such studies, any technology development and implementation may face the problem of data absenteeism and technology chauvinism. Thus, to achieve a more equitable and inclusive use of digital health technologies, researchers need to consider both the individuals and the contexts in which the technologies are used.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Mean scores of the System Usability Scale items.
[PNG File , 81 KB - games_v12i1e47600_app1.png]

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Abbreviations

HERO: Hand Extension Robot Orthosis
RQ: research question
SUS: System Usability Scale

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Original Paper

Views of Specialist Clinicians and People With Multiple Sclerosis on Upper Limb Impairment and the Potential Role of Virtual Reality in the Rehabilitation of the Upper Limb in Multiple Sclerosis: Focus Group Study

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Abstract

Background: Finding enjoyable and effective long-term approaches to rehabilitation for improving the upper limb (UL) function of people with multiple sclerosis (MS) is challenging. Using virtual reality (VR) could be a solution to this challenge; however, there is a lack of reporting on the views of people with MS and clinicians on VR-based approaches and recommendations for games for rehabilitation.

Objective: This study aims to identify common UL problems and their related current therapeutic approaches for people with MS, and to explore the opinions of people with MS and specialist clinicians on VR and obtain suggestions for the development and design of VR games.

Methods: Separate focus groups were conducted with people with MS, recruited through the MS Society UK's research network, and clinicians, recruited through the MS Trust Therapists in MS network. A total of 10 people with MS (2 focus groups) and 8 clinicians (5 physiotherapists, 2 occupational therapists, and 1 MS nurse in 2 focus groups) were involved. The focus groups were recorded and transcriptions were analyzed using theme-based content analysis.

Results: People with MS commonly reported that their UL problems interfered with activities of daily living and resulted in the loss of meaningful hobbies such as writing. Many people with MS neglected UL exercise and found strategies for adapting to the UL impairments. Similarly, clinicians stated UL rehabilitation was neglected within their service and that it was challenging to find interesting treatment strategies. VR was suggested by both participant groups as a solution, as it was convenient for people with MS to access and it could provide a more engaging and disguised approach to exercise. There were shared concerns with cybersickness and disengagement with using VR approaches. Both groups agreed games should be meaningful and adaptable for users but suggested different VR activities, with clinicians suggesting games directly reflecting activities of daily living and people with MS suggesting more abstract activities.

Conclusions: VR was well received by both people with MS and clinicians for UL rehabilitation. Recommendations were made for the development of VR rehabilitation games which are personalized and customizable for the varying abilities of people with MS.

(JMIR Serious Games 2024;12:e51508) doi:10.2196/51508

KEYWORDS

virtual reality; multiple sclerosis; upper limb rehabilitation; coproduction; activities of daily living; exercise games; upper limb impairment

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Introduction

Background

Multiple sclerosis (MS) is an inflammatory demyelination disorder of the central nervous system that is estimated to affect 2.8 million people worldwide [1]. Over a third of the people with MS have upper limb (UL) dysfunction, including weakness, tremors, and spasms in one or both ULs [2]. This can result in difficulties with activities of daily living (ADL), negatively impacting quality of life and the likelihood of remaining in employment [3,4]. Problems specifically with dexterity are related to higher health care costs [5] and a higher association with depression-like psychological measures compared to problems with lower limb function [6]. Rehabilitation and physical exercise improve motor function for people with MS [7,8]. The evidence regarding UL rehabilitation is lacking in comparison with the lower limb, despite the high frequency of UL impairments and their impact on ADL [9]. In addition, there are particular challenges in finding effective yet motivating rehabilitation strategies in MS due to the long-term, progressive nature of the disease and diversity of symptoms [10].

Virtual reality (VR) is increasing in popularity in rehabilitation research and is proposed as a possible approach to encourage long-term rehabilitation [11]. VR includes digital environments that often simulate real-world experiences with reported benefits of high motivation and engagement, with real-time feedback [12]. VR has shown promising results within MS populations, but this evidence is limited in comparison with stroke, especially regarding UL function [13]. Our systematic review, investigating the effect of VR in improving UL function in MS, found early, but limited, evidence suggesting VR has the potential to improve function in people with MS [14]. There was also a low number of dropouts in most studies within the review, supporting that VR could improve adherence compared with conventional rehabilitation; therefore, VR could be useful in conditions such as MS, where prolonged rehabilitation is required.

VR is often investigated alongside video games played within a VR setting, which can be commercially available or specifically tailored games designed with a target population in mind. Commercially available exercise games, targeted at a healthy population, can be unsuitable for disabled individuals and lead to discouragement and anxiety [15]. It is beneficial to involve a sample of target users in the creation and development of effective VR-based gamified approaches [16]. This process is known as coproduction [17]. To date, no study has systematically coproduced VR games specifically for UL rehabilitation in people with MS.

Objectives

The aims of this study were to determine the views of people with MS and specialist clinicians on UL dysfunction or function in MS, challenges faced by clinicians when delivering UL therapy, barriers and motivators for exercise in MS, opinions on VR, and suggestions for development and design of VR games. These findings will guide the future development of VR applications and interventions for UL rehabilitation for people with MS.

Methods

Ethical Considerations

Ethics approval for this study was provided by the School of Health and Life Sciences Ethics Committee at Glasgow Caledonian University (HLS/PSWAHS/20/002). Informed consent was obtained from the participants and clinicians.

Recruitment

The study aimed to recruit up to 12 people with MS and 12 specialist MS clinicians to take part in online focus groups. The sample size was determined in line with the design of other similar studies and general recommendations for qualitative analysis [18,19]. To be included in the study, people with MS were required to be aged ≥18 years and have a diagnosis of MS (self-reported) with self-reported UL impairment. Clinicians were required to have experience (any duration) in delivering MS rehabilitation within the National Health Service (NHS) or the third sector. In addition, all participants were required to have access to and the ability to operate videoconference software. There were no specified exclusion criteria. Participants with MS were identified through the MS Society UK's research network, which advertised the study to its members. Those who were interested in participating contacted the research team directly and were emailed a participant information sheet. In terms of recruitment of clinicians, the MS Trust Therapists in MS network advertised the study to its members. Interested clinicians contacted the research team and were emailed a participant information sheet.

Coproduction Focus Groups

The focus groups for people with MS and clinicians were conducted separately with a maximum of 5 people per focus group. To comply with COVID-19 pandemic regulations at the time, focus groups were held online using Zoom (Zoom Video Communications) or Teams (Microsoft Corp) videoconference software; this also provided an opportunity for recruitment of participants from across the United Kingdom and Ireland. The focus groups were conducted in a semistructured style using a focus group schedule split broadly into three sections important for the development of VR interventions for UL problems in people with MS: (1) UL dysfunction and exercise or therapy; (2) opinions on VR; and (3) suggestions for development and design of any developed VR games (Multimedia Appendix 1). In addition, clinicians were asked what information and feedback they would want from a patient's VR therapy session. The questions included prompts that allowed more targeted responses from participants regarding their experiences and views [20]. Within the focus groups, participants were shown three videos demonstrating different commercially available head-mounted devices (HMDs) and hand-tracking devices: (1) a nonimmersive VR set up using a Leap Motion controller and computer monitor, which is a hand motion capture device that allows users to visualize their hand movements and interact with virtual environments; (2) immersive VR using the Oculus Rift HMD with a mounted Leap Motion device for hand tracking; and (3) immersive VR using the Oculus Quest, with in-built hand tracking (Figure 1 [21,22]; Multimedia Appendix 2). Videos were shown as participants were unable to try these devices

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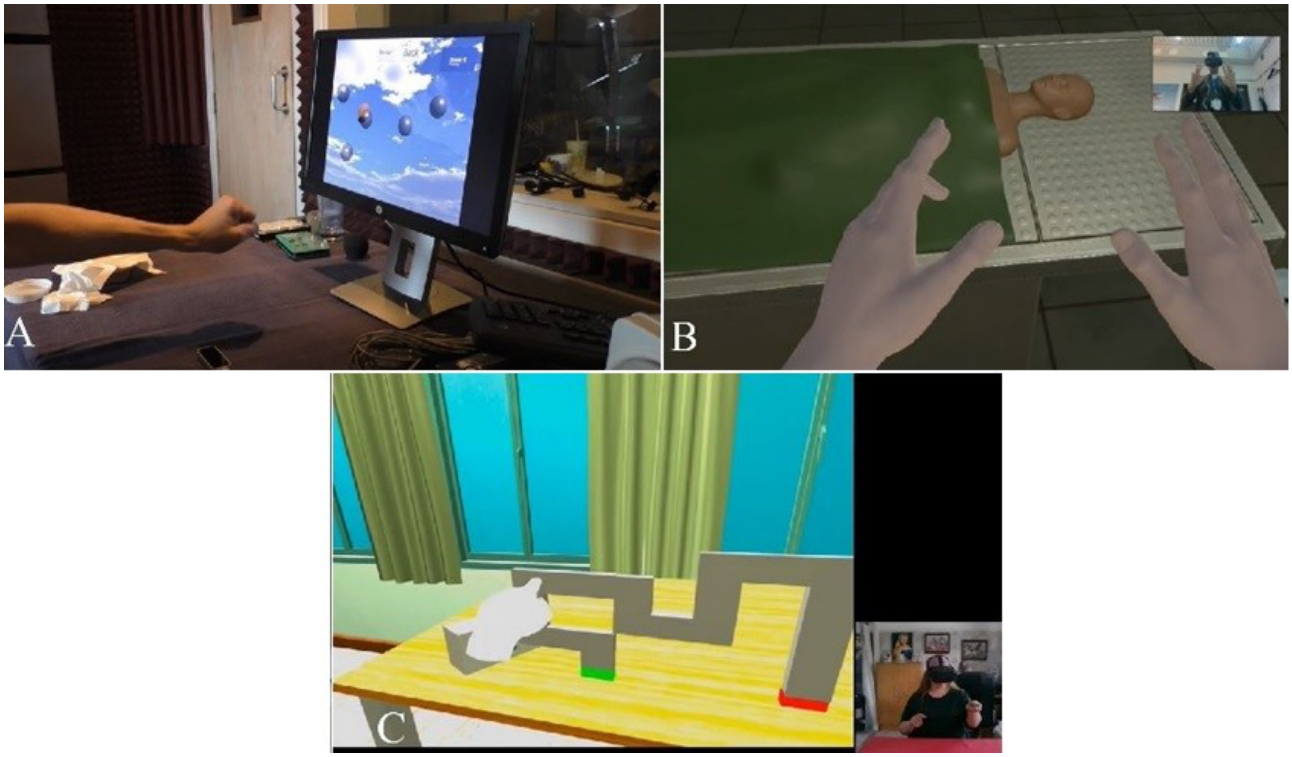
since the focus groups were online due to the COVID-19 pandemic. These videos attempted to contextualize and demonstrate the different VR and motion capture devices in terms of users interacting with environments, possible hand movements, and previous games developed from prior research. After watching the videos, participants were encouraged to share their initial thoughts on each of the technologies. The focus groups involving people with MS and clinicians lasted approximately 90 minutes and 60 minutes, respectively. The focus groups were facilitated by a female researcher (AW) who had been involved in the recruitment of participants and an additional senior, female researcher (LP) attended.

Figure 1. Stills from videos shared with participants during focus groups, demonstrating different virtual reality technology. (A) Video 1 shows Leap Motion only; (B) video 2 shows Leap Motion and Oculus Rift; and (C) video 3 shows Oculus Quest.



Data Analysis

All focus groups were audio recorded and transcribed verbatim. Qualitative analysis of the data was performed based on theme-based content analysis (TBCA) as described in the study by Neale and Nichols [23]. This qualitative method groups responses into content-related themes to enable researchers to view the user preferences more easily and has been used to influence the development or evaluation of a VR environment [23-25]. TBCA is a flexible qualitative data analysis method that involves five key steps: (1) data collection, (2) data collation, (3) raw theme definition and classification, (4) higher order theme selection, and (5) presentation of classification matrix [23]. Owing to the large number of higher order themes, we added an additional step by grouping the higher order themes into main themes. The raw themes were assigned independently by 2 researchers in the transcripts of people with MS (AW and LF) and clinicians (AW and LP). After agreement on the raw themes, the responses were then independently grouped by 2 researchers (AW and LP) into higher order themes. Any discrepancies in assigning the themes were resolved through consultation with a third reviewer, if necessary. Once the higher order themes were determined, the main themes were determined by 2 researchers (AW and LP). The main themes with their associated raw and higher order themes are presented in tables. The raw and higher order themes were quantified manually within the matrix based on the number of responses necessary to display popularity or consensus [23], and example quotes for each higher order theme were included. Focus groups of people with MS and clinicians were analyzed separately to allow comparison of the findings between the 2 groups.

Results

Participant Demographics

A total of 10 people with MS were recruited to the study and took part in 1 of 2 focus groups, each of which had 5 participants. Most participants with MS were female (7/10, 70%), with a mean age of 56.4 (SD 16.5) years and a mean time since diagnosis of 14.4 (SD 12.3) years. Participants had varying MS types (Table 1).

A total of 8 clinicians were recruited (5 physiotherapists, 2 occupational therapists, and 1 MS specialist nurse). Among them, 6 participants worked in the NHS and 2 worked in other settings. There were 2 focus groups for clinicians with 4 participants in each group. All clinicians were female, with a mean age of 46.2 (SD 9.6) years, and the mean length of experience was 17.9 (SD 10. 2) years.

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Table 1. Demographic details of people with multiple sclerosis.

Participant ID	Age (years; mean 56.4, SD 16.5)	Sex	Multiple sclerosis type	Time since diagnosis (years; mean 14.4, SD 12.3)
P1	60	Female	SPMS[a]	30
P2	38	Female	RRMS[b]	4
P3	68	Male	SPMS	35
P4	58	Female	SPMS	1
P5	42	Female	SPMS	11
P6	28	Female	RRMS	3
P7	56	Female	PPMS[c]	5
P8	70	Male	PPMS	16
P9	60	Male	SPMS	12
P10	84	Female	SPMS	27

[a]SPMS: secondary progressive multiple sclerosis.

[b]RRMS: relapsing-remitting multiple sclerosis.

[c]PPMS: primary progressive multiple sclerosis.

People With MS: TBCA

Overview

Following TBCA of the focus groups of people with MS, 20 higher order themes were determined based on the grouping of the assigned raw themes. These 20 higher order themes were grouped into four main themes: (1) Impact of MS on the UL; (2) Exercising with MS; (3) Views of people with MS on VR; and (4) Recommendations for development and user requirements (Table 2). A full version of this table, including more example quotes from participants, is available in Multimedia Appendix 3.

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Table 2. Main, higher order, and raw themes from theme-based content analysis of people with multiple sclerosis focus groups.

Main theme and higher order themes (number of responses)	Raw themes (number of responses)
Impact of MS[a] on the UL[b]	
Interference with functional activities (35)	Dressing (8); eating (6); dropping items (5); writing (5); grooming (3); dependence on others for activities of daily living (3); carrying items (3); and traveling (2)
Symptoms and signs that impact activities (25)	Fatigue (10); numbness (6); sensory overload (4); weakness (3); tremors (2); proprioception (2); and coordination (1)
Strategies people with MS adopt to assist with ADL[c] (24)	Strategies for functional activities (8); adapting (7); making a difference (5); technology assistance (2); and mobility-assistance equipment (2)
Struggle with loss of meaningful activities and skills (14)	Loss of skills (6); impact of losing ability to write (4); and keeping meaningful activities (4)
UL actions people with MS find difficult (13)	Dexterity (6); range of motion (4); and grip (3)
Sharing and sympathy (13)	Sharing strategies (4); sharing advice on exercise (4); taking advice (3); and sympathizing (2)
Difficulty with progression and unpredictable nature of MS (10)	Variation in MS (6); unpredictable (2); and progression (2)
Exercising with MS	
Views and attitudes on exercise (49)	Maintenance (10); negative perceptions of exercise (8); keeping muscle strength (8); determined to exercise (7); benefits of exercise (6); multitask approach (4); legs focus (3); and in control (3)
Previous experience of UL rehabilitation or exercise (40)	Outcomes from UL exercise or rehabilitation (12); neglecting UL exercise or rehabilitation (10); UL equipment (6); UL physiotherapy (4); driven for UL exercise (3); UL exercise resources (3); and adherence (2)
Barriers to exercise (28)	Personal barriers (8); environmental barriers (8); COVID-19 barriers (7); and verbal disengagement (5)
Facilitators to exercise (28)	Verbal encouragement (10); health care professionals (8); MS center (4); gym facilitators (3); and pushing self for results (3)
Adverse effects of exercise (11)	Induce symptoms (4); tiring (3); recovery time after exercise (2); affecting socializing (1); and overdoing exercise (1)
Approaches to exercise used by people with MS (26)	Routine (7); exercise bikes (6); exercise aims (5); low impact or stretching exercise (4); and physiotherapy approaches (4)
Views on group vs individual exercise (26)	Competition in exercise (10); motivation of group exercise (5); downsides of group exercise (5); importance of socializing in exercise (2); camaraderie (2); enjoyment (1); and interest in group exercise (1)
Views of people with MS on VR[d]	
Positive views on VR (55)	Home use (9); outcome benefits (6); personal opinions on VR (5); fun (5); adaptable (5); positives of technology (5); wireless convenience (5); accessibility convenience (4); incentives (3); meaningful (3); online socializing (2); and immersion (1)
Negative views on VR (40)	Cybersickness (17); HMD[e] discomfort (6); technology discomfort (5); HMD dislike (3); disengagement (3); accessibility concerns (3); and unsuitability (3)
Views on trying or participating in VR rehabilitation (25)	Openness to VR (12); challenging (4); safety considerations (3); need results (2); technology considerations (2); and unsuitable for them (2)
Recommendations of people with MS for development and user requirements	
Considerations for development of VR games (84)	Mindful of target audience (9); tracking progress (8); discouragement of feedback (8); knowing UL outcomes (7); end result (6); score targets (6); challenging self (6); competition in games (5); education (5); time feedback (4); supervision (4); community involvement (3); multipurpose (3); continuous development (3); be fun (3); hardware (2); and learning patterns concern (2)
Suggestions for VR activities (36)	Suggested UL actions (9); game ideas (7); real-life vs abstract tasks (4); haptic activities (4); strength in games (4); writing and drawing (3); demonstrated games (3); additional objectives (2); and atmosphere (1)
Importance of choice (23)	Offer different movements (8); having a variety of games (6); personal preferences (6); and variety of different levels (3)

[a]MS: multiple sclerosis.

[b]UL: upper limb.

[c]ADL: activities of daily living.

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[d]VR: virtual reality.

[e]HMD: head-mounted device.

Impact of MS on the UL

The most common higher order theme was "Interference with functional activities" with 35 responses (Table 2). Participants reported a wide range of activities they found difficult to perform due to their MS, the most frequent being ADL, including personal care, eating, and carrying heavy items. "Symptoms and signs that impact activities" had the second highest number of responses (n=25), where participants particularly noted the impact of fatigue on activity (n=10); however, sensory problems such as numbness and pins and needles were also highlighted. Other MS symptoms impacting UL function were, for example, weakness, tremors, and coordination problems. In "Strategies people with MS adopt to assist with ADL" (n=24), because of losing function, participants discussed the use of assistive equipment, for example, button fasteners, specialized cups, and voice control. Other strategies included using their less affected hand or pacing to manage fatigue. The remaining 4 higher order themes had fewer responses. In brief, dexterity, range of joint movement, and grip were the main "UL actions people with MS find difficult" (n=13). These were often compounded by the unpredictability and progressive nature of MS ("Difficulty with progression and unpredictable nature of MS," n=10). Participants reported the emotional impact of losing the ability to carry out personal and meaningful activities specifically because of loss of UL function ("Struggle with loss of meaningful activities and skills," n=14), with one participant stating the following:

> *I used to be a writer and it was very, very hard because I couldn't write anymore...I was really motivated [to relearn writing], felt really cut off from the world.* [P8; age 70 years; male participant with primary progressive multiple sclerosis]

The final higher order theme was "Sharing and sympathy" (n=13 responses), where participants empathized and shared experiences and suggestions of assistive equipment.

Exercising With MS

Most responses under this main theme related to "Views and attitudes on exercise" (n=49; Table 2). Participants were motivated to exercise with a "*use it or lose it*" attitude and a desire to, if not improve then at least maintain, their function and prevent further deterioration. Participants also described negative perceptions of exercise, such as finding it "*very boring*" and guilt from not participating in exercise. In "Previous experience with UL rehabilitation or exercise" (n=40), many participants (5/10, 50%) discussed not undertaking any UL exercise or rehabilitation, currently or previously. Many UL programs previously undertaken by some participants aimed to build strength, reduce pain, and improve hand function with varying outcomes. There were similar numbers of responses in terms of "Barriers to exercise" (n=28) and "Facilitators to exercise" (n=28). Personal barriers to exercise included comorbidities, MS symptoms (fatigue, pain, and bladder and bowel dysfunction), difficulty using exercise equipment, and expense. The COVID-19 pandemic had negatively impacted the participants' exercise due to services closing down. Environmental barriers to exercise included lack of local facilities and not having space to exercise at home. Verbal encouragement was described as both a barrier (could be off putting) and a facilitator (motivating) to exercise. Other facilitators were seeing improvements, feeling motivated, and the attitudes of health care professionals, personal trainers, and carers. Conversely, health care professionals with a lack of experience in MS overwork people with MS, leading to exhaustion ("Adverse effects of exercise," n=11). Participants undertook many different forms of exercise ("Approaches to exercise used by people with MS," n=26), including exercise bikes, Pilates and yoga, dog walking, and gym exercises. There were varying "Views on group versus individual exercise" (n=26). Some found competition within a group to be motivating while others did not, with one participant suggesting social support and camaraderie was more important than competition:

> *I'm not too fussed about being in competition with others, but if it was a more social thing that would maybe encourage me to perhaps join in a group that's doing something together.* [P4; age 58 years; female participant with secondary progressive multiple sclerosis (SPMS)]

Negative aspects of group exercise included the fear of letting others down.

Views on VR

The initial reaction to VR was positive ("Positive views on VR," n=55; Table 2). Participants stated it looked fun or enjoyable with the potential to improve or maintain muscle strength, dexterity, and spatial awareness, especially with repeating the actions and concurrently perhaps learning a new skill (for example, playing the piano):

> *I think [VR's] still very good because... it's...maintaining those motor skills that is so easily slip away when you're not using them.* [P9; age 60 years; male participant with SPMS]

There were positive comments in relation to the convenience and accessibility of VR facilitating exercise at home at a suitable time and eliminating travel to physiotherapy services and gyms. Participants highlighted that the wireless HMD was more convenient as it was portable and did not need a computer. The advantage of linking up with others online was raised. However, "Negative views on VR" (n=40) were related to concerns regarding cybersickness, linked to dizziness and balance problems:

> *With MS a lot of people suffer from nausea or motion sickness. That can be a concern for the headsets.* [P6; age 28 years; female participant with relapse and remitting multiple sclerosis]

Other negative responses related to the HMD discomfort regarded weight, usability concerns, wearing it with glasses, and being disconnected from the real world. Two participants indicated that interest in VR may reduce over time. Participants

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were also concerned about fatigue and the usefulness of VR for UL sensory dysfunction. Most participants (6/10, 60%) expressed they were open to trying VR ("Views on trying or participating in VR rehabilitation," n=25), but would like to understand the benefits, long-term outcomes, and any safety issues.

Recommendations for Development and User Requirements

With regard to "Considerations for development of VR games" (n=84), a variety of UL movements was desirable with clarity in terms of the aim and outcome in relation to the UL being important (Table 2). Competition within the VR games, interacting with others or challenging themselves, were frequently discussed as being motivating. Tracking improvements during VR gameplay was vital to some participants, including monitoring improvements in score, exercise time (rather than countdown which could be stressful), and progressive challenges. The games should offer the ability to challenge users, with one participant saying the following:

> *That challenge to try and be better the next time, whereas if you've got no idea...you've got nothing to fight against or to work against.* [P10; age 84 years; female participant with SPMS]

Conversely, other participants emphasized the potential demotivating effect of feedback given the progressive nature of MS, by warning that score feedback should not be "*disheartening*," and should therefore be made optional to the user. There was a strong feeling that the VR games should be "*fun*" with abstract gameplay potentially being more fun. Participants felt that demonstrations and supervision to assess progress were important. They also stated that the VR games had to account for the differences in the ability of people with MS and that older people may need more basic VR games. The idea of the VR games having an educational outcome or in learning a new skill was suggested to help with engagement. Participants suggested that reaching, punching, and other aerobic activities could be incorporated ("Suggestions for VR activities," n=36). Having haptic approaches was frequently proposed with gripping, squishing games, such as kneading bread. Participants proposed activities with a cognitive element, such as a puzzle or maze, and whole limb movements, such as Whack-a-Mole (Mattel), writing or drawing. Participants liked the VR piano which had been demonstrated. There was a variety of opinions in terms of abstract or real-life activity with most preferring abstract games but some ADL-type activity was also suggested. "Importance of choice" (n=23) related to having variety in games, UL movements, and levels of difficulty with abstract games or real-life gamified tasks, with 1 participant declaring the following:

> *I'd like to make sure I'm not doing a whole lot of exercises that are all doing the same things...Got to be mixing them up: one for coordination, one for dexterity.* [P1; age 60 years; female participant with SPMS]

Clinicians: TBCA

Overview

From the clinician focus groups, there were 15 higher order themes grouped into four main themes: (1) Current methods and challenges for delivering UL rehabilitation; (2) Clinicians' views on VR; (3) Recommendations for development and user requirements; and (4) Implementation of VR into practice (Table 3). A full version of this table, including more example quotes from participants, is available in Multimedia Appendix 4.

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Table 3. Main, higher order, and raw themes from theme-based content analysis of clinician focus groups.

Main themes and higher order themes (number of responses)	Raw themes (number of responses)
Current methods and challenges for delivering UL[a] rehabilitation	
Challenges clinicians face when delivering exercise for people with MS[b] (52)	MS-specific challenges (13); patient adherence (11); service challenges (9); UL-related challenges (7); patient differences (6); challenges with current methods of delivery (4); COVID-19 impacts (2)
Recommended UL exercises for people with MS (29)	Actions (10); systematic approach (7); functional tasks (6); strength and range of movement (5); relapse care (1)
Experience with long-term, progressive condition (24)	Deterioration (11); acceptance in patients (8); difficulty with patient improvements (5)
Factors clinicians consider when prescribing exercise for the UL (22)	Meaningful and patient-focused (9); patient assessments (6); symptoms (4); repetition (3)
Current methods of UL exercise delivery for people with MS (15)	Technological approaches (4); programs (4); accessible equipment (3); clinician routines (2); patient lead (2)
Socializing in exercise (14)	social motivation (6); support (5); recommending social exercise (3)
Clinicians' views on VR[c]	
Positive views on VR (50)	Solutions to current challenges (10); personal opinions on VR (7); facilitating movements or tasks (6); VR-specific qualities (6); meaningful (5); engagement (5); visualization (4); novel (3); cognitive appeal (2); adaptability (2)
Negative views on VR (38)	Disengagement (10); cybersickness and safety (8); HMD[d] discomfort (7); accessibility concerns (5); feedback concerns (5); validity concerns (3)
Questioning benefits and the unknowns of VR (14)	Questioning purpose of VR (4); questioning benefits of VR (4); neural mechanisms (3); research (2); different VR systems (1)
Clinicians' recommendations for development and user requirements	
Considerations for developing VR games for people with MS (41)	Communication between clinician and patient (12); purposeful (7); social components (7); selecting tasks (4); slower tasks (3); competition (3); feedback for clinician (3); positive feedback (2); end point (2)
Suggestions for VR activities (18)	Activities of daily living (6); hobbies (6); objectives (6)
Importance of choice (15)	Preferences (6); having variety (5); setup (4)
Implementation of VR into practice	
Suggestions for incorporation of VR into practice (18)	Home use (7); VR in clinics (7); long-term treatment (4);
Challenges with implementation of VR into practice (24)	Funding (7); demanding on services (6); availability of equipment (5); risk (3); adjustment (2); uncertainty of practice (2)
Finding the target audience for VR (8)	Who would use VR (3); niche group (3); age (2)

[a]UL: upper limb.

[b]MS: multiple sclerosis.

[c]VR: virtual reality.

[d]HMD: head-mounted device.

Current Methods and Challenges for Delivering UL Rehabilitation

"Recommended UL exercises for people with MS" (n=29) included strength training and active movements related to functional activity, such as hand-to-mouth movements (Table 3). Treatment for the UL often involved equipment such as Therabands and Theraputty but also technology such as the Gloreha robotic system and functional electrical stimulators with different models of care for UL exercises described as part of community-based classes, within third sector organizations and online programs ("Current methods of UL exercise delivery for people with MS," n=15). Within "Factors clinicians consider when prescribing exercise for the UL" (n=22), most responses were regarding meaningful and goal-focused exercises. Clinicians also considered the patient's symptoms, for example, spasticity, pain, and the ability of patients. The importance of repetition of movement was reinforced. Most responses (n=52) were in relation to "Challenges clinicians face when delivering exercise for people with MS." Clinicians expressed that UL-focused exercise was neglected compared to the lower limb and the challenge of making UL exercise interesting:

> *A bit more difficult for upper limb things...it's much easier to maybe...go for a walk with somebody or you know, or cycle or whatever. Upper limb is maybe a wee bit more difficult.* [C6; physiotherapist]

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Clinicians also mentioned the use of Theraputty described as "*juvenile*" and lists of exercises "*boring*."

Service-related challenges included limited time and capacity to see patients and large geographic areas to cover. Other challenges were keeping patients engaged with exercise in the long term, especially at home, and finding an activity that would be attractive to patients. Under "Experience with long-term, progressive condition" (n=24), clinicians raised being realistic about improvements with a progressive condition while also keeping patients motivated, minimizing deterioration or maintenance, rather than improving:

> *Trying to motivate people with progressive MS, you're trying to get them to continue to maintain where they are rather than improve.* [C5; occupational therapist]

Clinicians expressed the positive benefits of "Socializing in exercise" (n=14) for support and motivation.

Clinicians' Opinions on VR

Clinicians were very positive about VR (n=50), describing it as being interactive, fun, meaningful, and a novel potential approach to rehabilitation, which could help engagement (Table 3). They were positive about the escapism aspect and the potential to improve mental health:

> *What appeals about VR stuff is that it is focused and takes you into a different place...You're doing tai chi on a beautiful, Japanese garden rather than actually in your grumpy living room...I think even that in terms of the escapism aspect, maybe from a mental wellbeing.* [C1; physiotherapist]

Clinicians liked the visual feedback to help with, for example, coordination, but which could also reinforce movements and introduce a cognitive component. Clinicians commented that VR provided the opportunity to undertake activities not possible within the clinic and to exercise without the activity seeming like an exercise. Most of the "Negative views of VR" (n=38) were regarding patient safety using VR headsets, especially cybersickness, including dizziness and disorientation, specifically in patients with vestibular issues. Other general concerns with HMDs were usability with glasses, the weight of the HMD, and feeling claustrophobic. Clinicians suggested that VR activities should not be too simplistic to avoid patronizing patients and at an appropriate skill level. The longevity of engagement of patients after the initial novelty was questioned. Clinicians also questioned the use of VR for activities that can be done in the real world and similarly how VR activities might translate to real function. The importance of feedback on the quality of movement as well as the quantity was highlighted. Finally, accessibility and digital poverty were also raised. The final higher order theme was "Questioning benefits and the unknowns of VR" (n=14), where some clinicians felt there was insufficient evidence on the purpose and benefits of VR and its effect on neural mechanisms:

> *I think it's important to think about how is [VR] different to just doing [activities] in real life as well...What can you augment in your rehab through this virtual reality that you can't just do in real life anyway?* [C7; physiotherapist]

Recommendations for Development and User Requirements

Under "Considerations for developing VR games for people with MS" (n=41), clinicians discussed the importance of the VR games having purposeful activity, translation of tasks into real life, and having an end point (Table 3). The games should consider movements of individual joints of the UL with extension movements at the wrist and fingers being important as where people with MS lose the most function. Games should incorporate strength, coordination, proprioception, and range of motion exercise as well as exercises for the core. Feedback was important, with clinicians able to monitor the program. Clinicians were not interested in scores for the games but wished feedback on the quality of the movements and patient engagement. Clinicians stated that undertaking VR activities with others or in group settings with elements of competition was desirable. Clinicians provided "Suggestions for VR activities" (n=18), including ADL such as putting on makeup; writing or chopping vegetables; and hobbies including pottery, sewing, or piano playing. Clinicians raised the "Importance of choice" (n=15) in the VR setup, choice of games, and choice within games, for example, levels of difficulty, to appeal to as many people as possible:

> *I think, it is about having a variety of things that push as many buttons with patients that you can manage and cover as many options as you can.* [C2; physiotherapist]

Implementation of VR Into Practice

Under "Suggestions for incorporation of VR into practice" (n=18), clinicians felt long-term, regular use of VR was needed for positive outcomes (Table 3). Home use was felt to encourage frequent use, with clinicians monitoring progress remotely, thus saving in person contact time. There were a number of "Challenges with implementation of VR into practice" (n=24) with cost and funding (service and individual) being the most commonly reported, which included potential increased demand on services:

> *I know if I brought it to my bosses they would want a breakdown of cost of monthly rate, how are we going to utilise it, how often are we going to utilise it. What figures could we get from this particular item and what outcomes could we achieve.* [C4; MS specialist nurse]

Equipment-related challenges were ownership, availability, supply of equipment, and infection control. A full risk assessment would be required before implementation and guidance would be needed on intervention duration and frequency. Clinicians discussed for whom VR would be appropriate, in terms of age or other factors, and identified this as an area for future research ("Finding the target audience for VR," n=8).

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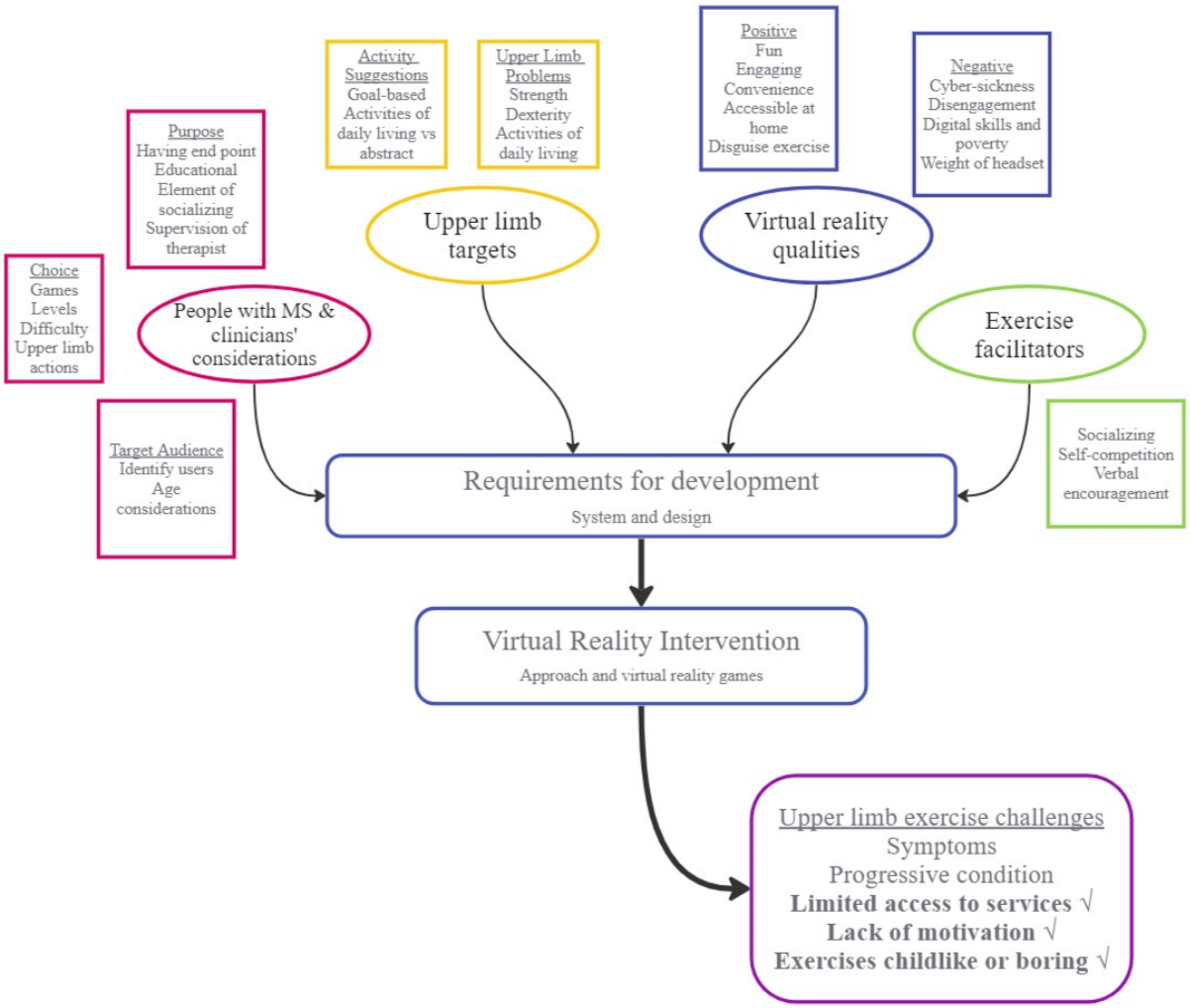
Discussion

Principal Findings

This study aimed to explore the views of people with MS and clinicians on UL impairment associated with MS and the potential role of VR as a rehabilitation approach to address this impairment. The discussion focuses on the combined findings from the 2 groups of participants: people with MS and clinicians (Figure 2). Figure 2 is a visual representation of the principal findings based on the higher number of responses assigned, which should inform the development of VR applications and interventions aiming to improve the UL function for people with MS and how VR could tackle challenges of existing UL exercise raised by clinicians and people with MS in this study.

The findings agree with those of previous studies that people with MS commonly have UL impairments that impact function, including problems with dexterity and ADL, which leads to loss of meaningful activities [26-28]. Despite UL difficulties, UL exercise was neglected due to MS symptoms, such as fatigue, lack of motivation, and dislike of exercise, as well as the challenges clinicians faced regarding time constraints and finding appropriate therapies that were not childlike or boring. Lack of focus on UL rehabilitation has been reported previously in MS [9] and in other long-term neurological conditions such as stroke [29]. The progressive and unpredictable nature of MS was raised by both groups, and consequently, clinicians raised the importance of setting realistic expectations with therapy, sometimes focusing on maintenance of function rather than improvement.

Figure 2. Flow diagram of the results from theme-based content analysis of people with multiple sclerosis (MS) and clinicians' coproduction focus groups and how this will guide the requirements for developing virtual reality–based games or interventions, which will aim to tackle certain achievable upper limb exercise challenges within MS.



Both groups (people with MS and clinicians) were optimistic about the use of VR and believed VR could be a solution to their exercise challenges. Positive comments, including avoiding traveling, being accessible, and being engaging or fun addressed the identified barriers for UL rehabilitation. This concurs with previous VR studies [30,31] and specifically in UL rehabilitation in MS, with a recent home-based, feasibility study using the Oculus Quest 2 VR headset in which participants described VR as fun, interesting, and innovative [32]. Participants in the study by Kamm et al [32] suggested adding difficulty levels and scoring to their exercises, competitive elements previously described to be motivating by people with MS using nonimmersive exercise games delivered through the Nintendo Wii [33]. In this study, both groups were especially positive regarding the immersive approach of the Oculus Quest. Participants thought the escapism properties and visualization

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of movements could potentially "disguise exercise," which may occur with the "fun" element of VR reducing the perception of exertion during exercise [34], therefore encouraging more UL therapy.

Negative views about VR were also expressed, mainly the potential for cybersickness. Cybersickness is thought to be caused by conflict of stimuli, leading to nausea, disorientation, and pain in the eyes and head [35]. Women are more susceptible to cybersickness [36], which is relevant in MS, with a higher number of women affected. Although cybersickness with VR has been reported previously in people with MS [37], there are development strategies for reducing cybersickness, such as designing VR activity with less overall movement within the virtual environment. Cybersickness is, however, thought to reduce over time with exposure to VR [38]. There were unnecessary concerns raised for those wearing glasses as the HMD can accommodate glasses, but there were valid concerns about the weight of the HMD for some users. Disengagement was another concern both groups expressed, with limited data on long-term adherence to VR in MS rehabilitation. Exercise is a behavioral intervention, and long-term adherence to exercise can be supported by evidence-based behavior change techniques [39]. These behavior change techniques, such as goal setting, rewards, and feedback, can be incorporated into VR games or activity to support long-term engagement in UL exercise. While VR can be more engaging than other methods of exercise [40], frequent performance, feedback on progress, and adjusting levels of difficulty can maximize VR engagement for those with long-term neurological conditions [41]. Finally, clinicians had specific concerns regarding digital poverty, the technical ability of people with MS, and insufficient technical services to support VR.

Considerations for VR game development align with user-centered design principles for VR in motor rehabilitation in survivors of stroke, such as being fun, tracking progress, having an element of competition, challenging oneself, and providing feedback [42], and are not specific to any clinical population. Participants raised that VR development should be mindful of the different end users (people with MS) who may differ in ability and preferences. Clinicians suggested VR would appeal to younger individuals with MS, whereas people with MS felt older people with MS might need more basic gameplay. While there is some, albeit limited, evidence for lower usability scores for older VR users compared with younger users, there can be higher user enjoyment [43], and there is moderate evidence for good usability of VR in older populations [44]; therefore, this concern may be overly cautious.

Consideration of the end user links to the importance of choice when designing VR interventions, with a variety of games to appeal to as many as possible. Participants felt the games should include different movements, levels of immersion, level of difficulty, or feedback on performance. Accommodating individual preferences is a key element for the design of VR games for rehabilitation, as it increases user engagement [45]. However, our previous systematic review found that a choice of games was rarely included in VR interventions in MS [14].

There were differing views in terms of the type of feedback people wished from VR. Some people with MS wanted to track scores and visualize results, which is supported by reward theories for users during both entertainment and serious games [46]. Conversely, concerns were raised about feedback potentially being discouraging or demotivating, especially given the variable nature of MS. As an example, countdown timers provide slight pressure to motivate players to increase engagement [47]; however, in this study, people with MS felt they could be stressful. Feedback on the duration of exercise completed was appealing to people with MS, as reported previously [19]. As well as the quantity of VR exercise, clinicians also wished feedback on the quality of movement when performing the games. Rehabilitation often involves highly repetitive movements to stimulate neuroplasticity; however, stroke specialist therapists have also previously reported concerns that quality of movement in VR rehabilitation for UL maybe sacrificed for a good gaming outcome [18], although this has not been explored in people with MS. Both groups were interested in the reported outcomes of using VR approaches which, if positive, would increase engagement.

Clinicians and people with MS felt VR activity had to be related to the patient's personalized and meaningful goals, which is known to increase motivation in physiotherapy settings [48]; however, this is often neglected in VR regimes [14]. Goals need to be adjusted over time in a progressive condition, such as MS, and to avoid disengagement as raised earlier. Participants with MS frequently stated that their goals were related to not only improvement but also the maintenance of ability and the prevention of further deterioration. In terms of suggestions for VR activities, the groups differed with clinicians suggesting ADL or hobby simulations and people with MS being more ambivalent, stressing activity to be fun with a variety of real-life and abstract VR games. Previous studies of VR have often involved ADL activities such as cooking or other kitchen activity [49,50]. Although VR can provide a safe environment to practice ADL for people with mobility issues [51] people with MS in this study were less interested in ADL, especially kitchen simulations. Both groups suggested an "end result," such as creating a drawing, or learning a new skill would be positive and facilitate a feeling of accomplishment. There were also suggestions from people with MS to incorporate haptic activities, such as grabbing and gripping. However, the user is not able to receive tactile feedback when interacting with a virtual environment, and handheld controllers may need to be considered for some VR activities [52]. Another solution could be to incorporate pseudo haptics, the use of different stimuli such as visual or auditory stimuli, to mimic a variety of haptic properties in a virtual environment [53]. This is an emerging field that could be explored in VR for people with MS. Similarly, as many of the participants suggested finger-related exercises, it is important that VR systems use good hand-tracking motion capture devices to allow visualization of the movement of fingers and wrists within a VR setting.

Many people with MS were supportive of VR for home use, as being more convenient and accessible. However, there was recognition that users needed demonstration of the technology and a level of clinician supervision. Assessing quality of

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movements and monitoring of patient progress are reported challenges for VR home use [54]. A recent study with a small number of participants found VR to be feasible for home-based UL rehabilitation in people with MS, after 3 supervised sessions [32], but larger studies of home-based VR for UL rehabilitation are required. There was agreement in both groups that an element of social interaction could be considered in the development of VR games. Generally, there is a lack of evidence on the effect of socialization within UL therapy, but it may improve adherence and motivation [55] and provide better outcomes [56]. Specifically in relation to VR, there is some evidence that social aspects increase motivation through competition [57], but participants in our study were more interested in self-competition rather than competing against others. This is similar to a study of a walking app for MS where users were less interested in sharing their goals or achievements with others [58].

Strengths and Limitations

Recruiting participants through online sources may result in a biased sample, as those comfortable with technology and access to online services are more likely to take part. Being online allowed the involvement of people with MS with varying abilities and clinicians who worked in the NHS and the third sector across the United Kingdom. However, the online nature meant it was not possible for participants to physically test the VR equipment and explore their reactions. While it can also be challenging to engage all participants in online focus groups, this was resolved by asking questions using participants' names or by getting participants to use the raise hand function within the videoconference software and encourage discussion between participants.

The TBCA methodology groups responses into themes to quantify them but does not allow consideration of the interaction between participants. Participants had a number of specific questions, such as the long-term outcomes of using immersive VR, the optimal target users for VR (level of disability), and the extent of translation of VR activity into "real-life" function. However, there is currently a lack of literature to provide responses to these questions, which highlights areas for future research.

Conclusions

This is the first study exploring the views of people with MS and clinicians in terms of VR for UL rehabilitation for people with MS and has highlighted the current challenges in UL rehabilitation even though UL impairment is common and impacts meaningful activity. Overall, people with MS often found dexterity-related activities difficult, which impacted multiple ADL and challenges faced in therapy related to motivation, lack of resources, and difficulty finding interesting UL exercises. There was positive support for VR for UL exercise. Overall, to improve engagement and satisfaction for the user, this study suggests any VR games developed for people with MS should (1) be fun and engaging; (2) have clear aims related to the individual user's goals; (3) offer personalization, such as a variety of games (abstract and ADL based), different movements, levels of difficulty, and methods of feedback; (4) monitor quality as well as quantity of movement during gameplay; (5) incorporate design features to reduce the potential for cybersickness; (6) consider if the games can incorporate education or skill development; (7) incorporate aspects of social interaction; and (8) consider including haptic properties. The findings support the need for the creation of bespoke serious games rather than using commercially available exercise games, which can discourage users with motor dysfunction [15,59]. Overall, future development of VR games for UL rehabilitation should focus on a personalized and customizable approach to encourage long-term engagement to improve meaningful outcomes for people with MS.

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Authors' Contributions

AW, MP, EC, and LP designed and conceptualized this study. AW, LF, and LP performed the analysis. AW and LP wrote and prepared the manuscript, with support from MP, EC, and LF.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Focus group interview questions for both participant groups.
[DOCX File , 26 KB - games_v12i1e51508_app1.docx]

Multimedia Appendix 2
Compilation of 3 videos shown to participants during focus groups showing 3 different virtual reality systems.
[MP4 File (MP4 Video), 20062 KB - games_v12i1e51508_app2.mp4]

Multimedia Appendix 3

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Main, higher order, and raw themes from theme-based content analysis of people with multiple sclerosis focus groups, with example quotes.
[DOCX File , 26 KB - games_v12i1e51508_app3.docx]

Multimedia Appendix 4
Main, higher order, and raw themes from theme-based content analysis of clinician focus groups, with example quotes.
[DOCX File , 25 KB - games_v12i1e51508_app4.docx]

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Abbreviations

ADL: activities of daily living
HMD: head-mounted device
MS: multiple sclerosis
NHS: National Health Service
SPMS: secondary progressive multiple sclerosis

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TBCA: theme-based content analysis
UL: upper limb
VR: virtual reality

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Original Paper

Measuring the Reliability of a Gamified Stroop Task: Quantitative Experiment

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Abstract

Background: Few gamified cognitive tasks are subjected to rigorous examination of psychometric properties, despite their use in experimental and clinical settings. Even small manipulations to cognitive tasks require extensive research to understand their effects.

Objective: This study aims to investigate how game elements can affect the reliability of scores on a Stroop task. We specifically investigated performance consistency within and across sessions.

Methods: We created 2 versions of the Stroop task, with and without game elements, and then tested each task with participants at 2 time points. The gamified task used points and feedback as game elements. In this paper, we report on the reliability of the gamified Stroop task in terms of internal consistency and test-retest reliability, compared with the control task. We used a permutation approach to evaluate internal consistency. For test-retest reliability, we calculated the Pearson correlation and intraclass correlation coefficients between each time point. We also descriptively compared the reliability of scores on a trial-by-trial basis, considering the different trial types.

Results: At the first time point, the Stroop effect was reduced in the game condition, indicating an increase in performance. Participants in the game condition had faster reaction times (P=.005) and lower error rates (P=.04) than those in the basic task condition. Furthermore, the game condition led to higher measures of internal consistency at both time points for reaction times and error rates, which indicates a more consistent response pattern. For reaction time in the basic task condition, at time 1, $r_{\text{Spearman-Brown}}$=0.78, 95% CI 0.64-0.89. At time 2, $r_{\text{Spearman-Brown}}$=0.64, 95% CI 0.40-0.81. For reaction time, in the game condition, at time 1, $r_{\text{Spearman-Brown}}$=0.83, 95% CI 0.71-0.91. At time 2, $r_{\text{Spearman-Brown}}$=0.76, 95% CI 0.60-0.88. Similarly, for error rates in the basic task condition, at time 1, $r_{\text{Spearman-Brown}}$=0.76, 95% CI 0.62-0.87. At time 2, $r_{\text{Spearman-Brown}}$=0.74, 95% CI 0.58-0.86. For error rates in the game condition, at time 1, $r_{\text{Spearman-Brown}}$=0.76, 95% CI 0.62-0.87. At time 2, $r_{\text{Spearman-Brown}}$=0.74, 95% CI 0.58-0.86. Test-retest reliability analysis revealed a distinctive performance pattern depending on the trial type, which may be reflective of motivational differences between task versions. In short, especially in the incongruent trials where cognitive conflict occurs, performance in the game condition reaches peak consistency after 100 trials, whereas performance consistency drops after 50 trials for the basic version and only catches up to the game after 250 trials.

Conclusions: Even subtle gamification can impact task performance albeit not only in terms of a direct difference in performance between conditions. People playing the game reach peak performance sooner, and their performance is more consistent within and across sessions. We advocate for a closer examination of the impact of game elements on performance.

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KEYWORDS

cognitive assessment; gamification; serious games; Stroop task; reliability

Introduction

Background

In 1886, James Cattell observed that it takes people longer to name the colors and pictures of objects than it does for them to read the corresponding word [1]. This experiment, along with others, paved the way for the development of what Cattell would call *mental tests* and what we now call *cognitive tasks*. On the basis of these and other results, JR Stroop developed a test of cognitive ability in which study participants read the color but not the meaning of a color word aloud [2]. The results revealed an interference effect if the word color and word meaning did not match. Typical cognitive tasks require people to respond to such visual or auditory cues, and data about their responses, often reaction time and accuracy, are collected. These data can then be used to study human cognition, create population norms, and inform medical decisions, such as dementia diagnoses [3].

Cognitive tasks are most useful when collecting high-quality, high-quantity data. However, this is a challenging process. Traditionally, capturing large data sets has been time consuming and expensive, requiring highly trained professionals to administer and score tasks with individual participants. With technological advancements, tasks can now be administered via computers, deployed remotely, and automatically scored [4,5]. This automation makes it easier to collect large quantities of data but raises new concerns about data quality. Many factors influence cognitive test performance beyond cognitive capacity, such as motivation, stereotype threat, and fatigue [6,7]. Cognitive tasks are often repetitive and boring, leading to high attrition rates [8] and suboptimal effort from participants [9,10].

In attempts to improve the quality of data collected by such tasks, researchers have increasingly turned to gamification, with the hope that tasks can be made more engaging through the addition of game elements, such as points and graphics.

Cognitive Task Gamification

Overview

Deterding et al [11] defined gamification as “the use of game design elements in nongame contexts.” In the context of cognitive tasks, this process typically involves layering game elements over an already existing task. For example, the Go No-Go task has commonly been gamified by adding points [12], narrative elements [13], and fun graphics [14] to the basic task.

Enjoyment and Motivation

Typically, tasks are gamified with the intent of increasing participant enjoyment and motivation. Nicholson [15] noted that gamification can target both extrinsic and intrinsic motivations depending on the game elements used. Reward-based elements, such as points, achievements, and badges, target extrinsic motivation, whereas elements such as play, exposition, and choice target intrinsic motivation. By targeting motivation, researchers aim to combat attrition and encourage repeated, prolonged play [16-18].

However, there is little examination of whether participants experience increased enjoyment when tasks are gamified. In a systematic review of gamified attention tasks, only 25 of the 74 studies reported results from an evaluation of gameplay [16]. When enjoyment is measured, the research shows mixed results. Some studies have found that gamification increases motivation; for example, participants in a stop signal task study experienced higher enjoyment and more flow-like experiences in the gamified condition (as opposed to the basic task) [19].

Other studies have found that certain game elements, especially thematic or narrative elements, can have a negative effect on self-reported enjoyment of cognitive tasks [8,20,21], possibly due to the “chocolate-covered broccoli” effect [22]. Tasks can only be gamified and retain the important elements of a task. When participants expect a fun game and must still complete a repetitive cognitive task, they may experience even lower enjoyment than if they expected a boring task [20]. Game elements can also be used to introduce other emotions. For example, Levy et al [23] found that some older Jewish participants were uncomfortable with their cooking-themed game as they required making recipes containing pork products.

Do these mixed findings imply that researchers should move away from gamifying tasks? Not necessarily, participants might not *enjoy* assessment games more than a control task, but the data they produced may still be of higher quality.

Performance

Groening and Binnewies [24] note that enjoyment is only one way to operationalize motivation, one closely linked to intrinsic motivation. They found that adding achievement-based game elements to a series of simple tasks did not improve self-reported motivation but did improve persistence—when participants could earn achievements, they engaged with a Stroop task for longer before voluntarily switching tasks, compared with when no achievements were available. Similarly, Mekler et al [25] found that when they gamified an image annotation task, participants generated significantly more annotations, despite no reported differences in intrinsic motivation or competence need satisfaction when compared with the basic task.

Adding game elements to a task may improve performance (without affecting enjoyment) in various ways. For example, Jung et al [26] compared the performance of participants who were given a numeric goal (ie, generating 22 ideas) with those who were asked to “do their best.” Participants who were given a specific goal generated higher quantity and higher quality responses. When completing cognitive tasks, participants are often instructed to respond “as quickly and accurately as possible.” This nebulous goal can be clarified and reinforced through game elements that provide immediate feedback such

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as scoring points for fast reactions or losing points for incorrect responses.

When designing gamified tasks for research and assessment purposes, it may be beneficial to focus on influencing performance rather than on enjoyment. Levy et al [23] noted that changes in emotions can influence cognitive abilities, which may interfere with the collection of valid and reliable data when using games as scientific tools. When Vanden Abeele et al [27] compared 2 games designed to measure psychoacoustic thresholds in preschoolers, they found that the more fully developed and motivating game was able to detect lower thresholds. As another example, Delisle and Braun [28] found that changing a task to resemble a fast-paced videogame normalized the performance of participants with attention-deficit/hyperactivity disorder (ADHD), meaning that participants with and without ADHD performed similarly on a gamified task (but differently on a standard task). In some cases, such an effect may be desired, but it depends on why the task is used and gamified.

Psychometric Properties of Gamified Tasks

Tasks may also be gamified with the goal of improving the psychometric properties of a task, such as validity (how well a task measures what it claims to measure) and reliability (how consistent the measurement obtained by the task is) [29]. There are also different types of evidence for reliability that must be considered when gamifying cognitive tasks. Internal consistency refers to the stability of the task data within an assessment; for example, the similarity of a participant's reaction time at the beginning of a task to their reaction time at the end of the task. Test-retest reliability refers to the stability of the task data over time; for example, how similar a participant's score on a task is at one time point compared with their score on the task a month later.

Typical cognitive tasks are boring, repetitive, and long partly because of the issue of reliability. From one trial to the next, people will perform quite differently, so multiple trials are needed to decrease measurement noise [30]. Adding game elements to a task may change the reliability of its measurement. Participants may be sufficiently engaged that their performance is more stable over time; for example, perhaps only 20 trials are needed for a reliable measure, instead of 200. Friehs et al [19] found that response variability in a gamified stop signal task was lower than that in the nongame version. Shorter tasks would require fewer resources to administer and would reduce the burden on participants, which would be particularly beneficial for clinical and pediatric populations.

Game elements also offer the ability to guide participants' performance. Most cognitive tasks use measures of reaction time and accuracy, which leads to classic speed-accuracy trade-offs—the faster a participant responds, the less accurate they will be, and vice versa. Individual participants also favor speed or accuracy differently than one another [30]. These behaviors can be manipulated through instructions (eg, asking participants to respond as quickly as possible). Game elements can also indirectly encourage participants to emphasize speed or accuracy, for example, by awarding points or feedback for faster or more accurate responses, generating more consistency across participants [30,31].

This Study

Overview

Few gamified cognitive tasks are subjected to rigorous examination of psychometric properties [16], despite their use in experimental and clinical settings. Parsons et al [32] noted that psychology lacks a standard practice of reporting the reliability of cognitive task measurements. This problem is exacerbated when tasks are adapted, such as gamification. Even small manipulations of cognitive tasks require extensive research to understand their effects [33].

In this study, we sought to research how game elements can affect the reliability of scores on a cognitive task, specifically the Stroop task. As a typical cognitive task that demonstrates robust experimental effects in the general population [34], the Stroop task is well suited for this research.

The Stroop Task

Building on the 1886 work by Cattell [1] with cognitive tasks, in 1935, Stroop [2] conducted an experiment in which he asked participants to either name the colors of colored rectangles or name the colors of mismatched words (eg, the word "blue" printed in red ink). Participants responded much more slowly when naming incongruent colored words, a paradigm we now call the Stroop effect [2].

Since Stroop's first experiment and subsequent development of the experimental protocol [35-37], the Stroop task has become one of the most widely used tasks in both cognitive and clinical psychology [34,38]. Recently, the Stroop task has been gamified for experimental and clinical applications. For example, Groening and Binnewies [39] used the Stroop task to investigate the effects of game elements on participants' motivation and performance. They found that when points and story elements were added to the task, participants were more persistent (they engaged with the task for longer before switching to a new task) and reported higher motivation. Gomez-Tello et al [40] used gamified tasks as part of a battery of tests for neuropsychological screening of children and found evidence of the Stroop effect in a gamified version of the task. However, previous studies have not considered the reliability of the Stroop effect in a gamified task, either in terms of internal consistency or test-retest reliability. Thus, we have little guidance when gamified tasks can or should not be used in assessments.

We created 2 versions of the Stroop task, with and without game elements, and tested each task with participants at 2 time points. In this paper, we report on the reliability of the gamified Stroop task in terms of internal consistency and test-retest reliability, compared with the control task. We also compared the reliability of these scores on a trial-by-trial basis. Our objective was to demonstrate how game elements can affect the reliability of scores on a Stroop task.

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Methods

Ethical Considerations

This research project was approved on ethical grounds by the University of Saskatchewan Research Ethics Board (BEH 17-418). The participants were given GBP £6 (USD $8.3 at time of study) compensation at each time point.

Tasks

The control task was designed using the basic computerized Stroop task described by Macleod [34] and Hedge et al [41] as models. Participants were shown words in the middle of their screen in various colors (red, blue, green, or yellow). The word could be the same as the font color (congruent condition), a noncolor word (lot, ship, cross, or advice; neutral condition), or a nonmatching color word (eg, the word "blue" shown in green; incongruent condition). After each word, participants were asked to press a key corresponding to the font color (z-key for red, x-key for blue, n-key for green, and m-key for yellow). The participants first completed a training exercise to learn each keymap. The task consisted of 240 trials in each condition (congruent, neutral, and incongruent) for a total of 720 trials.

The gamified version was designed to increase reliability by manipulating the speed-accuracy trade-off [30] and improving engagement through game elements. On the basis of prior research, which demonstrated increased enjoyment from points and decreased enjoyment from themes added to a gamified task [20], we focused on adding points-based game elements to the Stroop task. Points-based elements also target extrinsic motivation (rather than intrinsic motivation), which may be more effective in influencing participant performance [24]. We followed the feedback category of the Gameful Design Heuristics from Tondello et al [42], which states that the system should offer users clear and immediate feedback, actionable feedback, and graspable progress.

Using feedback also allowed us to manipulate the speed-accuracy trade-off by preferentially awarding points for faster (but still correct) answers. In the game version of our task, participants saw their response time for each trial and whether they answered correctly. A record of the fastest response time was also displayed at the corner of the screen. They lost 5 points for any incorrect answer, gained 5 points for any correct answer, and were rewarded with a bonus of 25 points for responses that broke their previous "fastest time" record. A progress bar at the bottom of the screen tracked the points (Figure 1).

Figure 1. Game version of the task after a correct response was entered.

Participants

Participants were recruited through Prolific, a web-based platform for recruiting research participants. Web-based platforms are commonly used in human-computer interaction research to conduct studies [43] and have been shown to yield reliable data when precautionary methods for data gathering and analysis are used [44,45]. Each participant completed either the control task or the gamified task at 2 time points, 3 weeks apart (time 1 and time 2). The participants signed a consent form, were given instructions and training for the task, and then completed the task. After completion, they answered questionnaires collecting demographic information, including information about their experience with the task (Intrinsic Motivation Inventory [46]), their general gaming behavior, and self-reported attentional control (Attentional Control Scale [47]).

The study design was between-subjects, with half the participants completing the control version of the task and the other half completing the points version. The participants were randomly assigned to a condition. The study took approximately 40 minutes to complete.

Our analyses were based on the methods of Parsons et al [32] and Hedge et al [41]. Both studies used the same data sets, which had data from 47 (study 1) and 56 (study 2) participants for the Stroop task. In these studies, this sample size was sufficient to

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observe effects with medium effect sizes. Thus, based on these prior studies, we aimed to obtain approximately 50 participants for each condition [48].

We only analyzed data from participants who had completed both sessions. We also set quality thresholds and removed participants who did not meet them at either time point. Finally, we also removed outlying data points, such as individual trials that were much slower than the average for each participant, to reduce noise in the data, as the study was web-based, and we could not otherwise account for participant distraction from the tasks.

Statistical Analysis

Reaction Time and Error Rate Data

We conducted 2-way ANOVAs with task type (basic or game) and trial condition (congruent, neutral, or incongruent) for reaction time and error rate data. We used 1-way ANOVAs to compare the effect of task type on the skewness and kurtosis of the distribution of reaction time data for each participant. In addition, we conducted 3-way repeated measures ANOVAs (task type × trial type × time) for reaction time cost and error rate cost data. We also created groups representing low and high attentional control based on the median of 51.0 of our participants and then conducted 3-way repeated measures ANOVAs (task type × attention × time) for reaction time cost and error rate cost data.

Internal Consistency and Test-Retest Reliability

For measuring and reporting reliability, our analysis followed the recommendations from Parsons et al [32]. To evaluate internal consistency, we used a permutation approach, which involves repeatedly randomly splitting the data, calculating the reliability estimate, and then averaging all estimates. This approach provides a more stable estimate, independent of how trial stimuli and conditions are presented [32]. To evaluate test-retest reliability, we calculated the Pearson correlation between each time point. We also used intraclass correlation coefficients (ICCs) to indicate the degree of consistency and agreement between each time point. On the basis of Parson recommendations, we used ICCs labelled ICC(3,1) and ICC(2,1), as described by Shrout and Fleiss [49]. Finally, we plotted the test-retest reliability as the number of trials increased. To achieve this, we followed the method used by Hedge et al [41].

Results

Participants

For the first round of data collection (time 1), we received 135 responses, followed by 78 responses for time 2.

All participants met the criteria for questionnaire speed of completion (participants needed to spend an average of 1.5 seconds per item) and variance (participants needed to show some variance across items). In total, 13 participants were excluded because they too frequently provided an incorrect response on the Stroop task (total incorrect responses>1 SD above the mean number of incorrect responses) and because they responded to trials too slowly (mean reaction time>3 SD above the group mean reaction time). Before calculating the group mean reaction time, we also removed any individual trials that were slower than the average for each participant (reaction time>3 SD above the individual mean reaction time), as well as any remaining outlier trials that were slower than 2000 milliseconds. At time 1, we removed 1667 trials (out of 50,400). At time 2, we removed 1976 trials (out of 49,680). Notably, both at time 1 and time 2, significantly fewer trials needed to be removed from the game condition compared with the basic version; 38.6% of the removed trials were in the game condition at time 1, and 32.9% were in the game condition at time 2.

After exclusions, 65 participants remained (50 female, 13 male, 1 nonbinary, and 1 prefer not to disclose; mean age 23.91, SD 4.64 years), with 31 participants in the basic task condition and 34 participants in the game condition. Our sample had a high proportion of women because of the web-based platform we used [50]. The participants had a mean score of 51.8 (SD 7.54) on the Attentional Control Scale.

Intrinsic Motivation Inventory

At both time points, the basic task and game conditions showed no significant differences for any of the Intrinsic Motivation Inventory subscales (interest, competence, effort, and pressure).

Reaction Time and Error Rate Data

We averaged the reaction times and error rates across participants and then analyzed each measure by task type and trial condition at each time point. We also calculated reaction time and error rate costs (mean incongruent trials and mean congruent trials). Table 1 presents the descriptive statistics for each measure.

Histograms of reaction time for all participants are presented in Figure 2 by task type and time point. One-way ANOVAs revealed no significant effects of task type on the skewness and kurtosis of the distribution of reaction time data for each participant (Table 2).

The 2-way ANOVAs for reaction time and error rate demonstrated evidence of the Stroop effect at both time points (significant differences between incongruent trials and both congruent and neutral trials). Furthermore, congruence sequence effect analysis revealed the expected adaptive control effect but no effect of task condition, time, or an interaction between the 2 emerged. There were also significant differences between task conditions at time 1: participants in the game condition had faster reaction times and lower error rates than those in the basic task condition. There were no significant differences at time 2 (Tables 3 and 4).

Two-way repeated measures ANOVAs (task type × time) for reaction time cost and error rate cost data showed no significant interaction effects (Table 5). The 3-way repeated measures ANOVAs (task type × trial condition × time) for reaction time and error rate data showed no significant interaction effects (Table 5). On the basis of grouping our participants into low and high attentional control categories, we found a significant 3-way interaction between time, task type, and attention category for the error rate (Table 5). Participants who scored low in attentional control and were in the basic task condition had a

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lower error rate cost at time 1 than at time 2. In the game condition, participants who scored low on attentional control had a higher error rate cost at time 1 than at time 2. The error rate cost for participants who scored high on attentional control showed an opposite pattern. There were no significant simple 2-way interactions between task type and attention category at either time point.

Table 1. Descriptive statistics for reaction time and error rates, at times 1 and 2 for each task type.

	Time 1, mean (SD)	Time 2, mean (SD)
Basic task		
Congruent reaction time (milliseconds)	678 (103)	659 (104)
Neutral reaction time (milliseconds)	671 (94.0)	656 (94.7)
Incongruent reaction time (milliseconds)	796 (124)	758 (118)
Reaction time cost (milliseconds)	118 (50.9)	98.8 (39.8)
Congruent correct (%)	96.0 (2.86)	96.1 (2.52)
Neutral correct (%)	96.7 (2.33)	96.8 (2.43)
Incongruent correct (%)	93.1 (5.46)	93.6 (4.36)
Error rate cost (%)	2.86 (4.53)	2.55 (3.23)
Game task		
Congruent reaction time (milliseconds)	638 (94.5)	645 (95.3)
Neutral reaction time (milliseconds)	628 (84.1)	631 (79.1)
Incongruent reaction time (milliseconds)	753 (112)	730 (103)
Reaction time cost (milliseconds)	115 (48.8)	85.3 (42.3)
Congruent correct (%)	94.6 (3.70)	95.5 (2.50)
Neutral correct (%)	96.0 (2.53)	96.0 (2.79)
Incongruent correct (%)	92.1 (3.90)	93.0 (4.80)
Error rate cost (%)	2.52 (4.71)	2.53 (4.18)

Figure 2. Histograms of reaction time by time point and task type for each type of trial condition.

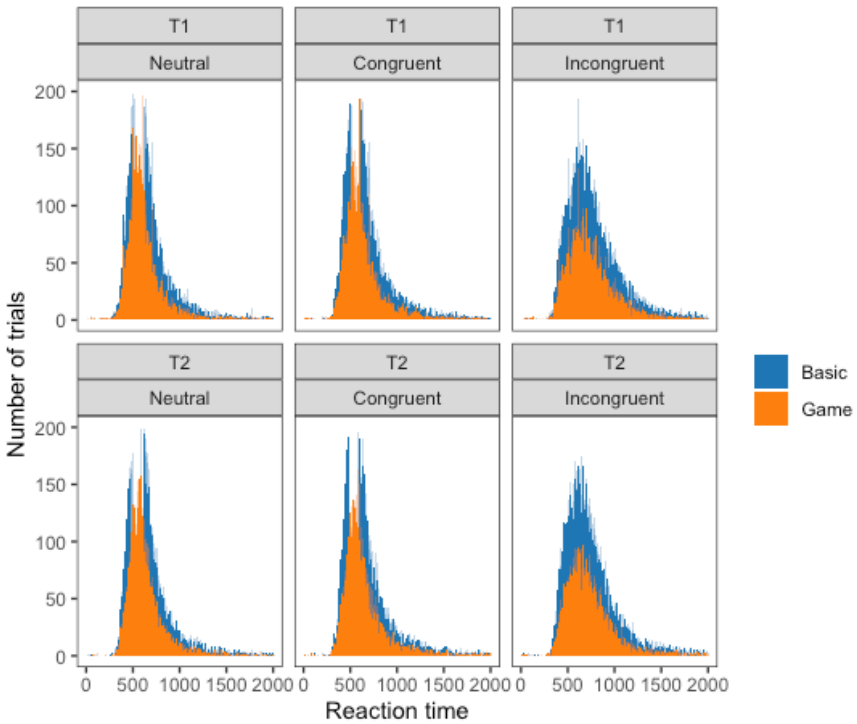

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Table 2. ANOVA summary table for reaction time distribution.

	Mean squares	*F* test (*df*)	*P* values	Effect size
Time 1				
Skewness	0.316	1.863 (1)	.18	0.029
Kurtosis	0.003	0.001 (1)	.98	0.000
Time 2				
Skewness	0.317	1.852 (1)	.18	0.029
Kurtosis	1.159	0.358 (1)	.55	0.006

Table 3. ANOVA summary table for reaction time.

	Mean squares	*F* test (*df*)	*P* value	Effect size
Time 1				
Task type	85,185.015	8.107 (1)	.005	0.041
Condition	317,396.780	30.205 (3)	<.001	0.242
Task type × condition	49.167	0.005 (2)	.10	0.000
Time 2				
Task type	23,700.032	2.402 (1)	.12	0.013
Condition	201,201.515	20.394 (2)	<.001	0.178
Task type × condition	788.555	0.080 (2)	.92	0.001

Table 4. ANOVA summary table for error rate.

	Mean squares	*F* test (*df*)	*P* value	Effect size
Time 1				
Task type	0.005	4.012 (1)	.05	0.021
Condition	0.024	18.301 (2)	<.001	0.162
Task type × condition	0.000	0.148 (2)	.86	0.002
Time 2				
Task type	0.002	1.945 (1)	.17	0.010
Condition	0.018	15.402 (2)	<.001	0.140
Task type × condition	0.010	0.022 (2)	.98	0.000

Table 5. Repeated measures ANOVA summary table for reaction time and error rate.

	Mean squares	*F* test (*df*)	*P* value	Effect size
Reaction time cost				
Task type × time	880.934	1.105 (1)	.30	.017
Reaction time				
Trial type × task type × time[a]	317.106	0.616 (2)	.49	0.010
Attention × task type × time	1325.711	1.665 (1)	.20	0.012
Error rate cost				
Task type × time	<0.001	0.106 (1)	.75	0.002
Error rate				
Trial type × task type × time	0.000	0.615 (2)	.54	0.010
Attention × task type × time	39.218	5.493 (1)	.02	0.083

[a]Owing to the interaction violates the assumption of sphericity (*P*<.001), *P* values are derived using the Greenhouse-Geisser statistic.

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Internal Consistency

Overview

We estimated the internal consistency of the basic task by using a permutation-based split-half approach [32] with 5000 random splits. Internal consistency ranged between 0 and 1, with higher numbers representing more consistency across an individual's complete set of trials.

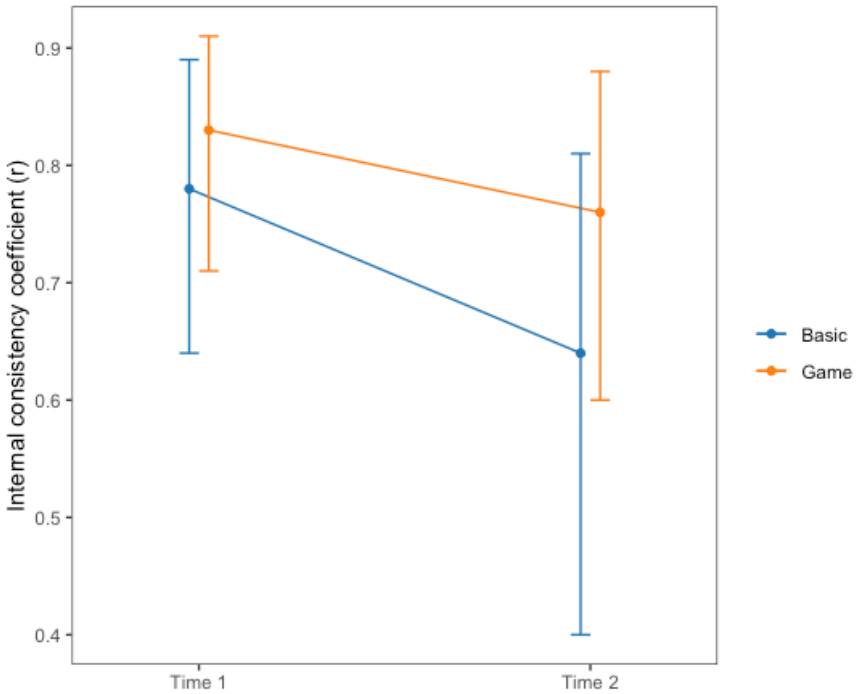
Reaction Time

When using the reaction time cost, the (Spearman-Brown corrected) split-half internal consistency for the basic task at time 1 was $r_{\text{Spearman-Brown}}$=0.78, 95% CI 0.64-0.89. At time 2, $r_{\text{Spearman-Brown}}$=0.64, 95% CI 0.40-0.81.

For the game condition at time 1, the split-half internal consistency was $r_{\text{Spearman-Brown}}$=0.83, 95% CI 0.71-0.91. At time 2, $r_{\text{Spearman-Brown}}$=0.76, 95% CI 0.60-0.88.

The internal consistency values were higher at both time 1 and time 2 for the game condition (Figure 3); however, converting the correlations to Fisher *z* scores indicated no significant differences between groups at each time point.

Figure 3. Internal consistency of reaction time cost for each time point and task type.



Error Rate

When using error rate cost, the (Spearman-Brown corrected) split-half internal consistency for the basic task at time 1 was $r_{\text{Spearman-Brown}}$=0.79, 95% CI 0.66-0.89. At time 2, $r_{\text{Spearman-Brown}}$=0.6, 95% CI 0.34-0.79.

For the game condition at time 1, the split-half internal consistency was $r_{\text{Spearman-Brown}}$=0.76, 95% CI 0.62-0.87. At time 2, $r_{\text{Spearman-Brown}}$=0.74, 95% CI 0.58,0.86.

The internal consistency values were higher at time 2 for the game condition at time 2 (Figure 4); however, similar to the reaction time data, converting the correlations to Fisher *z* scores indicated no significant differences between groups at each time point.

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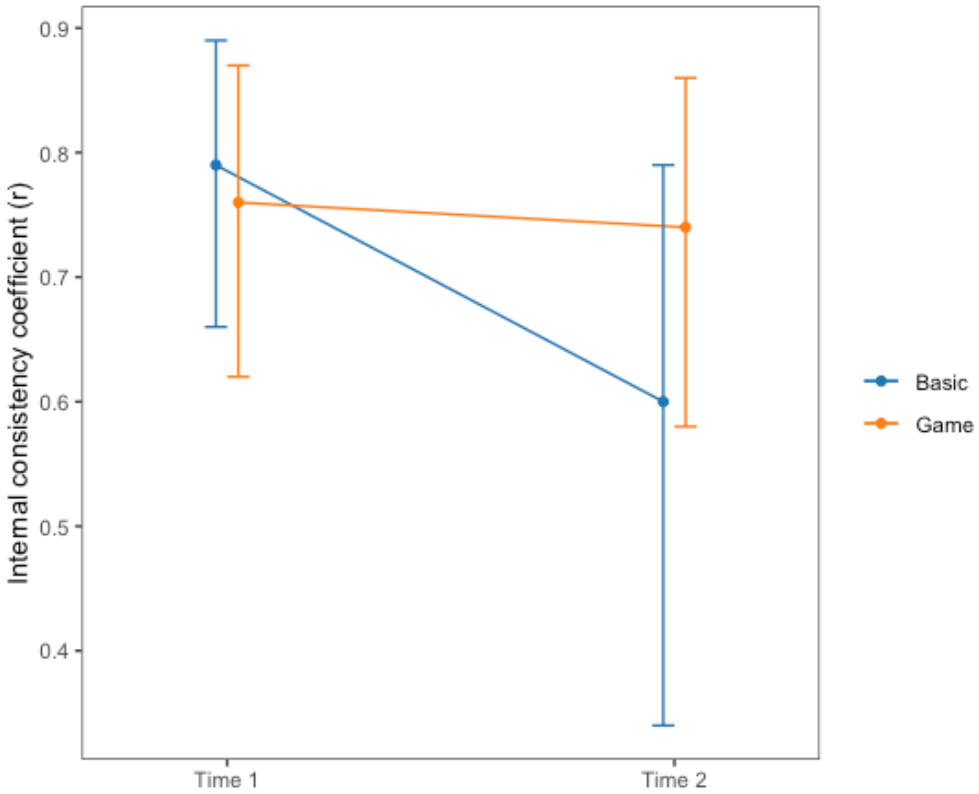
Figure 4. Internal consistency of error rate cost for each time point and task type.



Test-Retest Reliability

Reaction Time

Using reaction time cost data, for the basic task, the Pearson correlation between each time point indicated a test-retest reliability of 0.68, 95% CI 0.43-0.84. This correlation was significant (t_{29}=5.04; P<.001). For the game condition, we found a test-retest reliability of 0.58, 95% CI 0.31-0.77. This correlation was also significant (t_{32}=4.07; P<.001).

We also estimated the test-retest reliability between time 1 and time 2 with ICCs using the *psych* package in R (R Foundation for Statistical Computing) [51]. ICCs were used to measure the reliability of a measure between 2 time points. The ICC value can range from 0 to 1, with higher values indicating higher reliability. We report the results of 2-way mixed-effects models for absolute agreement, ICC(2,1), and consistency, ICC(3,1).

Using reaction time cost data, for the basic task, the estimated agreement was 0.61, 95% CI 0.36-0.78, and the estimated consistency was 0.66, 95% CI 0.46-0.80. For the game condition, the estimated agreement was 0.48, 95% CI 0.16-0.69, and the estimated consistency was 0.58, 95% CI 0.35-0.74.

Typically, cognitive tasks require many trials to reduce measurement noise. We plotted how ICC(3,1) changes as the number of trials increases, to see if a more stable estimate could be determined with fewer trials when using game elements. Figure 5 shows how the reliability of the Stroop effect (reaction time cost) changes with an increasing number of trials.

To investigate why the game condition shows lower test-retest reliability, we also plotted how the reliability of reaction time changes over time for each trial type (neutral, congruent, and incongruent trials; Figure 6). Comparing the plots suggests that the game condition reaches a higher level of consistency sooner for incongruent trials, compared with both neutral and congruent conditions. The basic task showed similar patterns of consistency across all trial types.

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Figure 5. Test-retest reliability of reaction time cost as the number of trials increases for each task type.

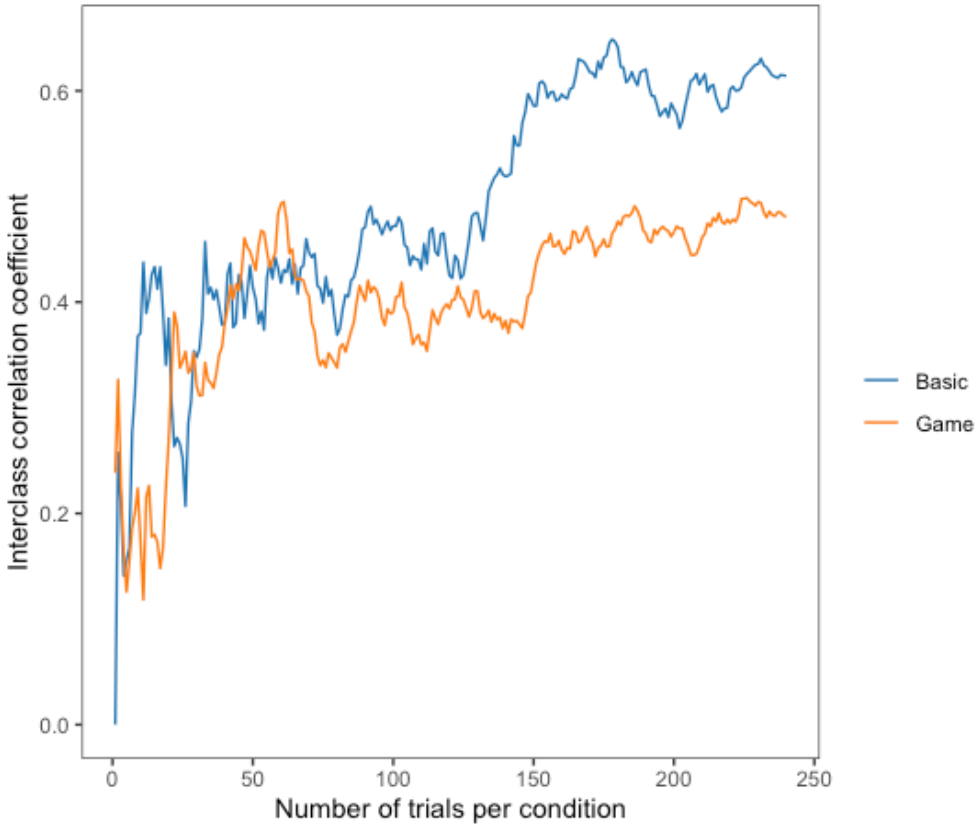
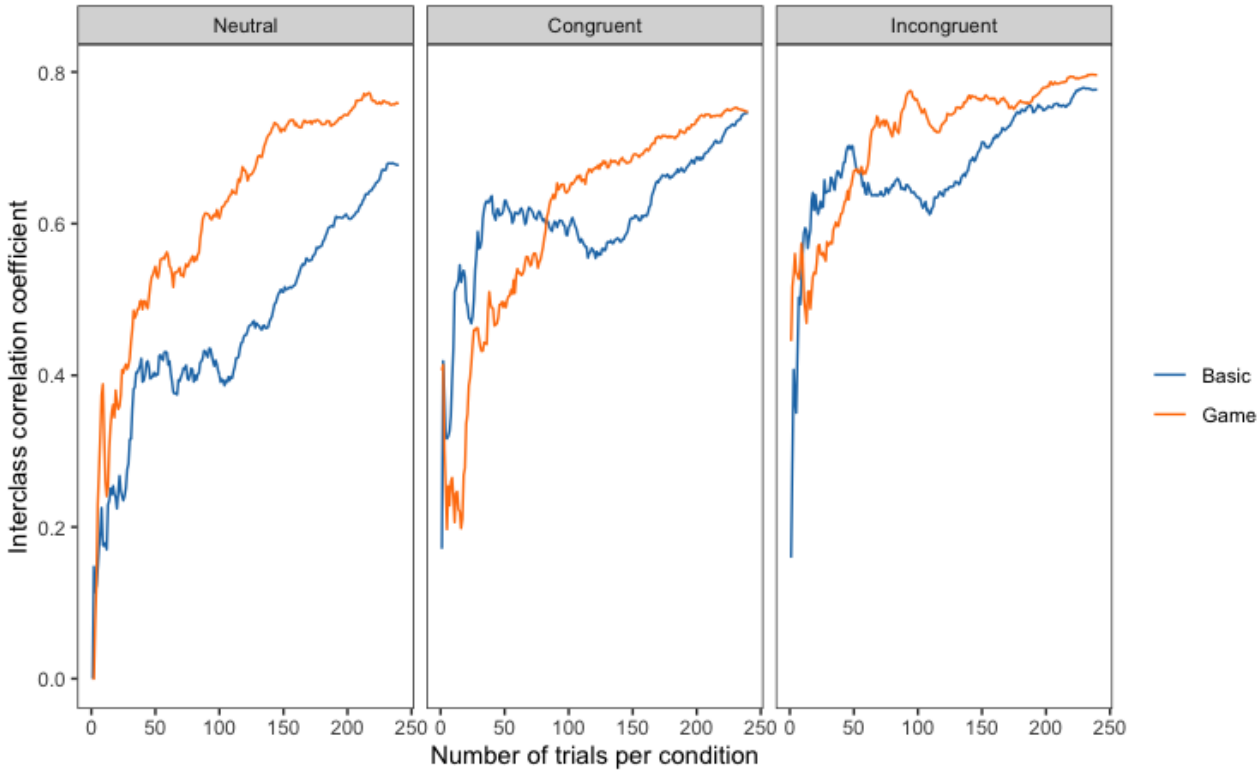


Figure 6. Test-retest reliability of reaction time as the number of trials increases for each trial type and task type.



Error Rate

Using error rate cost data, for the basic task, the Pearson correlation between each time point indicated a test-retest reliability of 0.55, 95% CI 0.24-0.76. This correlation was significant (t_{29}=3.56; P=.001). For the game condition, we found a test-retest reliability of 0.62, 95% CI 0.35-0.79. This correlation was also significant (t_{32}=4.45; P<.001).

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Using error rate cost data, for the basic task, ICC(2,1) (estimated agreement) was 0.53, 95% CI 0.28-0.71, and ICC(3,1) (estimated consistency) was 0.53, 95% CI 0.28-0.71. For the game condition, ICC(2,1) was 0.62, 95% CI 0.42-0.77, and ICC(3,1) was 0.62, 95% CI 0.41-0.77.

We plotted how ICC(3,1) changes as the number of trials increases, to determine whether a more stable estimate could be determined with fewer trials when using game elements. Figure 7 shows how the reliability of the Stroop effect using the error rate cost changes with an increasing number of trials.

Similar to the reaction time, we plotted how the reliability of the number of errors changes over time for each trial type (neutral, congruent, and incongruent trials; Figure 8). The basic task showed similar patterns of consistency across all the trial types, whereas in the game condition, only the neutral and congruent conditions were similar—the reliability of the incongruent trials continued to increase over time.

Figure 7. Test-retest reliability of error rate cost as the number of trials increases, for each task type.

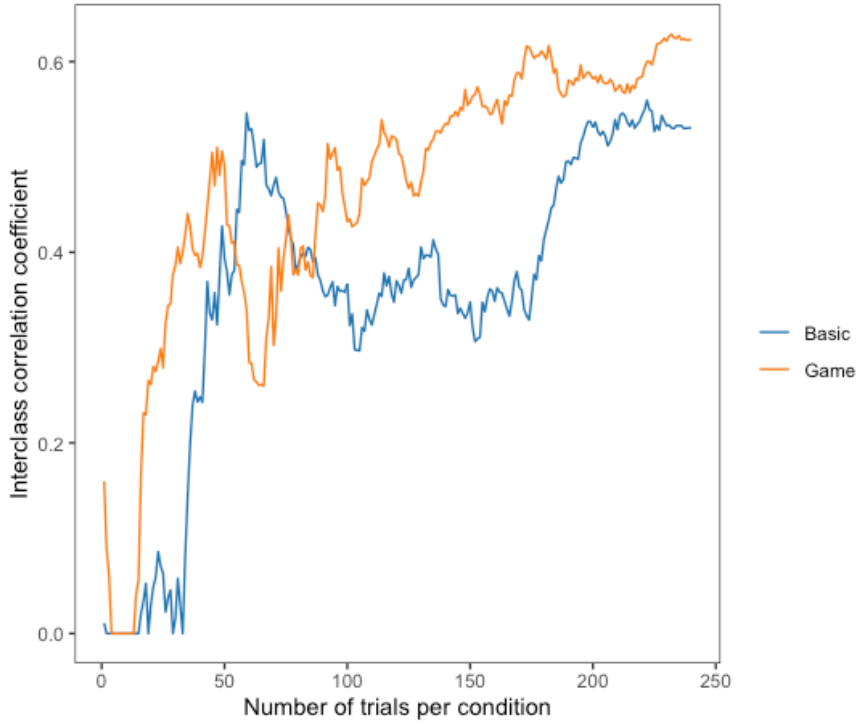
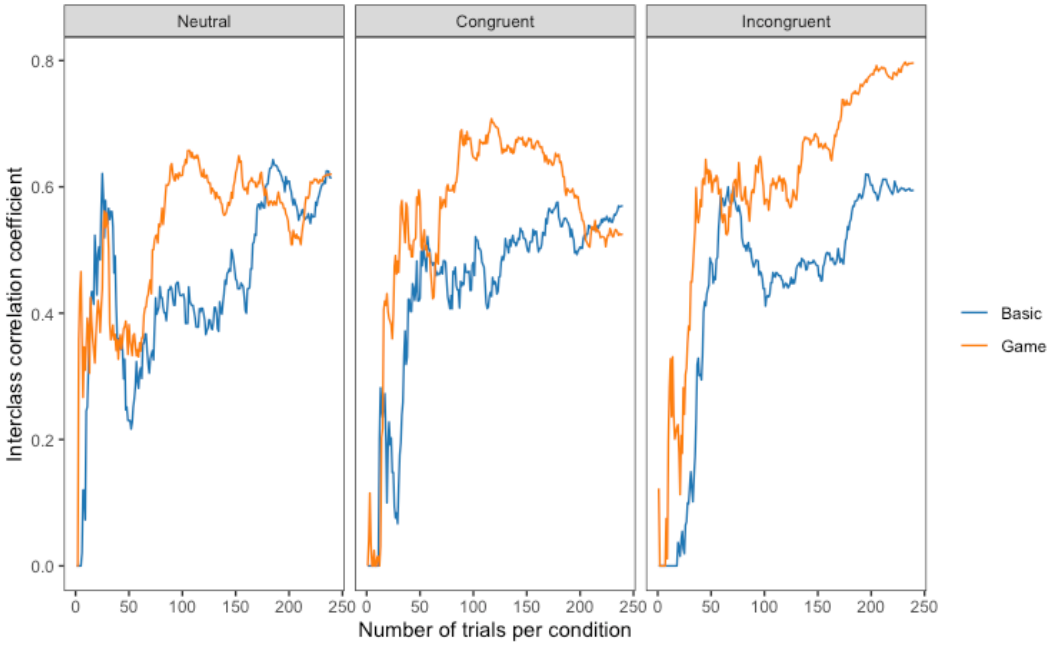


Figure 8. Test-retest reliability of error rate as the number of trials increases for each trial type and task type.



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Discussion

Summary and Explanation of Findings

Performance

Both versions of the task demonstrated the Stroop effect, meaning that the effect is robust to the addition of certain game elements. Gamification can affect the validity of cognitive tasks; for example, adding graphics (especially those that change the stimuli participants respond to) can worsen performance compared with a control task [8,12,21]. In this study, in the game condition, reaction times and a progress bar were perpetually displayed on the screen. Graphics indicating gained or lost points also appeared between stimuli. These elements did not interfere with the validity of the Stroop task.

There were no significant differences in performance-based measures between the basic task and game conditions, with one exception: Participants in the game condition had significantly faster reaction times and lower error rates than those in the basic task condition but only at time 1. There may be several reasons for these results.

Points that function as extrinsic motivators have been shown to improve performance in cognitive tasks [25]; however, this effect may be short lived. Nicholson [15] noted that reward-based game elements can drive immediate spikes in engagement but only as long as continuous rewards are provided. In our game condition, participants were continually awarded points for accurate responses; however, for reaction time, they were only awarded bonus points for responses that broke their previous “fastest time” record. There is a physical limitation on how quickly participants can react to stimuli—once that threshold is met, it will be near impossible to improve further, and the motivating influence of the bonus points may be diminished.

In the game condition, participants may also learn faster and reach their “peak performance” sooner. Participants were quickly incentivized to put forth their best effort. This effect may be particularly pronounced when the cognitive demands of the task are higher. When we plotted the reliability of reaction time and error rate as the number of trials increased, the incongruent trials showed an improved pattern of consistency only in the game condition. Specifically, after approximately 50 to 100 trials, the reaction time remained consistent in the game, whereas there was a significant variation in the basic version, with a noticeable drop after 50 trials. A similar pattern was observed for the error rates. For the basic task, the plots of all 3 trial types showed similar patterns across both performance measures. This is especially noteworthy because incongruent trials are arguably the most important trials in the Stroop task, as they are the trials wherein cognitive conflict needs to be resolved. Improved performance in the incongruent trials also explains why the reliability of the Stroop effect (reaction time cost) appeared lower in the game condition—participants in that condition performed better and more consistently in the incongruent trials.

The differences between the basic task and game conditions may be emphasized by incongruent trials because they are more cognitively demanding than the congruent and neutral trials. Evidence suggests that game elements can differentially affect cognition depending on how participants experience the demands of the task. For example, gamification can normalize the performance of participants with ADHD [28].

Another indication of improved performance consistency comes in the form of a significantly smaller number of outlier trials that need to be removed from the game condition compared to the basic version. Approximately twice the number of far-out outlier trials were removed from the basic task. These trials were not considered valuable data and were essentially lost time for both the researcher and the participant. By reducing the number of trials that needed to be removed from performance, the time investment for participants was reduced. Furthermore, this means that the previous results are a conservative estimate of the game’s reliability advantage because the most egregious outliers were already removed from the analysis.

Enjoyment

There were also no differences in the self-reported measures of motivation between the basic task and game conditions. These results align with those of other studies, which found that achievement-based game elements are only effective in promoting performance and not motivation [24,25].

Levy et al [23] note how carefully games must be designed to appropriately function as scientific tools and highlight the importance of using the research and data collection goals to inform the choice of game design. For this study, we specifically chose game elements that we thought would influence performance rather than enjoyment. Gamified tasks may be more successful if the game elements are just “good enough” to achieve the goals of the study without interfering with the validity of the task [23]. Because we wanted to improve participant performance irrespective of enjoyment, we did not add extraneous game elements, even if those elements would have made the game more fun.

Limitations and Future Work

One limitation of our study is the small sample size. The 2 task conditions were designed with subtle differences in the form of points and feedback. While this design was intentional, we also had a relatively small sample size, which may not have been powerful enough to reveal the small effects of our slight manipulation. We recruited 135 participants for time 1 with the intent of having at least 50 participants per condition. However, only 78 participants returned at time 2. It was difficult to incentivize participants to return to a web-based study. Future studies may find significant effects with a larger sample size.

Another limitation is that our sample was heavily skewed toward young adult female participants. We recruited participants through a web-based platform called Prolific. At the time of our study, a young woman made a video describing her hustle as a participant on the platform. Her video went viral on TikTok, resulting in an influx of new signups to Prolific, most of whom were, similar to the creator, female adults in their 20s [50]. However, given the fundamental nature of this research, this sampling bias is unlikely to have influenced the results.

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The addition of points and feedback is one simple approach to gamification. Other game elements may produce different results. As discussed, we had theoretical and practical reasons for using points, but even within the category of points and achievement-based game elements, we could have made different design and mechanical choices. For example, adding a leaderboard system may have influenced participant behavior because of increased competition. Mekler et al [25] found that for an image annotation task, participants in the point condition significantly outperformed those in a control condition, where no game elements were used. However, participants in the points condition were, in turn, significantly outperformed by those in conditions where leaderboards and levels were used.

Future studies should investigate other game elements. Other cognitive tasks could also be investigated to determine how game elements affect reliability across task types that target different cognitive domains. Our same methods for investigating reliability could be applied to any gamified task.

Implications

In this study, we show that the Stroop effect is robust to the addition of simple points-based game elements. Adding points to a Stroop task does initially increase participant reaction time, but this gamification may be most effective in the short term. Our results also suggest that game elements may differently influence *parts* of a cognitive task, such as the more cognitively demanding incongruent trials.

We also provide an example of reporting psychometric data for a gamified task. Despite a long history of cognitive task gamification, the field lacks standard practices regarding how these tasks are made and measured [16]. Any advancement in how these tasks are designed and used requires a stronger base of knowledge on how individual game elements affect cognitive behavioral measures [25,32]. One of the most cited reasons for gamifying tasks is to address the limitations of standard neuropsychological testing [16]; however, these games will never be acceptable replacements for traditional tests if they are not subjected to the same rigorous standards of reliability and validity.

The results of this study suggest a potential advantage of using game-like tasks to assess cognitive functioning, especially for difficult-to-reach populations or individuals who cannot be subjected to prolonged testing. For example, gamified tasks have been shown to provide a more engaging environment that creates a more captivating setting that may aid in collecting data from populations with a lower attention span, such as children or groups of patients with concentration or attention deficits [52].

Our results suggest that the game condition may provide faster onboarding to true performance and improved consistency, as demonstrated descriptively through the lower proportion of outlier trials removed, the reaction time distributions, the split-half internal consistency values for reaction time and error rate, and reaction time cost by trial number charts. This faster onboarding is also supported by the significantly faster reaction times and lower error rates in the game condition at time 1. However, these trends do not result in significant performance differences between the basic task and game conditions in analyses of reaction time cost and also do not influence test-retest reliabilities, suggesting that the game elements we included neither significantly improved nor compromised performance in a gamified Stroop task.

Acknowledgments

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Data Availability

The data sets generated and analyzed in this study are available from the corresponding author upon reasonable request.

Authors' Contributions

KW and RLM conceptualized the study and developed the methodology. KW and PB developed the tasks and administered the projects. KW curated the data. KW, MAF, and RLM performed analyses and interpreted the study findings. KW wrote the original draft of the manuscript, and all authors reviewed and edited the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
ICC: intraclass correlation coefficient

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Smartphone-Based Virtual and Augmented Reality Implicit Association Training (VARIAT) for Reducing Implicit Biases Toward Patients Among Health Care Providers: App Development and Pilot Testing

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Abstract

Background: Implicit bias is as prevalent among health care professionals as among the wider population and is significantly associated with lower health care quality.

Objective: The study goal was to develop and evaluate the preliminary efficacy of an innovative mobile app, VARIAT (Virtual and Augmented Reality Implicit Association Training), to reduce implicit biases among Medicaid providers.

Methods: An interdisciplinary team developed 2 interactive case-based training modules for Medicaid providers focused on implicit bias related to race and socioeconomic status (SES) and sexual orientation and gender identity (SOGI), respectively. The simulations combine experiential learning, facilitated debriefing, and game-based educational strategies. Medicaid providers (n=18) participated in this pilot study. Outcomes were measured on 3 domains: training reactions, affective knowledge, and skill-based knowledge related to implicit biases in race/SES or SOGI.

Results: Participants reported high relevance of training to their job for both the race/SES module (mean score 4.75, SD 0.45) and SOGI module (mean score 4.67, SD 0.50). Significant improvement in skill-based knowledge for minimizing health disparities for lesbian, gay, bisexual, transgender, and queer patients was found after training (Cohen d=0.72; 95% CI −1.38 to −0.04).

Conclusions: This study developed an innovative smartphone-based implicit bias training program for Medicaid providers and conducted a pilot evaluation on the user experience and preliminary efficacy. Preliminary evidence showed positive satisfaction and preliminary efficacy of the intervention.

(JMIR Serious Games 2024;12:e51310) doi:10.2196/51310

KEYWORDS

implicit bias; health care; Medicaid; virtual reality; augmented reality; smartphone; mHealth; mobile app; innovative; implicit bias training program; sexual orientation; sexual orientations; gender identity; gender identities; gender preferences; gender preference; efficacy; health care providers; health care provider; socioeconomic; mobile application; training; XR; extended reality

Introduction

Implicit Bias in Health Care Settings

Defined as unconscious associations or negative evaluations of a person or group of people on the basis of nonrelevant characteristics [1], implicit biases have been found to be prevalent among the general population against “marginalized’ groups such as those from minority racial, ethnic, or socioeconomic backgrounds [2]. Implicit biases, which present in health care settings as irrational and unconscious perceptions, stereotypes, or prejudices among health care providers when interacting with patients, are especially concerning [3]. Past research has found that implicit bias in health care settings is associated with a decrease in overall quality of care, with

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impacts including increased risk of misdiagnosis [4-7], inaccurate patient pain perception [8,9], differential treatment recommendations for patients who belong to sexual orientation or gender identity minority groups [10-12], and negative perceptions of patients from racial minority backgrounds [13-17]. Implicit biases may also exist during interactions between health care professionals, such as selection bias when choosing candidates for future health care practitioner residency [18], which may have wider implications for the quality and safety of patient care. Furthermore, such implicit biases have been found within adult and pediatric health care settings [19] across medical conditions including ADHD, asthma, cardiology, and child abuse, which could affect quality of care for these vulnerable populations [20-22].

Existing Efforts to Reduce Implicit Bias in Health Care Settings

In response, increasing efforts have been devoted to addressing the significant threat posed by implicit bias toward health care services and patient outcomes. The first type of interventional efforts focus on "environmental engineering," with the goal to minimize mechanisms in health care settings that may give rise to biased interactions between health care professionals and patients. One example of this type of intervention is the development and implementation of automatic patient care prompts through electronic portals, where computer algorithms are standardized for all patients regardless of sociodemographic backgrounds, attempting to reduce opportunities for human interference (beyond the algorithm development phase) [23]. A second type of intervention uses cognitive rehearsal to walk practitioners through potentially harmful scenarios to practice their ideal response; this has shown promise at changing health care practitioner behavior to reduce bullying and workplace turnover [24,25]. While not widely used in combatting health care bias explicitly, the methodology shows a clear avenue for its application to bias training.

A third type of intervention, which will also be the focus of this study, attempts to develop educational programs with the goal of improving knowledge and awareness of implicit bias among medical students or health care professionals, which can range from traditional educational seminars to experience-oriented storytelling, to highlight the importance of patient perspectives in daily practice [26-28]. Such efforts have so far yielded positive results where health care professionals were found to become more aware of their own biases and have resulted in improved communication between health care professionals and marginalized patient groups [29,30].

Application of Augmented Reality–Based Medical Training

Despite the promising results from educational programs in the existing literature, one limitation in existing approaches for implicit bias training is the lack of immersive learning experiences that may provide optimal learning outcomes and behavior changes. As a cutting-edge technology that prioritizes experiential learning, virtual reality (VR) and augmented reality (AR) could provide an ideal solution with immersive learning experiences for implicit bias training. For example, one recent study examined biases during interactions between virtual health care providers and virtual patients for medical triage training. Regardless of the skin tone of the avatar (ie, the health care provider), it took participants more time to initiate assistance and they were more likely to make errors when triaging dark-skinned virtual patients compared to light-skinned virtual patients [31].

AR, as a more recent member of the x-reality technologies, is posed to offer an even better learning experience that combines the immersion provided by VR and tailored customization that adapts to users' dynamic environments. Adoption of AR in medical education has been found in a wide range of medical branches from surgery (eg, laparoscopic procedure training) to anatomy [32]. Furthermore, because AR-based training is readily available on consumer-grade mobile devices such as smartphones and tablets, its mobility provides medical professionals with remote accessibility to training content regardless of their physical location (this advantage has been further acknowledged during the COVID-19 pandemic) [33]. However, despite the increasing adoption of AR in medical training, a recent systematic review has found little evidence on the availability of AR-based implicit bias training among health care professionals in the literature [33].

This Study

To address this important gap, this study aimed to develop a mobile training program, VARIAT (Virtual and Augmented Reality Implicit Association Training), specifically for improving the awareness of implicit biases among health care providers when interacting with patients in daily practice. The design considerations for developing this novel AR-based implicit bias training program are described, followed by a preliminary examination of initial user feasibility and learning outcomes, including user reactions; relevance to practice; and changes in knowledge, attitudes, and behavioral skills related to implicit bias before and after receiving the training program.

Methods

Designing the VARIAT Program

Overview of Technical Design Considerations

The VARIAT program focused on delivering an immersive, interactive learning experience to the broadest possible audience in self-contained segments, allowing users to complete the training over time and a variety of sessions while retaining their progress across sessions. When building the 3D worlds for delivery on the broadest number and sizes of mobile devices, simplified, realistic, and familiar spaces were built, including offices, lobbies, and examination rooms where the learner could experience the simulations. Characters in the world were designed with exaggerated cartoon features to provide visual distinction with skin tone, hair, size, outfits, and accessories, while minimizing unnecessary details and maximizing ease of recognition for interaction on mobile-sized screens. The approach to world design addressed design and performance considerations, allowing production of additional characters and scenarios without significant technical overhead in either the creation process or the learner's experience on their device. The dialogue and training content was presented via text.

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Hardware Requirements and Considerations

One key goal of the VARIAT program was the need to maximize audience reach and minimize specialty equipment for learners to access the content. At the time of its development, most iPhones and Android devices had the cameras, accelerometers, and gyroscopes needed to provide users the ability to see into and navigate virtual worlds by simply holding up and moving their devices. When the VARIAT program was introduced, learners needed at least an iPhone 8 with iOS 13 or an Android device running Android 9 or higher.

Software Requirements and Considerations

The maturity of the mobile app environment offers many development tools and approaches for developing mobile apps. For the VARIAT program, the developers used the Unity game engine (Unity Technologies) for game content with ARKit (Apple Inc) and ARCore (Google LLC) for the augmented reality component and deployed both iOS and Android apps that were readily available in their respective app stores. Blender (Blender Foundation) was used for 3D modeling and animation, and Photoshop (Adobe) was used to create 2D assets.

The learner downloads the app from the Apple App Store or Google Play on their device, and their progress is maintained on the device with evaluation, progress, and study data synchronized as the learner completes various modules. When synchronized, the data are stored and managed using Google Big Query Workspace, which produces data feeds for training evaluators and researchers.

Overview of Content Design Considerations

Training Framework of the VARIAT App

The VARIAT game was designed based on the integration of evidence-based cognitive psychology with the latest simulation technologies, including VR (eg, a simulated experience of interacting with a virtual clinician-patient scenario that is vulnerable to implicit biases in a virtual environment using 6-degrees-of-freedom motion- and gesture-based interactions) and AR (eg, converting a user's physical environment into a clinic's waiting room for interactive experiences). The goal of the app is to improve awareness of implicit biases among Medicaid providers, to educate them on how these biases can lead to inequitable care, and to offer strategies and resources that may minimize health disparities. This mobile app can be installed on any Apple iOS and Android device and is designed to be completed in one sitting or in short segments.

The game consists of 2 distinct but interconnected modules, targeting implicit biases within medical settings toward patients from minority racial backgrounds, with low socioeconomic status (SES), or from a minority sexual orientation or gender identity (SOGI) group. Learners enter an AR-based interactive role-playing game, in which they encounter a series of 6 scenarios. Each scenario takes approximately 5 minutes to complete and is related to the specific implicit bias being addressed in that particular module (Race/SES or SOGI). Each scenario within the module is designed to address specific issues related to disparities in medical settings that relate to the overall theme of the module. The primary outcome measure of this training program is to evaluate providers' attitudes and beliefs on key concepts related to implicit biases and health disparities in a medical setting before and immediately following the training.

Race/SES Module

The first module within the VARIAT mobile game is the race/SES module, which consists of 3 scenarios dealing with issues of racial bias, transportation and food instability, and implicit bias. The first scenario in this module addresses issues of racial bias within a health care setting and prompts the user to consider how issues of racial and ethnic identity could impact treatment recommendations and the resulting care for patients of minority groups. The next scenario is designed to promote self-reflection on how socioeconomic factors like unreliable transportation or housing could affect a patient's ability to show up for health care visits or comply with care recommendations by medical providers. The last scenario is designed to help users understand how implicit bias from medical providers could impact patient perception and negatively impact patient care.

Each scenario contains prompts where the user is asked to make a choice about the "case" presented within the VARIAT AR game. The user is then given information about the scenario and resources for how to better understand the specific issues for each scenario with the goal to educate them on how to improve practitioner behavior as it relates to the theme of the module. A summary of the scenarios and objectives for this module can be found in Multimedia Appendix 1.

SOGI Module

The second module in the VARIAT mobile game is the SOGI module, which consists of 3 scenarios dealing with issues of SOGI implicit bias, inclusivity for patient care settings, and lesbian, gay, bisexual, transgender, queer (LGBTQ+) patient considerations. The first scenario helps portray the way that microaggressions and implicit biases in patient-provider communication can promote negative disparities in treatment for SOGI minority patients. The second scenario asks users to design their own patient waiting room and helps educate and guide users on what considerations should be made to ensure a medical setting is a safe and welcoming environment for SOGI minority patients. The last scenario in the module helps users recognize the harmful effects of biased behavior toward LGBTQ+ patients and offers space for self-reflection on how to reduce enacted bias for this patient group.

The scenarios in this module also contain prompts for users to answer to better assess their understanding of key concepts or takeaways from each scenario. The SOGI module places an increased emphasis on self-reflection as the scenarios are designed to help users draw parallels to their own experiences in medical practice through reflective exercises following the conclusion of each scenario within the module. A summary of the scenarios and objectives for this module can be seen in Multimedia Appendix 2.

User Workflow

On start-up, users are given some brief instructions on how to prepare themselves for immersion in the VARIAT AR game.

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Users are then instructed to select any available module to start engaging with the content within. Once a module is selected, participants are placed in a virtual hospital setting and can check on the various patients within. When selected in the AR game, these patients display information on their illnesses and present the user with additional narratives about the patients from the "staff" in the AR game. Users are then given different decision options on what to do for each patient's individual case. After helping these patients, the user is provided with information and resources that relate to the content of the module. Unbiased choices "score" higher than choices that are considered to have been influenced by implicit biases toward marginalized patients. After completing the tasks in their module, the users are given a summary of their scores for that module with feedback on how to improve, and additional information to support that improvement relative to the context of their scenario. After completing a module, users are sent back to the home screen, where they can replay the same module or select a new module to explore. A depiction of the app layout, user experience, and scenario prompts is presented in Multimedia Appendix 3.

User Experience and Preliminary Efficacy of the VARIAT Program

Participants and Procedure

Eighteen clinicians (n=12 female) who were predominantly White (non-Hispanic) participated in the VARIAT training. Physicians comprised 8 of the 18 (44%) participants, and 12 of the 18 participants had more than 5 years' experience in health care. The most common workplace setting was hospitals, with private practices, health care system–affiliated clinics, and other workplace settings reported as well. Most participants estimated that Medicaid patients comprised more than 30% of their total caseload, with reported ages of patients seen varying between children, adults, and older adults. Demographic information is reported in Table 1 for the total number of participants (N=18), participants who participated only in the race/SES module (n=7), participants who participated in only the SOGI module (n=5), and participants who completed both the race/SES and SOGI modules (n=6). Participants were recruited through professional networks and were eligible for the study if they were Medicaid providers.

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Table . Demographic information for the participants.

Variables		Overall (n=18), n (%)	Race/SES[a] only (n=7), n (%)	SOGI[b] only (n=5), n (%)	Race/SES and SOGI (n=6), n (%)
Race/ethnicity					
	White (non-Hispanic)	16 (88)	6 (85)	5 (100)	5 (83)
	Non–White[c]	2 (11)	1 (14)	0 (0)	1 (16)
Gender					
	Male	6 (33)	2 (28)	2 (40)	2 (33)
	Female	12 (66)	5 (71)	3 (60)	4 (66)
	Prefer not to say	0 (0)	0 (0)	0 (0)	0 (0)
Profession					
	Medical resident	3 (16)	2 (28)	0 (0)	1 (16)
	Nurse	0 (0)	0 (0)	0 (0)	0 (0)
	Fully credentialed physician	8 (44)	3 (42)	2 (40)	3 (50)
	Social worker	5 (27)	1 (14)	2 (40)	2 (33)
	Other	2 (11)	1 (14)	1 (20)	0 (0)
Work setting					
	Health care system–affiliated clinic	2 (11)	1 (14)	1 (20)	0 (0)
	Hospital	9 (50)	3 (42)	3 (60)	3 (50)
	Private practice	2 (11)	1 (14)	0 (0)	1 (16)
	Other	4 (22)	2 (28)	1 (20)	1 (16)
	Missing	1 (5)	0 (0)	0 (0)	1 (16)
Experience in work setting					
	Less than 1 year	0 (0)	0 (0)	0 (0)	0 (0)
	1-5 years	6 (33)	3 (42)	1 (20)	2 (33)
	6-10 years	3 (16)	2 (28)	1 (20)	0 (0)
	11-15 years	2 (11)	1 (14)	0 (0)	1 (16)
	16-20 years	0 (0)	0 (0)	0 (0)	0 (0)
	21-25 years	2 (11)	1 (14)	1 (20)	0 (0)
	26-30 years	2 (11)	0 (0)	1 (20)	1 (16)
	31 years or more	2 (11)	0 (0)	1 (20)	1 (16)
	Missing	1 (5)	0 (0)	0 (0)	1 (16)
Percentage of Medicaid patients seen					
	Less than or equal to 30%	4 (22)	2 (28)	1 (20)	1 (16)
	Greater than 30%	12 (66)	5 (71)	4 (80)	3 (50)
	I do not see Medicaid patients	1 (5)	0 (0)	0 (0)	1 (16)
	Missing	1 (5)	0 (0)	0 (0)	1 (16)
Age of patients[d]					
	Children	10 (55)	5 (71)	3 (60)	2 (33)
	Adults	11 (61)	0 (0)	2 (40)	2 (33)
	Older adults	8 (44)	5 (71)	2 (40)	1 (16)

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Variables		Overall (n=18), n (%)	Race/SES[a] only (n=7), n (%)	SOGI[b] only (n=5), n (%)	Race/SES and SOGI (n=6), n (%)
	I do not see Medicaid patients	1 (5)	0 (0)	0 (0)	1 (16)

[a]SES: socioeconomic status.

[b]SOGI: sexual orientation and gender identity.

[c]Combined category.

[d]Multiple answers selected.

Questionnaires were administered to participants remotely through the VARIAT app, and data collection took place from March to June 2020.

Measures

User Experience Measures

Users' reactions to both the race/SES and SOGI modules of the VARIAT program were assessed by asking participants about their perception of the modules after the test. After experiencing the AR simulation, users were asked questions designed to test their engagement with the AR experience, such as if they felt a sense of "being there" in the AR experience or how real they found the AR experience to be. These answers were scored on a scale of 1 to 5, with higher scores indicating stronger agreement. Participants were also asked questions about how they might apply the AR experience to their job with questions such as "How do you think this training will help you on the job (Mark all that apply)?" with different response items to assess perceived benefits from the training. These items were scored using dichotomous coding for each option (0 for not applicable and 1 for applicable).

Preliminary Efficacy Measures

Training outcomes were reported through changes in affective knowledge and changes in skill-based knowledge measured by comparing pre-post test responses. Affective knowledge (items assessing how participants expect their perceptions to impact their patients) was measured by agreement with items that were adapted from the California Brief Multicultural Competence Scale [31]. Example items include the following: "I am aware of how my own values might affect my patients" or "I am aware of institutional barriers that affect patients." Skill-based knowledge was assessed differently for the race/SES and SOGI modules, with questions referring to each respective population focused on in the module. Race/SES skill-based knowledge was measured by rating participant agreement with the following internally developed statements: "I am confident that I can recognize the role that implicit bias plays in leading to inequitable care for patients of low socioeconomic status," and "I am confident that I can apply strategies and use resources to minimize health care disparities for patients with low socioeconomic status." SOGI skill-based knowledge was measured similarly, with "race/SES population" being replaced with "LGBTQ+ population" in the skills-based questions. Training outcomes were reported for each module separately, with the race/SES module (n=13) and SOGI module (n=11) consisting of all participants that completed each module. All measures were scored on a scale of 1 to 5, with higher scores representing stronger agreement.

Data Analysis Plan

All analyses were conducted using SPSS Statistics (version 27.0; IBM Corp). Demographic characteristics were described using frequencies and percentages for the categorical variables. Demographic characteristics were reported across 4 participant groupings: participants who took only the Race/SES module, participants who took only the SOGI module, participants who took both the Race/SES and SOGI modules, and an overall group of all unique participants.

After testing for normality using the Shapiro-Wilk test, the training reactions and pre-post skills and attitude outcome data were found to not be normally distributed ($P<.001$). As a result, we used nonparametric tests for analyzing these 2 outcome domains. For the usability data, we used the Wilcoxon signed-rank test to measure the continuous reaction items and report the mean and SD for participants who used both the race/SES module and the SOGI module. The categorical training reaction items were reported using frequencies and percentages. For analyzing the skills and attitudes outcome data, the Wilcoxon matched-pairs signed-rank test was used to report the mean, SD, effect size (Cohen *d*), and 95% CI for pre-post changes in scores. The scores for each module were analyzed separately for all participants who took each respective module. Given that some participants completed both modules (n=6), there is a small amount of overlap in participant representation across all reported outcome data. All data and study materials will be made available on request.

Ethical Considerations

The Ohio State University (OSU) Institutional Review Board has determined this study was exempt from review according to the Policy on Human Subjects Research of the OSU Human Research Protection Program.

Results

User Experience (Training Reactions)

For perception of the AR experience, participants who received training in the race/SES and SOGI modules reported similar ratings for the overall AR experience. Participants reported positive feelings of "being there" (race/SES module: mean score 4.62, SD 1.56; SOGI module: mean score 3.91, SD 1.97) and high relevance of the AR training to their respective jobs (race/SES module: mean score 4.75, SD 0.45; SOGI module: mean score 4.67, SD 0.50) across both modules. Participants across both modules perceived the AR experience as being "a little" realistic, with the SOGI participants reporting less realism on average (mean score 2.91, SD 1.64) compared to the

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race/SES participants (mean score 3.77, SD 1.83). For the reported intention to apply the AR experience to their jobs, only the participants who received training in the race/SES module responded to this item. On average, these participants reported that they were less likely to apply the AR experience to their jobs (mean score 2.31, SD 1.11).

Assessing the perceived benefits of the AR experience to the participants' jobs revealed that the race/SES and SOGI modules had some key differences in support across beliefs. Participants from both the race/SES and SOGI modules reported varying levels of positive agreement that the experience could improve their relationships with their patients (8/11, 73% SOGI participants; 8/13, 62% race/SES participants) and avoid undesirable events in patient care (8/11, 73% SOGI participants; 8/13, 62% SES participants). Conversely, 9 of 11 SOGI participants (82%) showed adequate agreement with the belief that the training would help improve tailored care and 7 of 11 participants (64%) believed that the training would improve patient satisfaction. For the race/SES participants, 7 of 13 (54%) showed moderate agreement with beliefs about improving tailored care, while 6 of 13 (46%) agreed that the training could improve patient satisfaction. The race/SES participants showed higher agreement with the belief that the module would improve their community resources (9/13, 69%) compared to the SOGI module participants (5/11, 45%). A detailed summary of user experience findings is reported in Table 2.

Table . User experience (training reaction) outcomes.

Variables		Race/SES[a] (n=13)	SOGI[b] (n=11)	Effect size (Cohen *d*)
Augmented reality experience scores, mean (SD)				
	Feeling of "being there"[c]	4.6 (1.6)	3.9 (2.0)	0.40
	Realism of augmented reality[c]	3.7 (1.8)	2.9 (1.6)	0.49
	Relevance to job[d]	4.8 (0.5)	4.7 (0.5)	0.17
	Intention to apply augmented reality experience[d]	2.3 (1.1)	N/A[e]	N/A
Participants reporting applicability to job, n (%) [f]				
	Improve relationship with patients	8 (62)	8 (73)	N/A
	Improve patient satisfaction	6 (46)	7 (64)	N/A
	Improve tailored care	7 (54)	9 (82)	N/A
	Avoid undesirable events	8 (62)	8 (73)	N/A
	Improve community resources	9 (69)	5 (45)	N/A
	Other benefit	0 (0)	1 (9)	N/A

[a]SES: socioeconomic status.

[b]SOGI: sexual orientation and gender identity.

[c]Measured on a scale from 1=not at all to 7=very much.

[d]Measured on a scale from 1=strongly disagree to 5=strongly agree.

[e]N/A: not applicable.

[f]Multiple answers selected.

Preliminary Efficacy

For the skills questions, there was no significant difference in pre-post scores assessing the changes in awareness of implicit bias for patients of varying race/SES groups (pre: mean 4.31, SD 0.48; post: mean 4.46, SD 0.52; *d*=0.22; 95% CI −0.77 to 0.33) or the ability to manage health disparities caused by race/SES group (pre: mean 3.85, SD 0.56; post: mean 4.31, SD 0.48; *d*=0.52; 95% CI −1.10 to 0.07) . This pattern was true for measuring awareness of implicit bias for LGBTQ+ patients (pre: mean 4.36, SD 0.51; post: mean 4.73, SD 0.47; *d*=0.54; 95% CI −1.16 to 0.11). For minimizing health disparities realted to LGBTQ+ status, there was a significant difference between pre- and posttest scores (pre: mean 3.91, SD 0.94; post: mean 4.64, SD 0.51; *d*=0.72; 95% CI −1.38 to −0.04) with participants scoring closer to "strongly agree" after experiencing the AR experience.

For the attitudinal questions, there were nonsignificant improvements in the race/SES module in assessing how personal values affected patients (pre: mean 3.92, SD 0.95; post: mean 4.31, SD 0.84; *d*=0.44; 95% CI −1.01 to 0.14), how institutional barriers affect patients (pre: mean 4.23, SD 0.60; post: mean 4.31, SD 0.48; *d*=0.12; 95% CI −0.66 to 0.43), and participants' ability to identify reactions based on stereotypes (pre: mean 4.15, SD 0.56; post: mean 4.38, SD 0.51; *d*=0.53; 95% CI −1.10 to 0.07). For the SOGI module, changes from pre to posttraining were also nonsignificant for all attitudinal items (pre: mean 4.18, SD 0.87; post: mean 4.45, SD 0.52; *d*=0.30; 95% CI −0.90

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to 0.31), institutional barrier items (pre: mean 4.36, SD 0.67; post: mean 4.36, SD 0.67; *d*=0.00; 95% CI −0.59 to 0.59), and items related to identifying stereotypical reactions (pre: mean 4.36, SD 0.51; post: mean 4.36, SD 0.92; *d*=0.00; 95% CI −0.59 to 0.59). A summary of preliminary efficacy findings for each module can be found in Table 3.

Table . Race/socioeconomic status (SES) pre- and posttest skills and attitude outcomes (n=13).

Variables		Pretest score, mean (SD)	Posttest score, mean (SD)	Cohen *d* (95% CI)
Skills questions				
	Implicit bias (race/SES)	4.3 (0.5)	4.5 (0.5)	0.22 (–0.77 to 0.33)
	Minimize health disparities (race/SES)	3.9 (0.6)	4.3 (0.5)	0.52 (–1.10 to 0.07)
Attitudinal questions				
	How my values affect patients	3.9 (1.0)	4.3 (0.5)	0.44 (–1.01 to 0.14)
	How institutional barriers affect patients	4.2 (0.6)	4.3 (0.5)	0.12 (–0.66 to 0.43)
	Identify reactions based on stereotypes	4.2 (0.6)	4.4 (0.5)	0.53 (–1.10 to 0.07)

Discussion

This study developed a VR and AR implicit association training program for Medicaid providers based on cognitive psychology and the latest mobile simulation technologies. Designed to improve awareness of implicit biases related to patients' SES and sexual orientation/gender identity, learners are able to complete six 5-minute interactive role-playing scenarios on their smartphones. Results of pilot user experience research among 18 participants found adequate acceptability and preliminary efficacy (ie, a nonsignificant increase in most outcomes) of the VARIAT program. These findings are consistent with recent literature in cognitive psychology about the possible benefits of AR interventions for health care providers [34-37].

While researchers have spent the last 20 years attempting to reduce implicit bias [38-41], few attempts have been made to integrate the latest immersive technologies, such as AR and VR, with provider-level implicit bias training. For example, a recent meta-analysis of 492 interventions on implicit biases found only a handful of studies attempting to change implicit bias used any kind of VR or AR [42]. Narrowing down to implicit bias training in the health care setting, another recent literature review found few studies that focused on addressing bias at the provider level [43-46]. Therefore, while implicit bias in health care more broadly has been long recognized as a prominent issue [3], there is an important gap in research that develops technology-assisted training programs so that such programs can be more readily available for health care providers and so that implicit bias training can be received at a time and location that works best for them rather than having to attend in-person training sessions. The VARIAT program reported in this study addresses this critical literature gap by offering a convenient and publicly available program that can be integrated into medical training for health care professionals interacting with Medicaid patients, whose training may have important beneficial impacts on patients from disadvantaged backgrounds and those who experience reduced access to high quality of care due to multiple individual and societal barriers [47]. For example, the VARIAT program is brief and can be completed on a mobile device during "fragmented" time windows that fit within the often-chaotic work schedule of medical professionals. Therefore, medical institutions may consider integrating the VARIAT training as a regular refresh of lengthier and more comprehensive in-person or on-site bias-reduction training for their health care professional teams.

Furthermore, among the studies that focused on mitigating health care provider biases, few documented detailed feasibility and efficacy data [48-51]. This study is among the first in the literature to measure both positive provider reactions and efficacy outcomes at multiple levels, including user experience with AR, perceived utility in users' professional work, and perceived attitudes toward patients and skills in mitigating implicit biases at work. It was interesting to find that although the study participants perceived relatively high levels of immersion ("being there"), AR realism, and job relevance from the VARIAT training, they expressed low levels of intention to apply this experience to their daily work. One possible explanation for this discrepancy might be the challenges of translating learned knowledge to behavioral changes, as commonly seen in educational interventions, potentially due to the limited scenarios provided by the training compared to the broad variations in participants' own daily work experiences. The collection of both pre- and postintervention efficacy outcomes further allowed us to measure the potential interventional effects of each of the VARIAT training modules (race/SES and SOGI). However, it should be noted that this paper focused primarily on sharing with the scientific community the development processes and design considerations of a novel implicit bias training program for Medicaid providers. Therefore, caution should be applied when interpreting the preliminary results of this pilot user experience study.

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Study Limitations

There are several important limitations to this study. First, the current iteration of the VARIAT program is being delivered on mobile devices. This training program might elicit different user experiences and efficacy outcomes should it be delivered on other platforms such as through an immersive VR headset. Second, the study sample for this user experience testing study was small and potentially unbalanced. Larger sample sizes and a more rigorous study design (eg, a randomized controlled trial) should be used in future research to formally evaluate the efficacy of the VARIAT program with sufficient statistical power and without inflating the type II error rate [52,53]. Third, the present version of the VARIAT program only consisted of 2 modular domains for implicit bias training, race/SES and SOGI, with only 3 training scenarios for each module due to limitations on study resources and team expertise. Further, although these modules were developed by an interdisciplinary team of clinicians and researchers, patient communities were not involved in the design process. Future research will invite patient advisory groups into the development and refinement process of additional modules and scenarios for VARIAT to provide training in more comprehensive implicit bias domains during clinician-patient interactions. Fourth, this study used only self-reported measures developed by the study team to assess the efficacy outcomes, which may not be able to accurately measure biases that are inherently "implicit." Future efficacy trials of the VARIAT program (and interventions alike) should incorporate validated implicit bias assessment tools such as the Implicit Association Test (IAT), which has been increasingly used by health care professionals in the existing literature [54]. Finally, several limitations of the study design should be noted. For example, this study did not restrict or record the number of times participants were allowed to undergo the training, which may have impacted usability and efficacy outcomes. Additionally, this study used an immediate pre-post training design. A more distant posttraining evaluation should be conducted to allow for examination of the impact of the modules on biases over time.

Conclusions

This study presents a novel intervention (VARIAT) that uses immersive mobile technology to improve awareness of implicit bias related to race/SES and SOGI among Medicaid providers. This publicly available training program has found a promising avenue for future research and practice in reducing implicit bias in health care workplaces. Future research should be conducted to formally evaluate the VARIAT program with large samples and implicit bias testing measures, as well as incorporate additional training domains to provide impactful benefits to both health care professionals and their patients.

Acknowledgments

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Conflicts of Interest

J Penka is the founder and CEO and J Patterson is the cofounder of LittleSeed Inc. Both authors are members of the board of directors of LittleSeed Inc.

Multimedia Appendix 1
Race and socioeconomic status (SES) - module 1.
[DOCX File, 24 KB - games_v12i1e51310_app1.docx]

Multimedia Appendix 2
Sexual orientation gender identity (SOGI) - module 2.
[DOCX File, 23 KB - games_v12i1e51310_app2.docx]

Multimedia Appendix 3
User workflow.
[DOCX File, 959 KB - games_v12i1e51310_app3.docx]

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Abbreviations

AR: augmented reality
LGBTQ+: lesbian, gay, bisexual, transgender, queer
SES: socioeconomic status
SOGI: sexual orientation and gender identity
VARIAT: Virtual and Augmented Reality-based Implicit Association Training
VR: virtual reality

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Efficacy of a Virtual 3D Simulation–Based Digital Training Module for Building Dental Technology Students' Long-Term Competency in Removable Partial Denture Design: Prospective Cohort Study

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Abstract

Background: Removable partial denture (RPD) design is crucial to long-term success in dental treatment, but shortcomings in RPD design training and competency acquisition among dental students have persisted for decades. Digital production is increasing in prevalence in stomatology, and a digital RPD (D-RPD) module, under the framework of the certified Objective Manipulative Skill Examination of Dental Technicians (OMEDT) system reported in our previous work, may improve on existing RPD training models for students.

Objective: We aimed to determine the efficacy of a virtual 3D simulation–based progressive digital training module for RPD design compared to traditional training.

Methods: We developed a prospective cohort study including dental technology students at the Stomatology College of Chongqing Medical University. Cohort 1 received traditional RPD design training (7 wk). Cohort 2 received D-RPD module training based on text and 2D sketches (7 wk). Cohort 3 received D-RPD module pilot training based on text and 2D sketches (4 wk) and continued to receive training based on 3D virtual casts of real patients (3 wk). RPD design tests based on virtual casts were conducted at 1 month and 1 year after training. We collected RPD design scores and the time spent to perform each assessment.

Results: We collected the RPD design scores and the time spent to perform each assessment at 1 month and 1 year after training. The study recruited 109 students, including 58 (53.2%) female and 51 male (56.8%) students. Cohort 1 scored the lowest and cohort 3 scored the highest in both tests (cohorts 1-3 at 1 mo: mean score 65.8, SD 21.5; mean score 81.9, SD 6.88; and mean score 85.3, SD 8.55, respectively; $P<.001$; cohorts 1-3 at 1 y: mean score 60.3, SD 16.7; mean score 75.5, SD 3.90; and mean score 90.9, SD 4.3, respectively; $P<.001$). The difference between cohorts in the time spent was not statistically significant at 1 month (cohorts 1-3: mean 2407.8, SD 1370.3 s; mean 1835.0, SD 1329.2 s; and mean 1790.3, SD 1195.5 s, respectively; $P=.06$) but was statistically significant at 1 year (cohorts 1-3: mean 2049.16, SD 1099.0 s; mean 1857.33, SD 587.39 s; and mean 2524.3, SD 566.37 s, respectively; $P<.001$). Intracohort comparisons indicated that the differences in scores at 1 month and 1 year were not statistically significant for cohort 1 (95% CI –2.1 to 13.0; $P=.16$), while cohort 3 obtained significantly higher scores 1 year later (95% CI 2.5-8.7; $P=.001$), and cohort 2 obtained significantly lower scores 1 year later (95% CI –8.8 to –3.9; $P<.001$).

Conclusions: Cohort 3 obtained the highest score at both time points with retention of competency at 1 year, indicating that progressive D-RPD training including virtual 3D simulation facilitated improved competency in RPD design. The adoption of D-RPD training may benefit learning outcomes.

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KEYWORDS

removable partial denture; RPD; virtual simulation; dental technology; computer-aided design; CAD; clinical practice; efficacy; cohort study; digital training; training; dentistry; treatment; design; virtual; assessment

Introduction

The partially edentulous population is increasing because of increased life expectancy and an aging population [1]. Removable partial dentures (RPDs) possess the advantages of cost-effectiveness and needing a less invasive procedure compared to fixed and implant-retained restorations; thus, RPDs remain an attractive treatment option for partially edentulous patients [2].

The design of RPDs is a crucial technical step that greatly impacts the long-term success of dental treatment and warrants high standards due to the complex structure and variation in the oral morphology of individual patients [3,4]. Poor RPD design can exacerbate plaque retention, leading to gingivitis, periodontitis, and other oral diseases [5]. RPD design has traditionally been a complex subject to teach and learn [6]. Unfortunately, shortcomings in RPD design training and competency acquisition among dental students have persisted for decades [7]. The lack of student supervision by qualified instructors and progressive training patterns, as well as the absence of practice on real patients, have been found to be the main factors limiting successful training in RPD design [8,9]. The lack of competency in RPD design can hamper clinical practice among dentists, often leading to the assignment of the task to dental technicians. Dental technicians, however, lack direct observation of the oral soft and hard tissues of the patients. This factor can limit the quality of prosthesis design and can cause patient discomfort, resulting in additional repairs and medical disputes [10].

Using a pencil-drawn design of the RPD framework on a physical cast or a paper prescription has always been the classic approach for teaching RPD design in most dental schools [11]. However, this classic approach is marked by several constraints. The cumbersome processes used where teachers collect, rate, and hand out paper prescriptions can result in communication gaps and potential wastage of time [11]. The COVID-19 pandemic has further limited the availability of real, patient-based physical casts, thus eroding practice time for RPD design on patient models [12]. Although advances in the dental laboratory digital workflow facilitate the use of computer-aided design (CAD) and computer-aided manufacturing (CAM) in the fabrication of RPDs and communication between dentists and dental technicians [13], multiple surveys confirm that CAD/CAM RPD design courses continue to present significant barriers to widespread adoption in dental education settings due to the cost, lack of faculty, and lack of time available within the curriculum. Moreover, the education editions of commercial CAD software programs for dental laboratories remain expensive and require instructors proficient in CAD/CAM technology to facilitate teaching. Furthermore, the learning curve to master the skills of using commercial CAD software is steep and requires a long time commitment, which presents a problem in undergraduate dental education settings.

In our previous work, we reported a digital RPD (D-RPD) module under the framework of the certified Objective Manipulative Skill Examination of Dental Technicians (OMEDT) system, which is a free web-based application for computer-aided drawing and 2D sketch–based RPD design training for dental and dental technology students [14]. This prospective cohort study aimed to report a significant update to the D-RPD module and to further explore the optimal design of the D-RPD module for teaching. We specifically asked the following questions: (1) How can a progressive approach using case-based virtual 3D simulation be incorporated in a D-RPD design training module to better prepare students for the needs of practice? (2) What is the efficacy of digital training approaches in RPD design compared to traditional training? (3) Does a virtual 3D simulation–based progressive digital training module benefit long-term RPD design competency acquisition and retention?

Methods

Development of a Progressive D-RPD Module Incorporating Case-Based Virtual 3D Simulation

The virtual 3D simulation was based on casts from actual patients. In order to construct patient-based virtual casts, a desktop portable application, showModels, has been developed with the Unity engine and C++ version 11 and C# version 4.0. All clinical cases used in the RPD design training were collected from the Dental Technology Laboratory of the Stomatology Hospital of Chongqing Medical University. Virtual casts were constructed from physical plaster casts of clinical patients using LabScanner (E4; 3shape) and saved in the stereolithography file format using Format Converter (Autodesk; Delcam Exchange) to remove possible surface texture indicators. Since any prepared rest seats on a patient's physical casts may provide hints for RPD design, such rest seats on the virtual cast were filled using 3D reverse software (Geomagic Wrap; 3D System). The resultant virtual casts of real patients may be rotated or zoomed in and out to view the cast details, and the user may specify whether to display the maxillary or the mandibular cast (Multimedia Appendix 1).

Participants and Recruitment

Eligible participants (junior students majoring in dental technology) were recruited at the Stomatology College of Chongqing Medical University. The RPD design theory curriculum in dental technology was organized by the Stomatology Hospital of Chongqing Medical University. All participants provided signed informed consent. The prospective cohort study began in September 2020 and ended in September 2022.

Ethical Considerations

The Research Ethics Committee of the Affiliated Hospital of Stomatology, Chongqing Medical University, approved this study protocol (COHS-REC-2022; LSNo. 096). Data reporting

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followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cohort studies.

Intervention Design

The study protocol and the participant flow diagram are depicted in Figure 1. A description of the training methods implemented is presented in Multimedia Appendix 2. In brief, after following the same RPD design theory curriculum, all participants were divided into 3 cohorts. Cohort 1 included 43 participants who received traditional RPD design training for 7 weeks. They received an RPD design task from the principal investigator each Monday, completed the RPD design using a paper prescription and red and blue pencil, and submitted it by Sunday. Cohort 2 included 36 participants who received D-RPD module training based on literal descriptions and 2D sketches for 7 weeks. They received literal case descriptions and 2D sketches for uniformly depicting missing teeth issued by the principal investigator in the D-RPD module every Monday, drew RPD designs using the D-RPD module, and submitted designs by Sunday. Cohort 3 included 30 participants who received D-RPD module training based on a literal description and 2D sketches for 4 weeks and continued to receive progressive instruction with the updated D-RPD module training based on the virtual casts of real patients for 3 weeks. The 7 RPD design tasks received by the 3 cohorts were all the same, and the types of dentition defects covered Kennedy classes I, II, III, and IV, with only some differences in presentation form. We set 1 month as the retention interval to avoid temporary effects from practice [15]. At 1 month and at 1 year after the training, RPD design tests using 3D virtual casts were administered using the updated D-RPD module and carried out for all of the cohorts. During the retention interval, participants' D-RPD module accounts were blocked to prevent participants from using the module for additional training. Within 1 year of completing their training, participants start a uniform dental laboratory internship, and the internship outline has uniform requirements for the design of RPDs with the same workload. For cohorts 1 and 2, a separate D-RPD module introductory session was held prior to the testing to ensure that the cohort could successfully complete the RPD design task using the updated D-RPD module.

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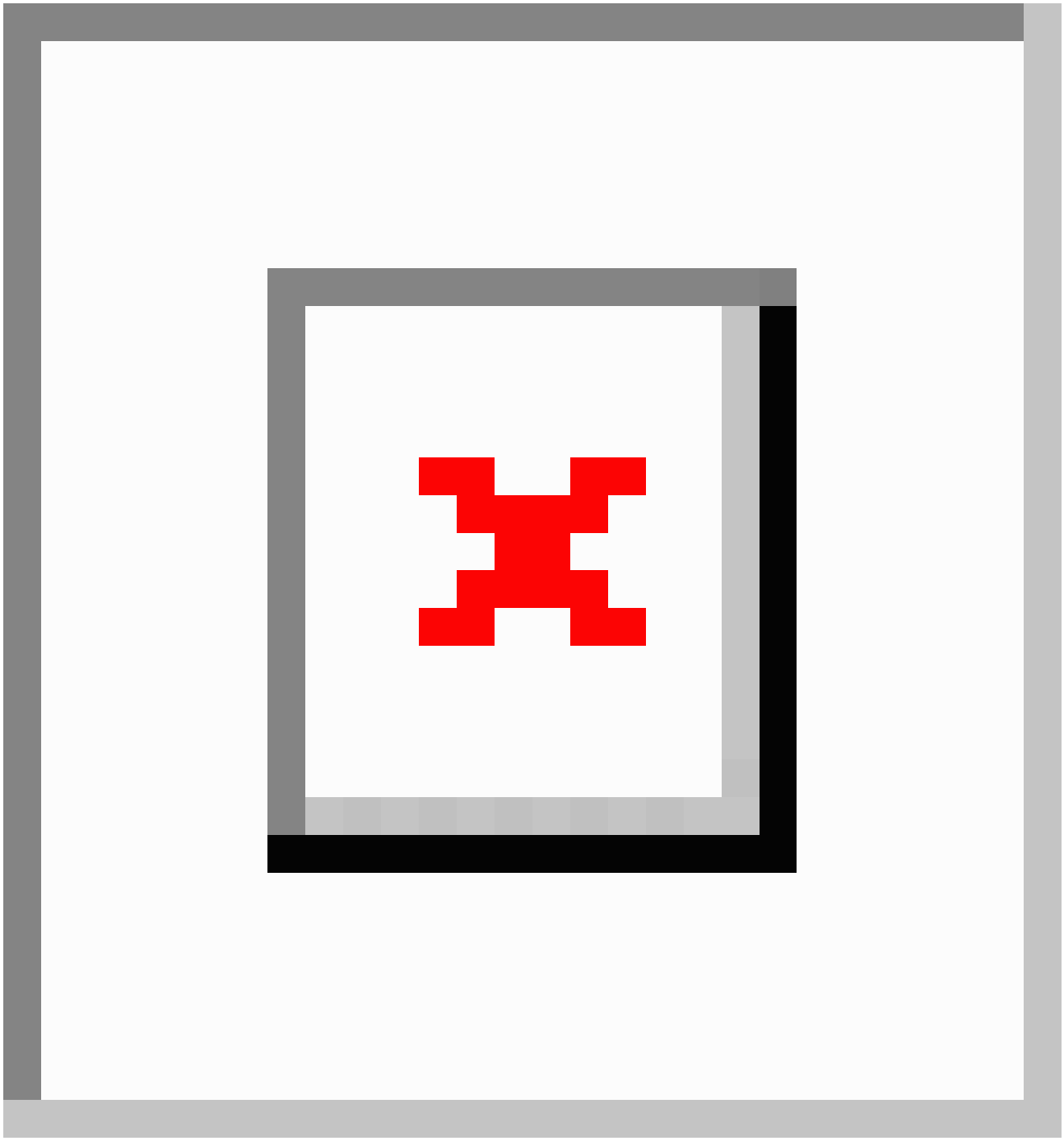
Figure 1. The flowchart of this prospective cohort study. D-RPD: digital removable partial denture; RPD: removable partial denture.



Recruitment of the Expert Panel and Development of the Scoring Rubrics

The principal investigator recruited an expert panel to develop the scoring rubrics [16] (Table 1), and the exercises of all 3 cohorts were rated accordingly. The expert panel consisted of a dental technician experienced in the field of RPD manufacturing and a clinical prosthodontist recruited from the Stomatology Hospital of Chongqing Medical University. The expert panel was blinded to the cohort assignments, had not participated in the teaching of the participants, and did not know about the participants' major or nature of the intervention.

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Table . The scoring rubric used to assess the removable partial denture design test task.

Scoring component	Met clinically acceptable criteria	Needs improvement	Clinically unacceptable
Case observation (20 points)	The missing tooth position was identified accurately and marked correctly on the drawing (20 points).	N/A[a]	The missing tooth position was identified inaccurately, marked incorrectly on the drawing, or both (0 points).
Design choices (40 points)	Design choices are ideal for the case (28-40 points).	Design choices have some flaws but are adequate (15-27 points). Examples include the following: no missing component; indirect retainer present but not in the optimal position; design choices do not violate biological principles; clasp choice adequate but not optimal for the case; inappropriate choice or extension of major connector; justified use of clasps/rests but excessive framework components.	Any missing component or inappropriate design for the case (0-14 points). Examples include the following: missing indirect retainer in a case requiring one; missing reciprocation; clasp choice inappropriate for situation; design choices violate biological principles; excessive and unjustified use of clasps/rests.
Drawing (20 points)	Drawing is ideal. Metal components are painted in blue and resin bases are in red (14-20 points).	Drawing has some flaws but is adequate (7-13 points). Examples include the following: components are represented by corresponding colors; minor inadequacy or inconsistency of spacing between components; components are occasionally not connected; the finish line is not drawn.	Drawing has major flaws (0-6 points). Examples include the following: components are not represented by corresponding colors; major inadequacy or inconsistency of spacing between components; component positioning significantly off optimal position; any component position that violates biomechanical design principles; components are frequently not connected; the finish line is not drawn.
Consistency with task description (10 points)	Exactly as described in the task description (8-10 points). Criteria include the following: clearly presents the requirements implied in the description, and the design is well aligned with the corresponding description; gives consideration to both aesthetics and function.	Some deviation from the task description, but it is acceptable (5-7 points). Examples include the following: conventional design carried out without addressing case-specific modifying factors or requirements listed in the task description; only function considered, consideration for aesthetics lacking.	Serious violation or deviation from the task description (0-4 points). Examples include the following: the design does not match the task description; lack of aesthetic and functional considerations.
Neatness and accuracy in presentation (10 points)	Neat and accurate, no inconsistencies between the table and drawing (8-10 points).	Some inaccuracy and neatness flaws, but it is adequate (5-7 points). Examples include the following: minor erasures; minor neatness issues but still legible.	Major inaccuracy and neatness flaws (0-4 points). Examples include the following: missing information; major neatness issues; writing not legible; any inconsistencies between the table and drawing.

[a]N/A: not applicable.

Data Collection

The main metrics collected were the time(s) to complete the RPD design exercise and the RPD design score (100 points) based on the scoring rubrics by the expert panel.

Statistical Analysis

Scores (ie, total points for each assessment) and time (ie, seconds needed to perform each assessment) were summarized descriptively as means and SDs, coefficients of variation (defined as the ratio of the SD to the mean), and IQRs [17]. Due to the small sample size, normality was tested using the Shapiro-Wilk test, and the homogeneity of variance was tested using the *F* test [18]. The results showed that the time and score data had a skewed distribution and heterogeneity of variance. Therefore, the nonparametric method was used to compare the data sets in this study. Since the Kruskal-Wallis test is widely used to determine whether 3 or more independent data sets are different on some variable of interest [19], it was used to compare the cohorts at the same time point (1 mo or 1 y later), using the 3 data sets in each analysis process. When the value of the Kruskal-Wallis statistic is calculated as statistically significant, it indicates that at least 1 of the compared groups is different from the others. Therefore, we chose the Bonferroni method for further analysis with pairwise multiple comparisons to locate the source of significance. As for in-cohort comparisons at different time points, the Wilcoxon matched-pairs test is a frequently used nonparametric test for paired data, especially for nonnormal data and categorical data, such as was present in this cohort study. Hypothesis tests were 2 sided with a significance threshold of P=.05. At the same

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time, when multiple sets of data are being processed and compared simultaneously, there is increased risk of a type I error, so to identify significant correlations, threshold levels of significance for correlation coefficients were adjusted for multiple comparisons; we used a set of κ correlation coefficients with Bonferroni correction to strictly control the occurrence of false positives (after Bonferroni correction, we used a significance threshold of *P*=.016) [20]. Statistical analysis was performed using SPSS (version 26.0; IBM Corp).

Results

This cohort study included 109 participants: 58 (53.2%) women and 51 (56.8%) men, with a mean age at the beginning the study in September 2020 of 22.5 (SD 0.7) years (Table 2). All 3 cohorts completed the experiment.

Table . Baseline characteristics of the participants in this cohort study. *P* values were estimated using the Kruskal-Wallis test.

Characteristics		Participants overall (n=109)	Cohort 1 (n=43)	Cohort 2 (n=36)	Cohort 3 (n=30)	*P* value
Gender, n (%)						.57
	Female	58 (53.2)	26 (60.5)	18 (50)	14 (46.7)	
	Male	51 (46.8)	17 (39.5)	18 (50)	16 (53.3)	
	Other	0 (0)	0 (0)	0 (0)	0 (0)	
Age (years), mean (SD)		22.5 (0.7)	22.3 (0.7)	22.6 (0.7)	22.5 (0.7)	.40

Intercohort Comparison of Performance

Scores

The scores of cohorts 1, 2, and 3 after 1 month showed a statistically significant difference (mean 65.8, SD 21.5; mean 81.9, SD 6.9; and mean 85.3, SD 8.6, respectively; *P*<.001). Pairwise comparisons showed that the mean score of cohort 1 was 16.1 points less than the mean score of cohort 2 (95% CI –23.0 to –9.0; *P*=.03) and 19.5 points less than that of cohort 3 (95% CI –26.7 to –12.2; *P*<.001), whereas the difference in scores between cohorts 2 and 3 was not statistically significant (95% CI –7.3 to 0.48; *P*=.29). At testing after 1 year, the scores of cohorts 1, 2, and 3 showed a statistically significant difference (mean 60.3, SD 16.7; mean 75.5, SD 3.9; and mean 90.9, SD 4.3, respectively; *P*<.001). Pairwise comparisons showed that the mean score of cohort 1 was 15.2 points less than that of cohort 2, but this was not significantly different (95% CI –20.5 to –9.9; *P*=.06). Meanwhile, the mean score for cohort 3 was 30.6 points higher than that of cohort 1 (95% CI –36.0 to –25.2; *P*<.001), and the mean score of cohort 3 was 15.4 points higher than that of cohort 2 (95% CI –17.4 to –17.3; *P*<.001); both represented a highly significant difference (Table 3 and Figure 2).

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Table . Intercohort comparison of the score and time spent on removal partial denture (RPD) design tests conducted after 1 month and after 1 year; intracohort comparisons of the score and time spent between the 1 month and 1 year time points.

	After 1 month							After 1 year							
	Mean (SD)	Coefficient of variation	Quartile 1 (IQR; range)	*P* value[a]	Difference[b] (95% CI; *P* value[c])	Difference[d] (95% CI; *P* value)[e]	Difference[f] (95% CI; *P* value[g])	Mean (SD)	Coefficient of variation	Quartile 1 (IQR; range)	*P* value[a]	Difference[b] (95% CI; *P* value[c])	Difference[d] (95% CI; *P* value[e])	Difference[f] (95% CI; *P* value[g])	*P* value[h]
RPD design test score				<.001	–16.0 (–23.0 to –9.0; .003)	–19.5 (–26.7 to –12.2; <.001)	–3.4 (–7.3 to 0.48; .29)				<.001	–15.2 (–20.5 to –9.9; .006)	–30.6 (–36.0 to –25.2; <.001)	–17.4 (–17.4 to –17.3; <.001)	
Cohort 1	65.8 (21.5)	0.33	53.0 (31.00; 23-95)					60.3 (16.7)	0.28	50.0 (25.00; 20-95)					.16[i]
Cohort 2	81.9 (6.9)	0.08	80.0 (5.00; 60-95)					75.5 (3.9)	0.05	73.0 (5.00; 86-67)					<.001[i]
Cohort 3	85.3 (8.6)	0.10	80.8 (9.50; 60-98)					90.9 (4.3)		89.0 (5.25; 80-98)					.001[j]
Time spent, s				.06	572.9 (–33.8 to 1179.5; >.99)	567.5 (14.4 to 1120.6; >.99)	44.65 (–576.7 to 666.0; >.99)				<.001	191.8 (–195.7 to 579.3; >.99)	–475.2 (–868.3 to –82.0; <.001)	–667.0 (–951.6 to –382.4; .004)	
Cohort 1	2407.8 (1370.3)	0.57	1088.0 (2132.00; 293-5286)					2049.2 (1099.0)	0.54	1256.0 (1398.00; 364-4623)					.10[i]
Cohort 2	1835.0 (1329.2)	0.72	938.0 (1317.75; 65-5950)					1857.3 (587.4)	0.32	1617.5 (567.25; 593-3224)					.31[j]
Cohort 3	1790.3 (1195.5)	0.67	901.5 (1284.50; 553-4614)					2524.3 (566.4)	0.23	2380.8 (535.25; 837-3276)					.003[j]

[a]Kruskal-Wallis *H* test for differences in the score or time spent among the 3 cohorts.

[b]Cohort 1 vs cohort 2.

[c]Kruskal-Wallis *H* test for differences in the score or time spent between cohort 1 and cohort 2.

[d]Cohort 1 vs cohort 3.

[e]Kruskal-Wallis *H* test for differences in the score or time spent between cohort 1 and cohort 3.

[f]Cohort 2 vs cohort 3.

[g]Kruskal-Wallis *H* test for differences in the score or time spent between cohort 2 and cohort 3.

[h]*P* value for differences in both the score and time spent between the 1 month and 1 year time points.

[i]Paired 2-tailed *t* test for differences.

[j]Wilcoxon matched-pairs test for differences.

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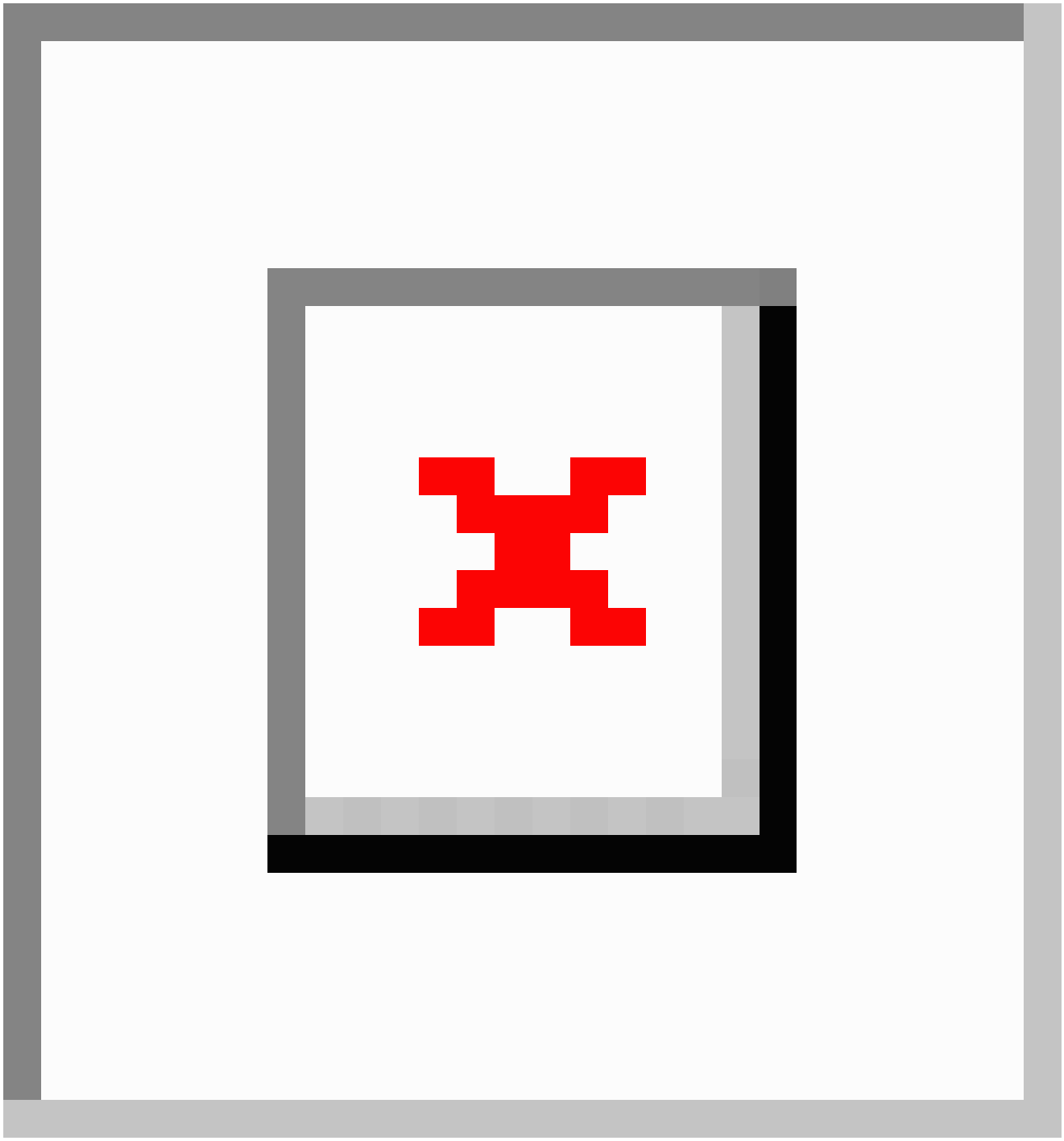
Figure 2. Intercohort comparison and intracohort comparison of the score of the removal partial denture (RPD) design test. ***P*≤.01, ****P*≤.001.



Time Spent

No significant difference was noted in the time spent by the 3 cohorts on the test after 1 month (cohorts 1-3: mean 2407.8, SD 1370.3 s; mean 1835.0, SD 1329.2 s; and mean 1790.3, SD 1195.5 s, respectively; *P*=.06). Pairwise comparisons also did not show any significant differences (cohorts 1-3: 95% CI –33.8 to 1179.5; *P*>.99; 95% CI 14.4-1120.6; *P*>.99; 95% CI –576.7 to 666.0; *P*>.99, respectively). However, the mean time spent on the test after 1 year did show a statistically significant difference between the cohorts (cohorts 1-3: mean 2049.2, SD 1099.0; mean 1857.3, SD 587.4; and mean 2524.3, SD 566.4, respectively; *P*<.001). Pairwise comparisons showed that the mean time spent by cohort 1 was 745.1 seconds shorter than that by cohort 3 (95% CI –868.3 to –82.0; *P*<.001), and the mean time spent by cohort 2 was 667.0 seconds shorter than that by cohort 3 (95% CI –951.6 to –382.4; *P*=.004); both represent a statistically significant difference, while the difference between cohorts 1 and 2 was not statistically significant (95% CI –195.7 to 579.3; *P*>.99) (Table 3 and Figure 3).

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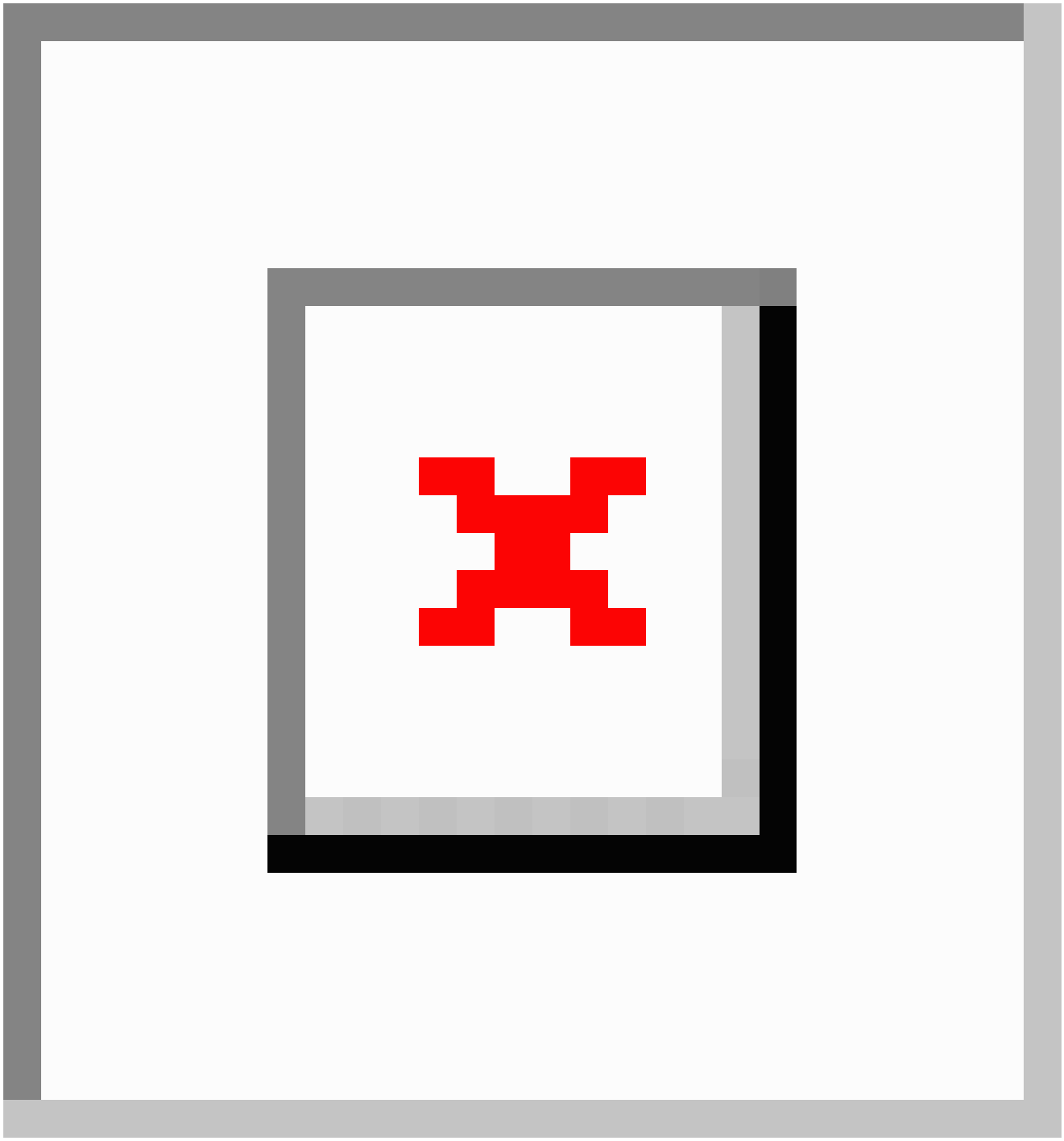
Figure 3. Intercohort comparison and intracohort comparison of the time spent on the removal partial denture (RPD) design test. ns: not significant. ***P*≤.01, ****P*≤.001.



Intracohort Comparison of Performance at Different Time Points

Scores

The difference in scores between the tests conducted 1 month and 1 year later for cohort 1 was not statistically significant (95% CI –2.1 to 13.0; *P*=.16). For cohort 2, the mean score obtained on the test conducted 1 month later was 6.4 points higher than that obtained 1 year later (95% CI 3.9-8.8; *P*<.001). For cohort 3, the mean score obtained on the test conducted 1 month later was 5.6 points less than that obtained on the test conducted 1 year later (95% CI –8.7 to –2.5; *P*=.001) (Table 3 and Figure 2).

Time Spent

The time spent by cohorts 1 and 2 on the tests conducted 1 month and 1 year later did not differ significantly (cohort 1: 95% CI –77.5 to 794.9; *P*=.10; cohort 2: 95% CI –372.5 to 327.9; *P*=.31). However, a significant difference was observed for cohort 3, where the time spent on the test conducted 1 month later was 734.0 seconds shorter than that conducted 1 year later (95% CI –1149.9 to –318.0; *P*=.003) (Table 3 and Figure 3).

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Discussion

Principal Findings

Historically, the process of learning RPD design is a potentially difficult part of dental education [21]. It requires that dental students first acquire a knowledge base and then use critical thinking skills based on evidence to apply that knowledge to a wide variety of clinical patient care situations. This characteristic suggests that a case-based learning mode is the most appropriate approach for RPD design learning. Case-based learning requires the use of real patient cases and scenarios to reflect realistic patient care situations, and students are asked to draw from their established foundational knowledge to make decisions about problems they may encounter in practice [22]. Previous studies have confirmed the effectiveness of case-based learning in RPD design learning [23]. These studies have typically used text and 2D sketches to describe structured clinical cases, but enhanced digital techniques are gradually being applied to transition from simple presentation documents to computer-aided teaching [11,24-27]. Some studies have further developed decision support systems for RPD design based on clinical case libraries to help trainee dentists complete RPD design by providing cases with similar task requirements [28,29]. More recently, 3D virtual casts and CAD software have been introduced to align with clinical cases and currently prevalent dental laboratory digital workflows [30,31]. Nevertheless, several challenges limit the application of these findings. First, many studies have only addressed students in clinical dental programs, ignoring the dental technology student populace, who, as future dental technicians, are key stakeholders for any RPD design education. Second, in assessing the validity of a training program, most studies have investigated short-term effectiveness without considering the effect on long-term retention of skills, which is the most important for translation to future practice. Our research approach fills these gaps.

When investigating relatively permanent changes in learning, the experimental design needs to incorporate a retention interval, which refers to a period without further practice. Following this interval, assessments can be conducted to evaluate learning outcomes. The inclusion of retention intervals aims to eliminate transient effects resulting from practice, such as fatigue or motivational factors [32]. Existing research lacks discussion on how to determine the length of the retention interval. In this study, the retention interval was determined using a combination of experience, design of relevant literature, and course scheduling. One month after the end of training is the latest time the participants can schedule a test before entering the semester vacation. One year after the end of training is the latest time the participants can schedule a test before graduation. Both time nodes are supported by relevant literature studies [33-35]. Within 1 year after completing the training, participants participate in a uniform dental laboratory internship, and the internship outline has uniform requirements for the design of RPDs with the same workload. At the same time, the user accounts of the participants were blocked in the RPD module, preventing the participants from using the module for additional training. However, participants may use paper and pencil for additional practice since they have different expectations for work content after graduation. Therefore, confounding factors related to different amounts of practice are inevitable.

We noted that the scores obtained on the test after 1 month for cohort 1 was significantly lower than the scores for cohorts 2 and 3, who received the D-RPD intervention. This finding reflects the higher efficacy of the D-RPD digital training approach compared to traditional training at improving short-term performance in RPD design. In addition, cohort 2 scored less than cohort 3, which was provided with the 3D virtual cast–based progressive intervention, albeit with no statistically significant difference, which is consistent with the results of Mahrous et al [30]. This finding suggests no significant short-term benefits of progressive digital training incorporating 3D virtual simulation over digital training using 2D sketches and text alone. However, the scores obtained in the tests conducted 1 year later showed that cohort 3 displayed significantly improved performance in comparison with the other cohorts, thus demonstrating improved long-term outcomes of the progressive digital training approach. Of note, added tacit knowledge from clinical practice gained during the internship curriculum that commenced soon after the first test, where students had additional opportunities to learn and participate in the process of RPD design, could have contributed to such an effect. Such practice enriches the experiential learning of students by allowing for case-based learning and greater practice [36]. The D-RPD module with the 3D virtual simulation–based intervention for cohort 3 was aligned with routine clinical production models to a large extent, which possibly facilitated higher competency over a period of time in cohort 3. These findings are in contrast to our short-term observations and those of Mahrous et al [30]. For the “time spent” evaluation dimension, the differences between the 3 cohorts were not significant at the 1-month test. The complexity of the RPD design process itself could account for this finding. After 1 year, a significant difference was notable, and cohort 3 showed the longest mean time spent on the test. It is feasible that the participants in cohort 3 took more factors into account in the RPD design after undertaking clinical practice in the intervening period and that the D-RPD process with 3D virtual casts was the most consistent with clinical practice; therefore, this effect was produced over a longer period of time. The longer time taken by cohort 3 in estimating more factors and spending more time could also have contributed to their higher score over time. These results indicate that the use of D-RPD, especially when incorporating the use of 3D virtual casts in a progressive mode, may facilitate an improvement in the RPD design competency of students compared with the traditional RPD design training approach.

The mean scores of cohorts 1 and 2 were less after 1 year compared to the scores after 1 month, showing a certain degree of loss of competency over time. In contrast, a significant increase was noted in the mean score of cohort 3. Before entering clinical practice, the participants in this cohort were exposed to experiential learning through virtual simulation that had similarities with clinical work, which might have produced a synergistic effect on improving RPD design competency. It is especially noteworthy that the scores and time spent at the 2 time points by cohort 1 showed very large SDs, indicating high

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variability in RPD design competency among the cohort 1 students. The opposite was notable in cohorts 2 and 3, which may be related to better teacher supervision, which D-RPD can facilitate. Moreover, previous research has shown that D-RPD design training has advantages that can be partly attributed to improved tracking of students' learning progress and their timely interactions with trainers [37,38]. D-RPD allows teachers to check the progress of the RPD design tasks of the students, make efficient corrections, and provide more frequent feedback. It is evident that this digital teaching mode can facilitate greater student engagement and problem-based learning compared to traditional paper-based teaching. These findings also reinforce that the approach involving D-RPD design combined with 3D virtual casts can provide students with more effective teacher supervision, while offering them virtual experiential learning consistent with clinical activity.

The intervention mode for cohort 3 was similar to the clinical CAD/CAM digital denture design process, which can improve the quality and efficiency of prosthesis design and facilitate improved management of design schemes [39,40]. Intraoral scanning produces 3D virtual casts that can improve precision, and it is readily accepted by the patient compared to the traditional impression method, producing models with higher accuracy [41,42]. The digital workflow allows dental technicians to design directly on these models and to perform postprocessing of multiple scanning data [14,43], thus rendering the entire workflow efficient and convenient. However, despite the rapidly increasing adoption of digital workflows in dental practices worldwide, preclinical education in dentistry and dental technology is typically lagging at imparting the relevant skills to students [12,44,45]. Taken together with our earlier research, this work proposes and validates a progressive digital teaching module for RPD design training that incorporates 3D virtual simulation, demonstrates greater efficacy for a digital training approach compared to traditional training, and provides evidence that a virtual 3D simulation–based progressive digital training module can enhance long-term learning outcomes of RPD design training.

Limitations and Future Work

The limitations of this study include a small sample size, a single center for recruitment, and a lack of randomization, which may have led to unaccounted differences in the inherent learning ability of students and their existing competency prior to participation in the experiment. In future work, bias may be avoided by using a randomized controlled study design to provide stronger evidence for this training module. In addition, there is a lack of data regarding the effectiveness of this training module for clinical dentistry students. Further studies are merited to enable more widespread adoption of 3D virtual simulation–based digital training approaches in dental education.

Conclusions

In this cohort study, we report in detail a major update to the D-RPD module and the design of an intervention experiment to observe the effects of traditional training, D-RPD training, and additional 3D virtual simulation–based digital training on the RPD design competency of students. Based on the results, we propose an effective, progressive, digital 3D virtual simulation workflow–based training module for RPD design, and we have preliminarily verified the efficacy of this novel training approach for facilitating improvement and long-term retention of RPD design competency among dental technology students. This training module should be further extended to clinical dentistry students, randomized controlled experiments should be designed, and feedback from students and teachers should be collected to enable its further optimization and eventual inclusion in curricula.

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Authors' Contributions

MP designed the structure of the digital removable partial denture module; organized the cohort study; collected, analyzed and interpreted the data; obtained funding; and wrote and revised the manuscript for important intellectual content; KL drafted the manuscript and helped analyze and visualize the data; XZ helped complete the digital removable partial denture module algorithm and revised parts of the manuscript; PJ and XF helped obtain funding; CM, NY, FT, YL, and YB performed as the teaching expert group; YX and XF performed as the scoring expert group; JW, DF, and HY helped with the program development and provided technical support; MC recorded the multimedia appendices; and HC, LJ, and MC provided administrative and material support; JS, PJ, LJ, and MP supervised the entire process. MP and XZ had full access to all of the data in this study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of Interest

None declared.

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Multimedia Appendix 1
Development of a progressive D-RPD module incorporating case-based virtual 3D simulation.
[MP4 File, 4446 KB - games_v12i1e46789_app1.mp4]

Multimedia Appendix 2
Display of the interventions of the three cohorts.
[MP4 File, 7529 KB - games_v12i1e46789_app2.mp4]

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Abbreviations

CAD: computer-aided design
CAM: computer-aided manufacturing
D-RPD: digital removable partial denture
OMEDT: Objective Manipulative Skill Examination of Dental Technicians
RPD: removable partial denture
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Original Paper

A Serious Game (“Fight With Virus”) for Preventing COVID-19 Health Rumors: Development and Experimental Study

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Abstract

Background: Health rumors arbitrarily spread in mainstream social media on the internet. Health rumors emerged in China during the outbreak of COVID-19 in early 2020. Many midelders/elders (age over 40 years) who lived in Wuhan believed these rumors.

Objective: This study focused on designing a serious game as an experimental program to prevent and control health rumors. The focus of the study was explicitly on the context of the social networking service for midelders/elders.

Methods: This research involved 2 major parts: adopting the Transmission Control Protocol model for games and then, based on the model, designing a game named “Fight With Virus” as an experimental platform and developing a cognitive questionnaire with a 5-point Likert scale. The relevant variables for this experimental study were defined, and 10 hypotheses were proposed and tested with an empirical study. In total, 200 participants were selected for the experiments. By collecting relevant data in the experiments, we conducted statistical observations and comparative analysis to test whether the experimental hypotheses could be proved.

Results: We noted that compared to traditional media, serious games are more capable of inspiring interest in research participants toward their understanding of the knowledge and learning of health commonsense. In judging and recognizing the COVID-19 health rumor, the test group that used game education had a stronger ability regarding identification of the rumor and a higher accuracy rate of identification. Results showed that the more educated midelders/elders are, the more effective they are at using serious games.

Conclusions: Compared to traditional media, serious games can effectively improve midelders’/elders’ cognitive abilities while they face a health rumor. The gameplay effect is related to the individual’s age and educational background, while income and gender have no impact.

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KEYWORDS

serious game; COVID-19; health rumor; game communication; game TCP model; Transmission Control Protocol; gaming; misinformation; disinformation; rumor; health communication; false information; elder; older adult

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Introduction

Background

In recent years, the arbitrary spreading of health rumors in mainstream social media on the internet has increasingly gained the attention of the public and raised concerns [1]. For health rumor researchers, a common concern is to propose a feasible and effective prevention and control program for current rampant rumors [2,3]. Furthermore, to prevent and control the spread of such rumors, it is necessary to strengthen the public's health knowledge to judge and identify the rumors [4]. The concept of a rumor involves a form of statement whose veracity cannot be quickly or ever confirmed. Generally, we have a "dream rumor" and a "bogie rumor," the former reflecting public desires and wished-for outcomes and the latter hiding some special purpose by somebody, both of them largely occurring during the early COVID-19 epidemic in Wuhan, China [4]. The traditional way of countering rumors often relies on media refutation, which can only be described as a "Band-Aid" solution. To fundamentally prevent and control COVID-19–related rumors and enhance the public's ability to resist them, we need to find a form of "information vaccine." Therefore, we chose serious games as a "vaccine" in this context.

The purpose of a serious game is to help people acquire knowledge by playing games. Serious games involve solving problems and studying via careful and thoughtful game ideas [5], while considering characteristics beyond gameplay (eg, purpose and scope [6]). In addition, game elements are used to improve information processing and identify relevant information, which is consistent with the purpose of health rumor prevention research [7]. COVID-19–related rumors are based on the content of serious games to experiment with health rumor prevention, mainly using the control variable method and the analysis-contrast method to apply serious game learning to health rumor prevention research. This paper explores how to help people acquire knowledge of health rumors and health commonsense from the prevention experiment using the relaxed approach of serious games [8].

Previously, serious games have provided a platform for education and business use. For instance, behavioral interventions can be carefully tested and designed to reduce risk-taking behaviors [9], where transmission risks and the usefulness of pandemic-like simulations were demonstrated in the laboratory to be safely and ethically comprehended at the initial state of a health crisis. In addition, other studies prove that serious games are used to accommodate informational and communication complexities in early warning disaster management to simulate and test how public information from social media is used in emergency operation centers to make (protective and communicative) decisions based on levels of trust, usefulness, and completeness [10,11]. Therefore, serious games as an "information vaccine" have certain feasibility, and this paper also explored this issue. Nevertheless, the prevention and control of health rumors have rarely been considered in the context of the social networking service (SNS) for elderly users.

Serious Games

Why are serious games chosen as a solution? Serious games refer to those electronic games whose main content is used for knowledge and skill development, professional training, and spreading culture. They are widely used in many fields. Compared to the limitations and congenital deficiencies of some communication models of traditional media, serious games have become an effective tool to address many social problems, because of their fast speed, wide range, and interactivity [12].

Abt [5] first defined the concept of serious games as follows: "These games have an explicit and carefully thought-out educational purpose and are not intended to be played primarily for amusement." Later, Sawyer [8], in his white paper titled "Serious Game 2 Initiative," redefined the concept of a serious game as being an entertainment game with nonentertainment goals. Several variants of the concept have also been proposed. Michael and Chen [13] defined serious games as games that educate, train, and inform. Meanwhile, Zyda [14] defined serious games as a mental contest played with a computer following specific rules. This situation led some analysts to describe serious games as the next wave of technology-mediated learning [15]. Although there is no single definition of the serious game concept, all the proposed definitions convey the same idea: using games to teach or transmit something [16].

Serious games are present in many areas. Westera et al [17] argued that serious games open up many new opportunities for learning complex skills, especially in the education and training domains [12,18-20]. Moreover, Yusoff et al [21] and Crookall [22] argued that good computer games are an excellent example of modern educational theory and that establishing simulation-based serious games as a discipline is a crucial endeavor that could benefit many other related disciplines.

Some early studies were systematically outlined by Connolly et al [23]. For instance, Ziebarth et al [18] and Diehl et al [19] adopted serious games to develop a prototype for the training and education of health students. Some scholars have emphasized the role of serious games in highly specialized skill acquisition (ie, drilling operation [24], mitigation of student dropout [25], improving the command performance of pilots [26]) and education (ie, medical surgery) [27,28], while providing the means to influence cognition and motivational driver [29].

Serious games are also being applied to pass on knowledge or expertise, which can be adopted for various purposes (ie, rehabilitation, psychotherapy, and brain disorders [30-32]). Sometimes, a serious game can also be used to increase risk awareness in the working area of the manufacturing floor [33]. The review by Abd-Alrazaq et al [34] showed that tools such as serious games are usable but are not replaceable options for rehabilitation and clinical intervention where long-term effects are required. Another review by Krath et al [33] revealed that serious games have also incorporated many theoretical foundations relevant to 3 significant landscapes: behavior, learning, and affect-motivation.

In research related to midelders/elders, several studies have demonstrated the potential of serious games to promote physical

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activity among older adults. For example, a randomized controlled trial conducted by Fu et al [35] found that a 6-month program of exergaming (exercise using video games) significantly improves the physical function of older adults. Similarly, a study by Jiménez-Pavón et al [36] showed that exergaming increases physical activity and cognitive performance in older adults with mild cognitive impairment.

Serious games have also been used to enhance cognitive training and disease management among older adults. For instance, a study by Anguera et al [37] found that cognitive training through a video game improves cognitive control in older adults. Additionally, a systematic review by Loerzel et al [38] indicated that serious games have the potential to improve self-management and quality of life among older adults with chronic diseases.

In COVID-19–related research, several studies have investigated the potential of gamification and serious games in promoting physical activity during the COVID-19 pandemic. For example, a study by Hall et al [39] proposed a project at a hospital's senior health center in Canada to discuss how health care can be addressed using serious games among middle-aged and older adults during the pandemic [39]. The study found that the game was effective in increasing physical activity levels and improving self-efficacy. Lau et al [40] demonstrated the potential use of serious game to improve physical activity, cognitive training, and mental health among the aging population during COVID-19 in Hongkong.

Similarly, a study by Suppan et al [41] developed a serious game designed to promote safe behaviors for infection prevention and control (IPC), with a specific focus on COVID-19 among health care workers (HCWs) and other hospital employees. Another study by Ferreira et al [42] explored the potential of gamification in promoting hand hygiene among HCWs during the pandemic. The study found that the game was effective in increasing hand hygiene compliance among the participants [42].

Overall, gamification and serious games have emerged as a promising tool to promote physical activity and health and well-being during the COVID-19 pandemic. These technologies have the potential to support health promotion initiatives and encourage people to adopt healthy behaviors in a fun and engaging way. Therefore, we believe serious games can also solve the issue of COVID-19–related rumors that existed among Chinese midelders/elders.

Health Rumor Analysis

Zhang et al [1] investigated all 453 features of health rumor data collected from a definitive online reference in China. A logistic regression model was adopted to determine the contribution of such features to true and false health rumors. There were measurable differences between true and false health rumors, where the length of a headline or statement and the presence of pictures were negatively correlated with the probability that a rumor was true. Meanwhile, a rumor was more likely to be true if it contained elements such as numbers, source cues, and hyperlinks. They also found that the dread health rumor is more likely to be true than a wishful one. Meanwhile, Chua and Banerjee [4] conducted a study on health rumors from 2015 to 2018. Users' trust in online health rumors was investigated using 2 factors: length and presence of an image. Additionally, 2 types of rumors were studied: pipe-dream rumor, which offers hope, and bogie rumors, which instill fear. A total of 102 people participated in the experiment, where the finding suggested that pipe-dream rumors are trusted when they are short and do not contain images, while bogie rumors are trusted when they are long and contain images.

Subsequently, Chua and Banerjee [3] investigated the role of epistemic belief in affecting internet users' decision to share online health rumors. The study focused on the characteristics of rumors—true or false, textual or pictorial, dread or wishful—shaping the decision-making among epistemologically naive and robust users separately. The study showed that epistemologically naive individuals are likelier to share online health rumors than epistemologically robust individuals. In addition, epistemologically robust participants were more likely to share textual rumors than pictorial ones. However, there were no differences between true and false rumors (or between dread and wishful rumors) among either epistemologically naive or robust participants. Meanwhile, Wu [43] modeled factors that predicted fake news sharing during the COVID-19 health crisis. Results showed that informational dependency and social dependency engender both positive and negative cognitive states, namely perceived information timeliness, perceived socialization, and social overload, which then invoke positive and negative affects. Considering that SNS dependency affects information-seeking behavior, it is important for individuals to be exposed to as much accurate information as possible and to build up rational communication against the spread of false rumors.

Ji et al [44] explored factors that influence people's engagement in scientific rumormongering of genetically modified (GM) food on the Chinese social media platform Sina Weibo at both the group and the individual level. In total, 9070 posts about GM food were obtained from 1 million users. Analysis using logistic regression of the effect of peer influence did not find that users would depend on their friendship network to spread rumors. Instead, results revealed that people with negative attitudes toward GM food and who are social media extroverts (ie, celebrities) are more likely to spread rumors. In contrast, social reputation did not influence the spread of rumors, overwhelming the voices of the scientific community and negatively influencing public attitudes and behaviors.

Meanwhile, Hui et al [45] conducted a study on the spread mechanism of rumors on social network platforms during COVID-19 and considered education as a control measure against the spread of rumors. A novel epidemic-like model was established to characterize the spread of rumors based on 2 dimensions of users (age and time), susceptibility based on education classes, control strategies to effectively restrain rumor propagation, and numerical simulations to verify the main theoretical results. The study concluded that improving education levels and conducting short-term online education are essential strategies for effectively controlling rumor spread. In addition, Pulido et al [46] focused on the social impact of research to identify types of false health information shared on

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social media (Reddit, Facebook, and Twitter) using the application of social impact in social media (SISM) methodology. The results indicated that messages focusing on fake health information are primarily aggressive, while those based on the evidence of social impact are respectful and transformative, and deliberation contexts promoted on social media overcome false health information. The findings provide insights into how public health initiatives can support the presence and interactions of evidence as an effective strategy to combat fake news.

A study by Kim and Kim [47] investigated the misinformation belief produced in the context of COVID-19 via 2 main factors: risk perception (psychometric paradigm) and communication. It was found that perceived risk and stigma positively impact belief in fake news, while source credibility and the quantity of information reduce it. Meanwhile, among communication factors, source credibility and the quantity of information reduce belief in fake news, while the credibility of information sources increases it. In addition, Zhao et al [48] used features of online health misinformation that were classified into central level (including topic features) and peripheral level (including linguistic features, sentiment features, and user behavioral features) to propose a health misinformation detection model using the elaboration likelihood model (ELM). Based on a data set collected from a real online health community (because of the lack of a labeled data set), the model correctly detected about 85% of health misinformation. Furthermore, the findings demonstrated the efficacy of behavioral features in health misinformation detection and offered suggestions for misinformation detection by integrating the features of messages and message creators. In COVID-19–related fake news research, Wang and Huang [49] found that although an official denial can initially reduce citizens' belief in unconfirmed information, later when the denial is revealed to be false, the citizens will have lower levels of belief, not just in the current denial, but also in the government's future denials of similar rumors. Moreover, the negative lasting effects will carry over to satisfaction with the authorities in the related policy area.

COVID-19 Background

This paper was initially written in 2020, and the experiment was conducted in the period from February to March 2020. Therefore, many things changed from then up to the Omicron strain of COVID-19. As such, we acknowledge that this paper has time constraints; however, the research still provides some valuable inspiration and conclusions on game studies, media development, and health care. Since the COVID-19 pandemic broke out in December 2019, the related health rumors also began to wreak havoc on the internet.

Rumor prevention is difficult in the case of rumors that rely on propaganda, and the educational means of traditional media are ineffective due to the lack of interaction and the complexity of information. On the internet, especially the midelders/elders were in a state of panic and information-blind obedience [50].

In China, an SNS group existed, in addition to many WeChat groups, similar to Discord and Facebook in the West. Therefore, we could easily find a target sample for our newly established experimental community, where any questions could be communicated at any time. Our experiment was conducted in early 2020, and some people could answer the questionnaire face to face, while others could not because of the lockdown. Therefore, some respondents were sent offline paper questionnaires, and we also requested them to fill in the online questionnaire. The Chinese midelders/elders were comfortable playing the game on their cell phones, so they easily believed the health rumor that the information communication channel is too fast. Some of them whom we could not meet face to face were contacted over a video call, and we confirmed their age and other personal information clearly to ensure accuracy in the experiment.

The original survey, questionnaire, and serious game are in Chinese, convenient for our non–English-speaking respondents, and all the concepts in this paper are the translated version. This means we just translated the statistical data and labels; during the experiment, there was no translation, and we followed the same steps for all the scales.

Elderly WeChat Users in China: Original Survey

According to our data collected in the original survey, the contemporary middle-aged and older adults, especially those aged 40-60 years, have a high frequency of use of WeChat; the number of elderly WeChat users with frequent use accounts for 66.09% of the total. According to interviews at different levels of the questionnaire survey process, middle-aged and elderly users of WeChat are aged from 50 to 65 years. They are also familiar with using the WeChat "circle of friends" function and other social media platforms (eg, TikTok). They often record their daily lives and travel through videos and pictures. Generally, this user group is also active in online social group chats, and their frequency of using online social media is no less than that of some young user groups. For example, 48.85% of middle-aged and elderly WeChat users said they occasionally read health information on WeChat, and only 16.67% said they had never received health information forwarded by relatives and friends (Figure 1).

The survey on the acquisition and dissemination of health information by elderly WeChat users was the focus of this study. Most people do not have the habit of reading health information regularly. It can be seen from the data that this depends to some extent on the frequency of obtaining information. People read health information only when it is forwarded to them by relatives and friends or when relevant health public accounts push this information or when it is in the form of characteristic health information news, as shown in Figure 2. Regarding access to health information, 62.07% of the respondents received health information from their WeChat friends. In addition, 83.33% of the respondents had the experience of forwarding health information to their children or parents, and 57.47% of those forwarded health information to their WeChat friends. Most respondents felt that the original intention of forwarding health information was to help others with a positive attitude.

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Figure 1. Reading frequency of SNS health information by Chinese midelders/elders. SNS: social networking service.

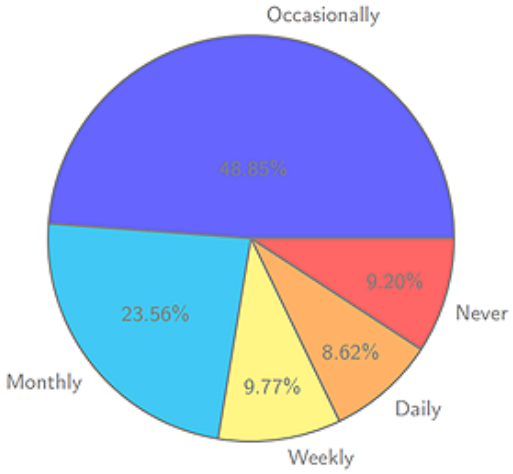
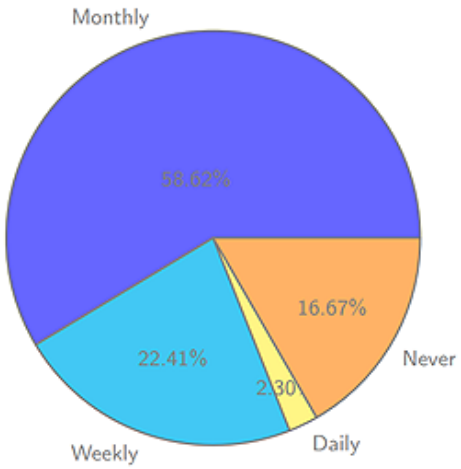


Figure 2. Receiving frequency of SNS health information by Chinese midelders/elders. SNS: social networking service.



However, many midelders/elders received health information without any judgment and recognition and then spread the information with a "good intention" motive, which is also why the health rumor issue is rampant. The data also show that the failure to recognize and identify health rumors is more likely to be the reason than the motive for spreading them. In addition, according to the questionnaire, 86.78% of elderly WeChat users trusted health information forwarded by relatives and friends and 45.4% considered it very trustworthy. The trustworthiness of health information forwarded by colleagues wa 82.18%. These data show that WeChat has become a hotbed for health rumors among the midelders/elders.

Therefore, this paper used a serious game as a tool to test the effect of game media on the prevention of health rumors. Compared with other media, the serious game had a special communication model and effect that could improve this situation (see the *Results* section for more details). Therefore, using the COVID-19 pneumonia rumor was suitable as the target and content of the serious game, involving not only the elderly closely related to COVID-19 pneumonia but also COVID-19 rumor communication relying on WeChat. Finally, the number of health rumors that emerged during the COVID-19 epidemic was enormous, and enough rumor cases could be collected for experimentation.

Methods

The Transmission Control Protocol Model of the Game

There are many theoretical models concerning the communication effect of games as media [51]. The computer networking concept was adopted as the inspiration for this research based on the idea of engineering. Two main protocols exist in network communication: Transmission Control Protocol (TCP) and User Datagram Protocol (UDP) [51]. TCP originated in the initial network implementation, complementing Internet Protocol (IP). TCP provides reliable, ordered, and error-checked delivery of a stream of bytes between applications running on hosts communicating via an IP network. Major internet applications, such as the World Wide Web, email, remote administration, and file transfer, rely on TCP because of the 3-way handshake mechanism (Figure 3) [52].

Having introduced the logical mechanism of UDP and TCP from the technical perspective of communication, we can see that all media communication models are suited to TCP and UDP (2 computer network theories). UDP uses a simple connectionless communication model, just from the information source to the information sink. For example, the newspaper provides information to readers without any interaction (request and response). However, for all current media, only games

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match the TCP model (Figure 4). In traditional media, no matter the newspaper, broadcaster, or television program, the audience only receives information; the UDP model does not have a feedback process, the timeliness is good, but transmission is unstable. As a result, users can refuse to accept information or hardly notice useful content. Therefore, serious games can help society to address health rumor issues. In this paper, we proved the effect on the health communication area [53].

Figure 3. Three-way handshaking in TCP. ACK: acknowledge; RTT: round-trip time; SYN: synchronize; TCP: Transmission Control Protocol.

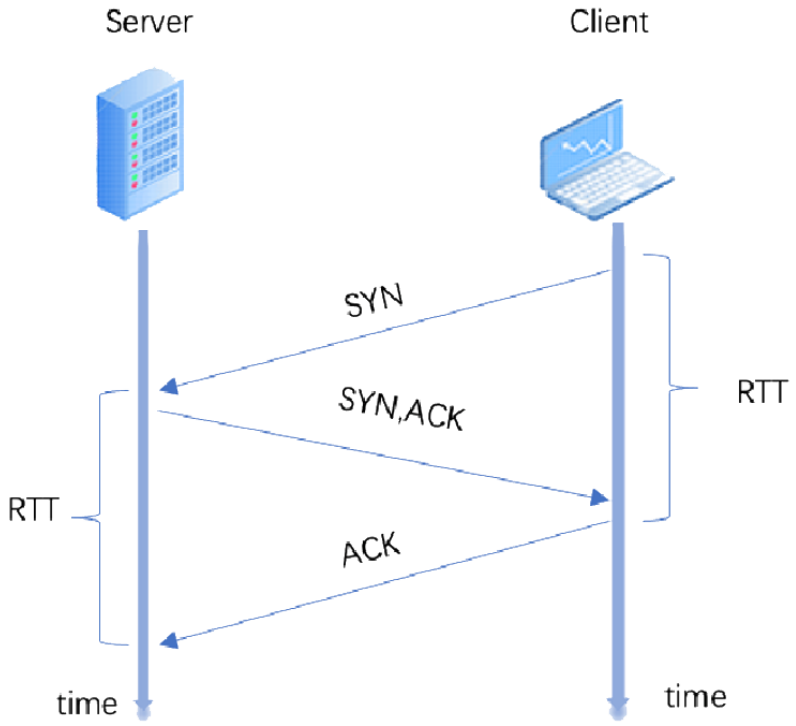
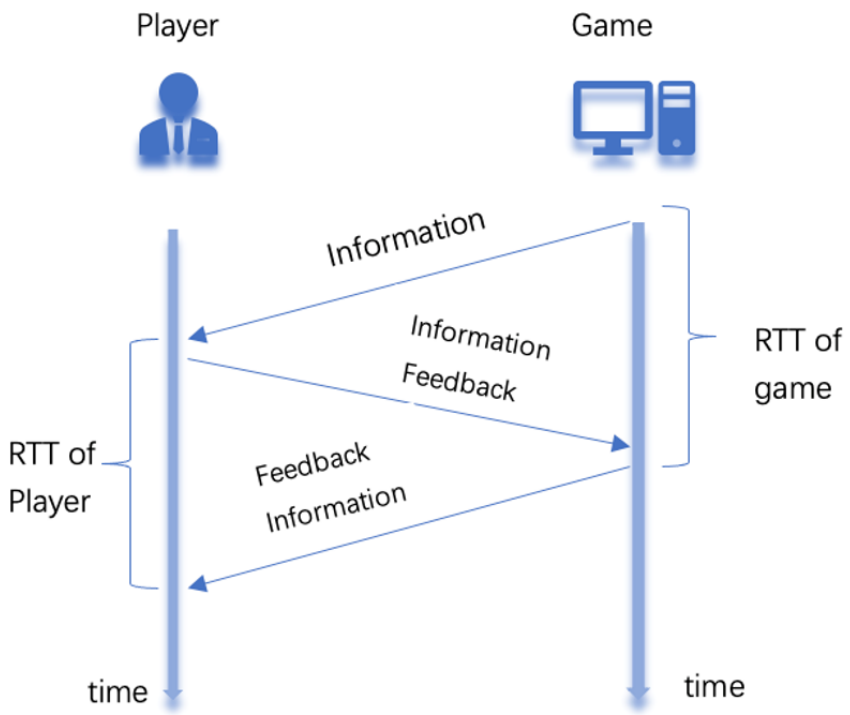


Figure 4. Serious game of TCP. RTT: round-trip time; TCP: Transmission Control Protocol.



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Study Design

This study investigated the prevention and control of health rumors in WeChat, as most elderly WeChat users are concerned about health information and are negatively affected by health rumors. Here, the term "elderly" in our paper is a macroscopic definition: it is not only a physiological age classification but also a description of the psychology or state. In China, people who believe a health rumor via the SNS in the age range of 40-60 years (midelders/elders) were considered. We recruited 200 midelders/elders in Tongren City, Guizhou Province, China, which did not have a serious spread of COVID-19 in early 2020. The participants got together for dancing and training in the city plaza, and then, we requested them to attend our game experiment.

The experimental program was constructed in 2 parts. The first part was developing a serious game based on the content of health rumors and health commonsense; we named it "Fight With Virus." The purpose was to apply this in a health rumor prevention experiment. The second part was developing a cognitive questionnaire with the theme of COVID-19 health rumor, with a 5-point Likert scale, which aimed to compare and analyze the prevention effects of traditional and serious game learning models on health rumors. Baishya and Samalia [54] extended the unified theory of acceptance and use of technology (UTAUT) into UTAUT2, incorporating 3 constructs into the original UTAUT: hedonic motivation, price value, and habit. Individual differences (ie, age, gender, and experience) were hypothesized to moderate the effects of these constructs on behavioral intention and technology use, thus affecting their learning of new technologies. Therefore, according to several past studies based on the UTAUT2 model [55,56], this study adopted the UTAUT2 model to analyze the effect of the serious game. We modified and added variables, which were analyzed using IBM SPSS Amos and IBM SPSS Statistics on factors influencing health information use and dissemination. On this basis, a suitable serious game experiment scheme was built.

The experiment was conducted in 4 steps. In steps 1 and 2, we selected the target participants (midelders/elders), while in steps 3 and 4, we designed the game for the experiment.

Step 1

The construction of the experimental program based on serious games and experimental research needed to be based on a full understanding of the use and dissemination of health information by the research participants. We analyzed the health information needs of the research participants, the frequency and channels of use and the dissemination of health information, and their ability to identify and judge health rumors.

Step 2

To investigate the phenomenon of the dissemination of health information in WeChat's midelder/elder user groups, we used a questionnaire designed in 3 parts: The first part involved a survey to collect personal information, such as gender, age, place of residence, income level, and education. The second part was a survey on the habit of using WeChat. The third part mainly involved the frequency, channel, and motivation of users to obtain and forward health information.

At the same time, 30 health rumor judgment questions were attached to this survey questionnaire, and respondents were asked to judge whether they were correct or incorrect. Through the correct rate of health rumor judgment, we determined the trust level and ability of the respondents to identify health rumors. We also popularized the 30 relevant health rumors, with the hope to popularize the degree of health rumor knowledge and also to strengthen the respondents' ability to recognize information. The questionnaire is shown in Multimedia Appendix 1.

Based on the cognitive ability determined through the questionnaire, 200 participants were selected and asked for their willingness to play the serious game.

Step 3

Based on the use and dissemination of health information by the research participants, the theme of the health rumor learning content was selected and a serious game experimental scheme suitable for this group was constructed through the design and production of serious game content. Considering the experimental length of the serious game and the understanding and acceptance level of the participants, the video game mode of a multiline plot was not applicable for our research, so a single-line plot and scenario was used in the design of the game.

The learning content of the serious game is mainly based on the theme of "a personal day," and the content of the game plot is a person's life from morning to afternoon, in the form of a single storyline. An explanation is provided at the beginning of the game to accurately communicate the theme, rules, and intent of the game to the players. In the learning content of the game, information such as health rumors and general knowledge about COVID-19 was selected, as shown in Table 1, and based on the selected content, failure/passing conditions were set for the game, which involved "risk of infection" and "psychological stress." Different scenarios are set up in a day's life, and questions are set up to interact with the game players to promote and increase the knowledge of COVID-19-related rumors in this interactive learning serious game. The main line design is shown in Figure 5, and the game logic is shown in Figure 6.

In this study, to achieve the effect of the serious game and the purpose of health rumor prevention, a feedback link of the serious game–based health rumor control prevention experiment was important. The feedback link was mainly achieved by setting up a feedback mechanism, which reflected the understanding of the research participants (players) of the game content (COVID-19 health rumor); by setting up the feedback mechanism, interactivity with the research participants could also be strengthened. At the same time, the feedback data were used to reflect the learning effect of the serious game.

The feedback mechanism of the serious game–based health rumor prevention experiment was implemented in the following 3 parts.

- The first part was to communicate the theme, rules, and intention of the game to the research participants by means of game instructions at the beginning of the game. This is an important step to quickly integrate the player into the

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learning process of a serious game and to let the player know what they will do next in the game.

- The second part was realized in the textual feedback of the gameplay process, where the player was provided with choices through interactive video scenarios, and instant feedback was provided. Instant feedback is an important part of the overall feedback process, which needs to be clearly communicated to the player. It is necessary to clearly communicate to the player whether their choices are correct and to strengthen the knowledge of health rumors and general health. The textual feedback content of the game process is shown inTable 2.
- The last part was to provide feedback after the player passed or failed in the game. At the end of the serious game, based on the player's overall understanding of COVID-19 health rumors and health knowledge, the feedback can strengthen the player's knowledge of health rumors.

The serious game created in this study used a COVID-19 health rumor as the learning content (see Figures 7 and 8). To achieve the purpose of preventing and controlling health rumors, a textual feedback mechanism was designed, involving 4 infection risks and 7 psychological stress settings. These were assigned to game failure or passing conditions, as shown in Figures 9 and 10. The game data reflected the performance of the research participant (player) in the game, with the settings shown in Table 3 to cater to the experiment's needs. The specific game data value settings and game passing/failure conditions are shown in Figure 11. Specifically, the story is as follows: The protagonist, a young person, suddenly finds themselves caught up in the COVID-19 pandemic in early 2020 in their city. Various pieces of information related to COVID-19 start to emerge around the protagonist, causing a massive explosion of fear and panic, particularly among many elderly people who turn to social media for information. They begin to demand that the protagonist follow their advice on preventing the pandemic. The goal of the game is to distinguish between real health knowledge and rumors throughout the daily life story, to use accurate knowledge to save the elderly citizens who are in a state of panic, and to slow down the spread of the virus. In the end, the game outcome is judged based on the actions and choices made by the protagonist.

Table 1. Selection of health rumors/health facts for the serious game content.

Time of day and COVID-19 health rumor/health fact	Setting
Morning	
R[a]1: Drinking plenty of boiled water at 60°C can prevent COVID-19.	Infection risk
R2: Domesticated dogs and cats can also spread COVID-19.	Psychological stress
R3: Putting used masks in a sterilizer can continue to provide protection and use.	Infection risk
The correct way to wear a mask (not an option).	General health knowledge
R4: Going out with ginger slices in the mouth can prevent COVID-19.	Psychological stress
R5: The government will use military aircraft to spread disinfectants in the sky.	Psychological stress
Noon	
R6: You should keep more than 1 m distance from strangers when you go out in times of an epidemic.	Infection risk
R7: Eye-to-eye contact may transmit COVID-19.	Psychological stress
R8: Shuanghuanglian Oral Liquid can effectively inhibit the COVID-19 virus.	Psychological stress
Afternoon	
R9: Disinfection is required for items after returning home from outside.	Infection risk
R10: High temperature can kill the virus, so hot blow-drying and hot water bathing can inhibit it.	Psychological stress
R11: Do not eat fish; pickled fish made from grass carp can transmit COVID-19.	Psychological stress

[a]R: rumor.

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Figure 5. The game process. R: rumor.

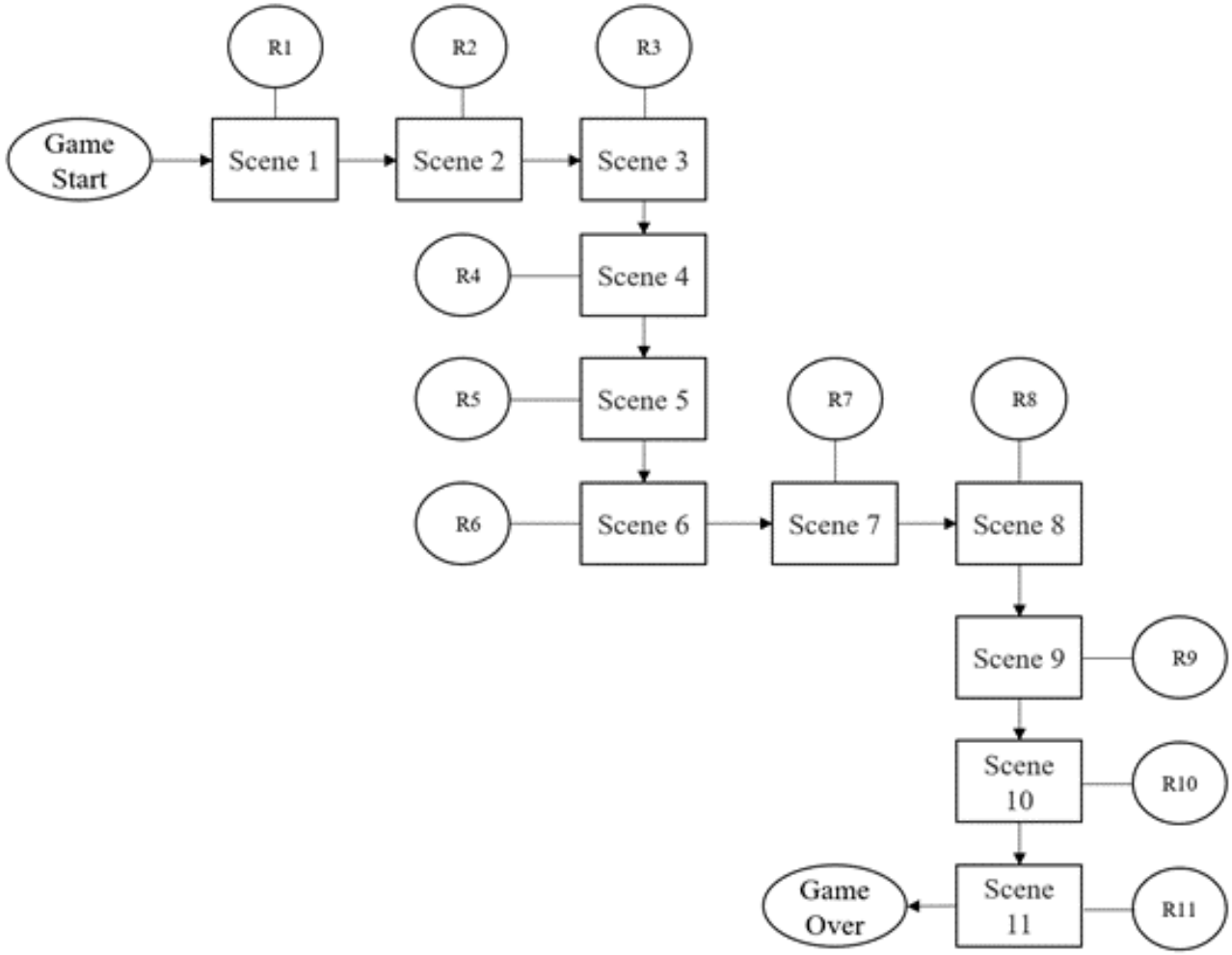

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Figure 6. The game judgment logic. N: no; Y: yes.

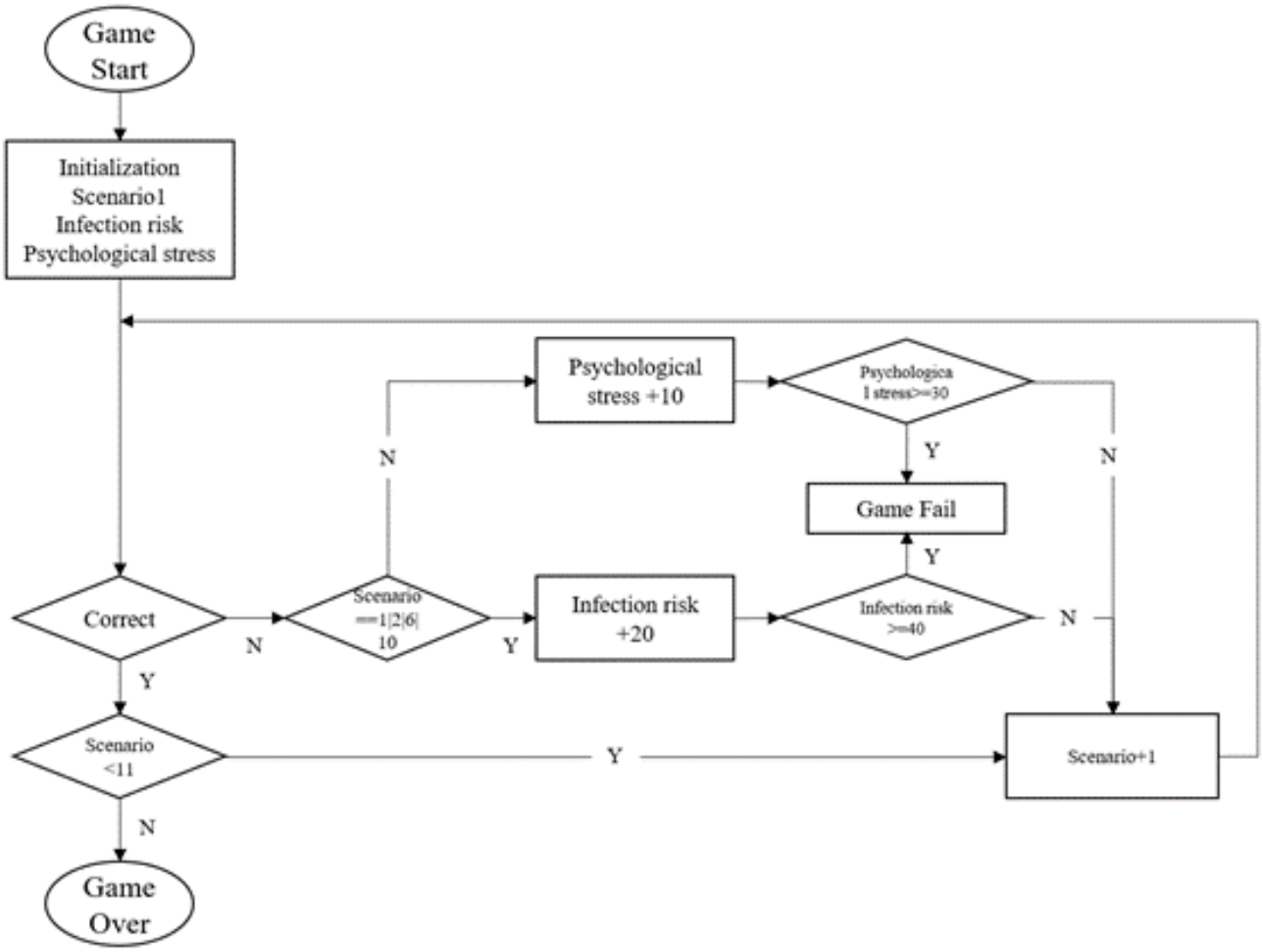

Table 2. Text feedback during gameplay.

Rumor number	Textual feedback (explanation and education) of scenario options during gameplay
R[a]1	Drinking water does not help, and scalding the mucous membrane of the mouth with hot water can increase the risk of infection.
R2	There is no evidence that COVID-19 can be transmitted to domesticated dogs and cats.
R3	Masks that have been used many times do not work to isolate droplets.
__[b]	Graphic feedback: follow the 3 steps (regulations) to wear the mask correctly.
R4	Ginger does not work to prevent the COVID-19.
R5	This is a rumor. There are no military aircraft to spread disinfectants in the sky; in addition, the local government has no right to do that. (This raises the players' sense of alertness and achieves the purpose of public education.)
R6	COVID-19 is spread via droplets and contact, and close contact increases the risk of infection.
R7	This is a rumor. The virus is transmitted through bodily fluids, droplets, and aerosols, not through the eyes. (This re-explains the mode of transmission of the COVID-19 virus.)
R8	Clearly inform that this is not yet clear information and should not be followed blindly.
R9	This is true. You should do that. (This provides possible contact transmission and health information on sterilization.)
R10	Dizziness and other symptoms can occur if you are exposed to bath bombs for too long or take a hot bath for too long.
R11	COVID-19 only infects mammals. Fish do not transmit COVID-19.

[a]R: rumor.

[b]Not applicable.

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Figure 7. The experimental serious game's gameplay content 1 (Chinese version). Question: "Hi boy, do you know where one can buy Shuanghuanglian Oral Liquid (a Chinese medicine)? I hear it is useful for COVID-19 treatment!" Answer options: (A) "Really? I also want to buy some." (B) "We do not know the drug's action, so do not drink it by yourself!".

Figure 8. The experimental serious game's gameplay content 2 (Chinese version). Question: "Please come back to home soon; the government will use military aircraft to spray disinfectants!" Answer options: (A) "Really? I'm leaving right now." (B) "Fake news, Mom!".

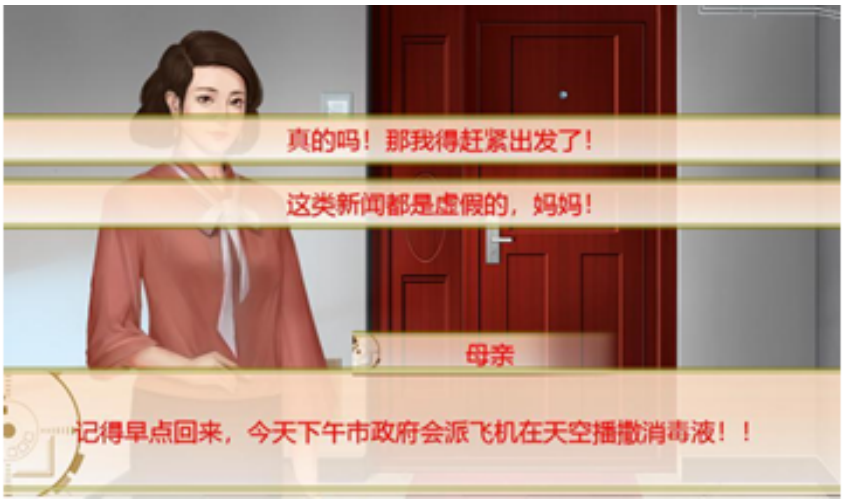

Figure 9. The experimental serious game: game over (Chinese version). Meaning: "The psychological pressure is 10, the risk of infection is 40, you are in a high-risk situation!".

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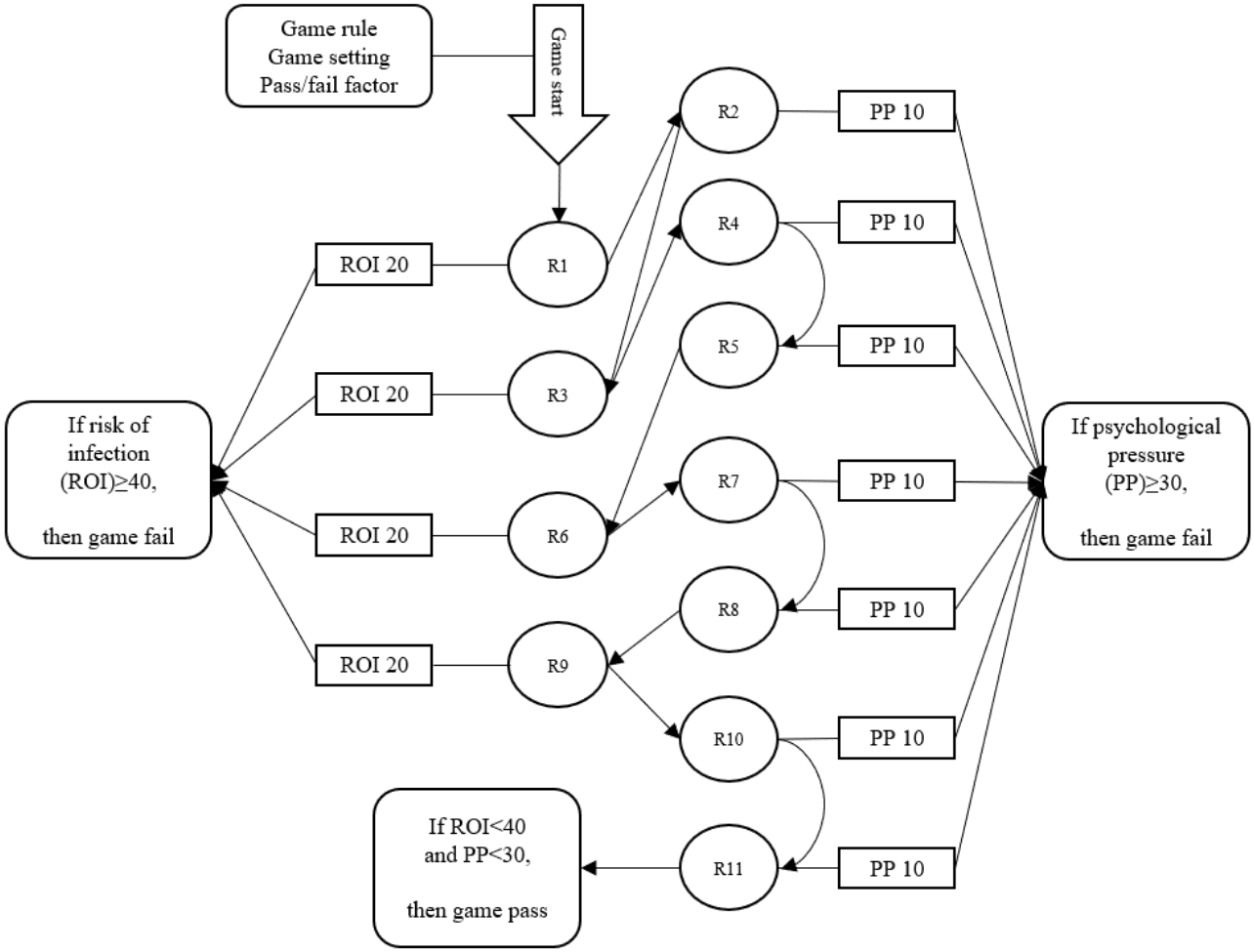
Figure 10. The preventive knowledge statement after the game, explaining how to wear a mask in 3 steps.

Table 3. Game data and game rating settings.

Game score	Error choice	Game failure	Game round
A	≤3	0	1
B	4-6	1	2
C	7-9	2	3
D	≥10	≥3	≥4

Figure 11. Game-related data values and failure/passing condition-setting thinking diagram.



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Step 4

Finally, the data and feedback of the participants were obtained, and the effect of the serious game on health rumor prevention was analyzed through the data and feedback to determine whether serious games are useful to prevent health rumors.

Data Collected

This study compared and analyzed the differences between acquiring and understanding health rumor information through the learning modes of serious games and traditional media. A total of 100 people were selected to participate in the serious game experiment (G1 group), while 100 people who did not participate in the serious game experiment only studied by traditional media (G2 group). To ensure the objectivity of the controlled experiment, the educational background of the 200 participants was investigated before the formal study while keeping the 2 groups as similar as possible in terms of gender and age, as Table 4 shows. Next, we sent the testing questionnaire related to health commonsense and health rumors to G1 and G2.

Table 4. Demographic information of groups G1 and G2.

Characteristics	G1 (n=100), n (%)	G2 (n=100), n (%)
Gender		
Male	42 (42)	40 (40)
Female	58 (58)	60 (60)
Age (years)		
40-45	24 (24)	27 (27)
46-50	30 (30)	25 (25)
51-55	19 (19)	17 (17)
56-60	18 (18)	21 (21)
≥61	9 (9)	10 (10)
Educational background		
Less than high school	15 (15)	15 (15)
High school/technical secondary school	50 (50)	50 (50)
Junior college	20 (20)	20 (20)
Bachelor's degree and higher	15 (15)	15 (15)
Income		
Low	29 (29)	24 (24)
Average	48 (48)	55 (55)
High	23 (23)	21 (21)

Variables and Hypotheses

Based on the framework of serious games, a questionnaire was designed that included the following variable definitions:

- Independent variables: The learning mode refers to the way that information is obtained and knowledge learned; the variables were M1 (learning through serious games) and M2 (learning through traditional and new media). For gender, age, income, and education, in the preparation stage of the research, education was used as the main grouping basis, and the age distribution and gender ratio of the 2 groups of experimental objects were kept consistent.
- Intermediary variables: Game data for serious game experiments (A/B/C/D) refer to the player's performance data during the game, including the number of selection errors, the number of game failures, and the number of game passings. Personal performance was divided into 4 mediating variables: excellent (A), good (B), medium (C), and poor (D).
- Dependent variables: The variables were cognitive questionnaire (1) overall correct response rate of judgment and recognition of the COVID-19 health rumor (X1 for G1, Y1 for G2 [G2 did not participate in the serious game experiment]), (2) correct rate of judgment and recognition the COVID-19 health rumor part 1 (X2 for G1 [COVID-19 health rumor not included in the serious game experiment], Y2 for G2), and (3) correct rate of judgment and identification of the COVID-19 health rumor part 2 (X3 for G1, Y3 for G2 [COVID-19 pneumonia rumor included in the traditional media experiment for G2]).
- Intervening variables: The comprehension, cognitive level, learning ability, learning interest, and information attention of the G1 group affected the outcome of the dependent variables to a certain extent. The specific influencing relationship between various variables is shown in Figure 12.

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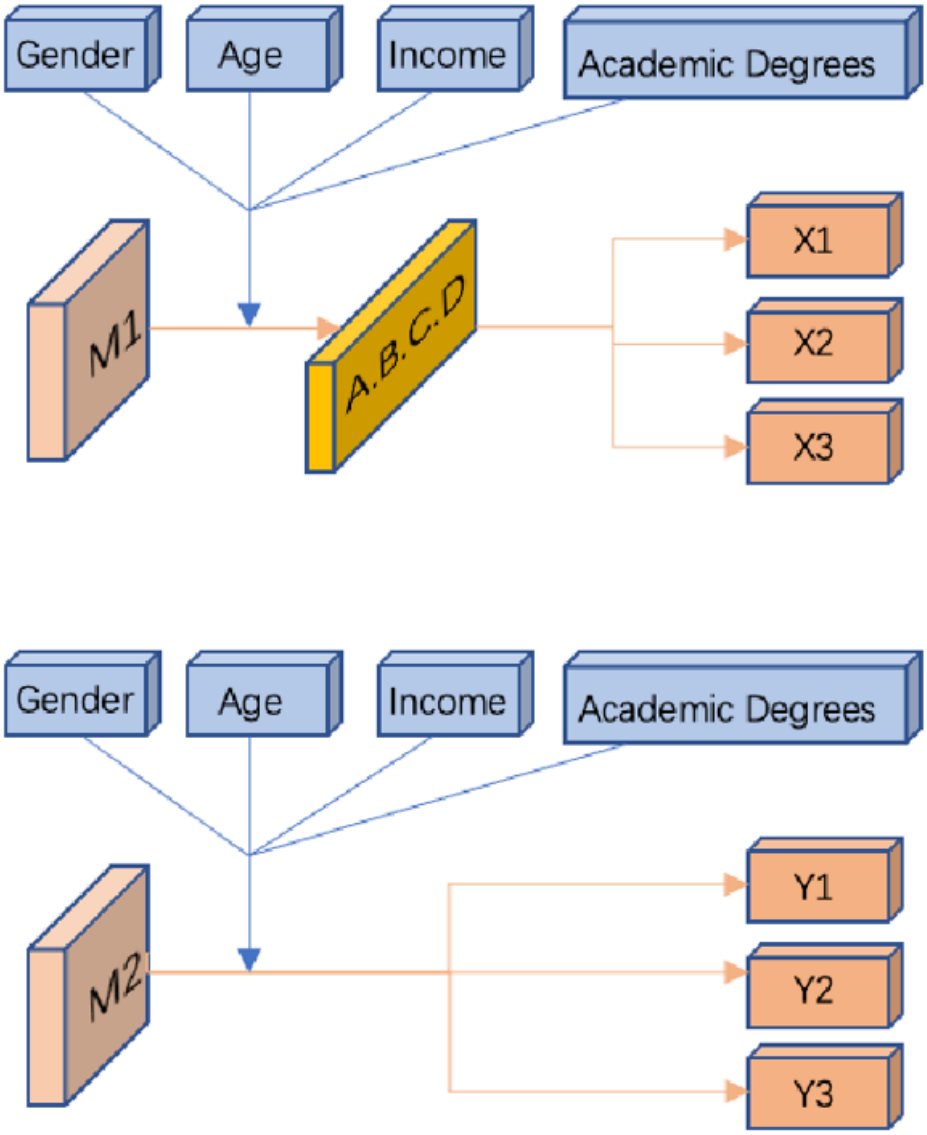
Figure 12. Relationship between experimental study variables.



The following 10 hypotheses were proposed in this experimental study:

- Hypothesis 1 (H1): Serious game experiments can help research participants acquire and understand health rumor knowledge and health commonsense.
- H2: The serious game learning mode is more capable of inspiring the interest of research participants in their understanding of the knowledge acquired and their learning of health commonsense compared to the traditional learning mode.
- H3: The serious game learning mode is more impactful than the traditional learning mode.
- H4: In judging and recognizing the COVID-19 health rumor, G1 has a stronger judgment ability than G2 and a higher accuracy in identifying the rumor in the serious game experiment.
- H5: In judging the COVID-19 health rumor, for the rumor not included in the serious game experiment, without the influence of M1, the ability of G1 and G2 is not much different, and the accuracy rate of identifying the COVID-19 health rumor is roughly the same for both groups. The manifestation in the variable is X2≈Y2.
- H6: In judging and recognizing the COVID-19 health rumor, G1 has an overall stronger judgment ability than G2 and a higher accuracy rate of identifying the COVID-19 health rumor. The specific manifestation in the variable is X3>Y3.
- H7: Gender affects G1's and G2's judgment and recognition of the COVID-19 health rumor.
- H8: Age affects G1's and G2's judgment and recognition of the COVID-19 health rumor.
- H9: Income affects G1's and G2's judgment and recognition of the COVID-19 health rumor.
- H10: Academic qualifications affect G1's and G2's judgment and recognition of the COVID-19 health rumor.

Ethical Considerations

According to the guidelines of the People's Republic of China [57], this study met the conditions for exemption from ethical review.

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Results

Analysis of Data Collected

According to the collected game data, 36% (72/200) of players received A, 41% (82/200) received B, 18% (36/200) received C, and the remaining 5% (10/200) received D. The accuracy rate of the judgment and recognition of the COVID-19 health rumor and health commonsense in the cognitive questionnaire of G1 and G2 groups are tabulated in Table 5. The overall accuracy was 84% for G1 and 78% for G2, with an average of 81%. The relationship of the parameters X1-X3 (G1) and Y1-Y3 (G2) are shown in Figures 13 and 14, respectively.

Table 5. Cognitive questionnaire data (judgment and recognition of rumor knowledge and health commonsense).[a]

Question number	Accuracy G1 (%)	Accuracy G2 (%)	Average accuracy (%), (G1+G2)/2
1	72	76	74
2	93	98	96
3	75	79	77
4	77	76	77
5	64	63	64
6	87	91	89
7	77	85	81
8	72	70	71
9	67	63	65
10	80	74	77
11	67	64	66
12	80	88	84
13	88	96	92
14	75	71	73
15	81	83	82
16	91	95	93
17	68	63	66
18	80	83	82
19	58	56	57
20	97	71	84
21	99	61	80
22	98	65	82
23	99	92	96
24	91	81	86
25	100	92	96
26	100	89	95
27	90	76	83
28	92	85	89
29	92	67	80
30	99	95	97

[a]All the correct rate values are kept to integer bits.

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Figure 13. Comparison of corresponding dependent variables (G1).

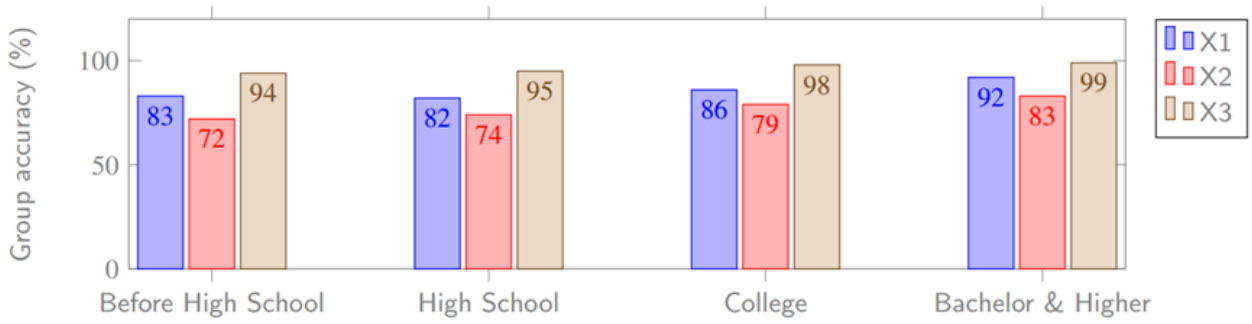
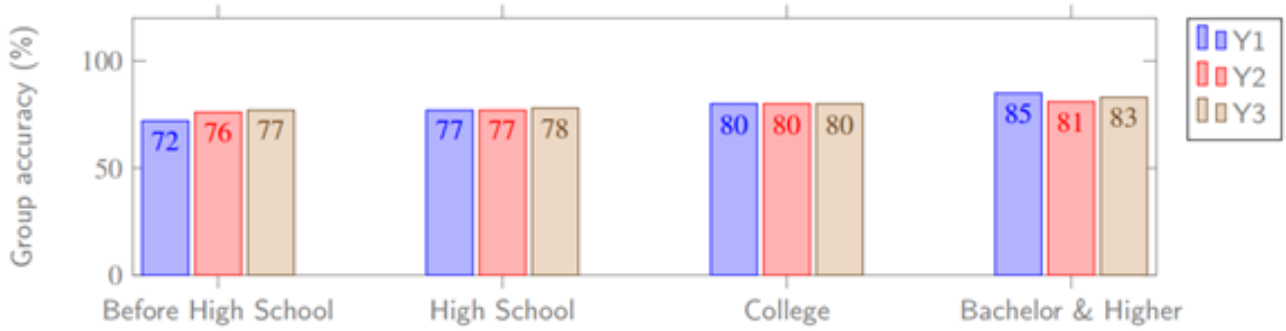


Figure 14. Comparison of two groups and corresponding dependent variables (G2).



According to the data, the overall average correct rate of judgment and recognition of G1 and G2 was 84% and 78%, respectively. In addition, the related data collected showed that 76% of the participants believed that the serious game learning mode is more interesting than the traditional learning mode. This finding shows that G1 has good interest in games. Furthermore, 60% of the participants thought that the game learning mode is more helpful than the traditional learning mode, and 65% thought that the serious game learning mode makes a more profound impression. Therefore, from the perspective of the selection of participants, the serious game learning mode is more interesting, helpful, and impactful than the traditional learning mode. Therefore, H2 and H3 hold.

Analysis of Dependent Variables (X, Y) and Intermediary Variables (A, B, C, D)

According to the data of the dependent variables in Table 6, we could not directly prove that the impact of M1 on X1 was greater than that of M2 on Y1. At the same time, when the knowledge of health rumors and health commonsense was not included in the game content, the correct rate of judgment and recognition of G1 and G2 was almost the same, and even G1 had a relatively lower rate. However, X3 was 96%, which is much higher than Y3 (79%), and X3 exceeded X2 by up to 23 percentage points. This condition implies that the impact of M1 on X1 is greater than the impact of M2 on Y1. It not only shows that G1 had relatively strong learning ability but also that after the serious game learning model experiment, there was a significant positive effect on the accuracy rate of the judgment and recognition accuracy of the COVID-19 health rumor and health commonsense. At the same time, X1>Y1, X2≈Y2, and X3 >Y3. Therefore, H4, H5, and H6 are established.

The intermediary variables A, B, C, and D were sequentially observed, corresponding to the dependent variables X1, X2, and X3. It can be clearly seen in Table 7 that A-X1>B-X1>C-X1>D-X1, A-X2>B-X2>C-X2>D-X2, and A-X3>B-X3>C-X3>D-X3. The dependent variables corresponding to the intermediary variables showed a decreasing trend from A to D, indicating that M1 affected X1 and X3 through A, B, C, and D and the degree of influence was in the order of A>B>C>D. These data showed that the higher the average game score, the higher the correct rate of recognition and judgment. Therefore, combined with the previous analysis, H1 holds.

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Table 6. Dependent variables X and Y.

Variable	Value (%)
X1[a]	84
X2[b]	76
X3[c]	96
Y1[d]	78
Y2[e]	78
Y3[f]	79

[a]X1: cognitive questionnaire overall correct response rate of judgment and recognition of the COVID-19 health rumor for G1.
[b]X2: cognitive questionnaire correct rate of judgment and recognition part 1 for G1.
[c]X3: cognitive questionnaire correct rate of judgment and identification of the COVID-19 health rumor part 2 for G1.
[d]Y1: cognitive questionnaire overall correct response rate of judgment and recognition of the COVID-19 health rumor for G2.
[e]Y2: cognitive questionnaire correct rate of judgment and recognition part 1 for G2.
[f]Y3: cognitive questionnaire correct rate of judgment and identification of the COVID-19 health rumor part 2 for G2.

Table 7. Intermediary variables (A, B, C, D) and dependent variables (X1-X3).

Intermediary variable	Dependent variables		
	X1[a] (%)	X2[b] (%)	X3[c] (%)
A	87	80	98
B	83	76	96
C	80	72	94
D	72	62	89

[a]X1: cognitive questionnaire overall correct response rate of judgment and recognition of the COVID-19 health rumor for G1.
[b]X2: cognitive questionnaire correct rate of judgment and recognition part 1 for G1.
[c]X3: cognitive questionnaire correct rate of judgment and identification of the COVID-19 health rumor part 2 for G1.

Analysis of Independent Variables

Gender

We grouped participants, ensuring the educational composition of the 2 groups was as consistent as possible. By observing and comparing the G1 independent variable (gender) and its corresponding intermediary variables (Table 8), we found that the game score reached A, where the male participants were better than the female participants but changed from B to D when the female participants were better than the male participants. This condition was especially true when the game score reached B, where the female participants were much better than the male participants. This situation may also be influenced by the unequal relationship of the overall gender. There was no gender difference in the numbers from game rating A to D.

Subsequently, by observing and comparing the G1 and G2 independent variable gender and the corresponding dependent variables (Table 9), we observed that regarding the dependent variables X1, X2, and X3, corresponding to the independent variable gender (female, male), the comparisons were female<male, female<male, and female>male, respectively. Regarding Y1, Y2, and Y3, corresponding to gender, the comparisons were female<male, female>male, and female<male, respectively. As such, there was no gender difference. Therefore, H7 does not hold.

Table 8. G1 gender and corresponding intermediary variables.

Intermediary variable	Gender		Comparison
	Female	Male	
A	16	20	Female<male
B	27	14	Female>male
C	12	6	Female>male
D	4	1	Female>male

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Table 9. G1 and G2 gender and corresponding dependent variables.

Dependent variable	Gender		Comparison
	Female (%)	Male (%)	
X1[a]	83	84	Female<male
X2[b]	75	77	Female<male
X3[c]	97	95	Female>male
Y1[d]	76	81	Female<male
Y2[e]	79	77	Female>male
Y3[f]	71	88	Female<male

[a]X1: cognitive questionnaire overall correct response rate of judgment and recognition of the COVID-19 health rumor for G1.

[b]X2: cognitive questionnaire correct rate of judgment and recognition part 1 for G1.

[c]X3: cognitive questionnaire correct rate of judgment and identification of the COVID-19 health rumor part 2 for G1.

[d]Y1: cognitive questionnaire overall correct response rate of judgment and recognition of the COVID-19 health rumor for G2.

[e]Y2: cognitive questionnaire correct rate of judgment and recognition part 1 for G2.

[f]Y3: cognitive questionnaire correct rate of judgment and identification of the COVID-19 health rumor part 2 for G2.

Age

There were apparent differences in the age ranges between the 2 groups, as shown in Table 4. Therefore, random sampling in G1 and G2 was conducted, and 25 participants under 51 and 56 years old each were selected, with 50 participants in each group for comparative observation and analysis of the corresponding variable data.

First, by observing and comparing the high-age and low-age groups' independent and variable age groups and their corresponding intermediary variables (Table 10), we found that the number of people who achieved A and B game scores were all of low age. As a result, the number of people in the low-age group was greater than the number of people in the high-age group; among those with game scores C and D, the number of people in the high-age group was greater than the number of people in the low-age groups, indicating that to a certain extent, the independent variable age positively affects the intermediary variables A, B, C, and D. Second, by observing and comparing the high- and low-age groups of the G1 and G2 independent variable age with corresponding dependent variables (Table 11), the values of independent variables X1, X2, and X3 could be determined. The values of the low-age group were greater than those of the high-age group; the independent variables Y1, Y2, and Y3 also exhibited this behavior. Therefore, H8 holds.

Table 10. G1 and G2 targets of different ages.

Intermediary variable	Age	
	Low (n=25), n (%)	High (n=25), n (%)
A	8 (32)	13 (52)
B	6 (24)	8 (32)
C	8 (32)	3 (12)
D	3 (12)	1 (4)

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Table 11. G1 and G2 age groups and corresponding dependent variables.

Dependent variable	Age	
	Low (%)	High (%)
X1[a]	76	87
X2[b]	69	80
X3[c]	88	98
Y1[d]	68	82
Y2[e]	66	80
Y3[f]	72	86

[a]X1: cognitive questionnaire overall correct response rate of judgment and recognition of the COVID-19 health rumor for G1.
[b]X2: cognitive questionnaire correct rate of judgment and recognition part 1 for G1.
[c]X3: cognitive questionnaire correct rate of judgment and identification of the COVID-19 health rumor part 2 for G1.
[d]Y1: cognitive questionnaire overall correct response rate of judgment and recognition of the COVID-19 health rumor for G2.
[e]Y2: cognitive questionnaire correct rate of judgment and recognition part 1 for G2.
[f]Y3: cognitive questionnaire correct rate of judgment and identification of the COVID-19 health rumor part 2 for G2.

Income

The relevant data collected are shown in Table 4. Nearly half of the participants in G1 and G2 believed that their income level was average, and the number of people who believed that their income was high or low was relatively small. By observing and comparing the high- and low-income subgroups in G1 and G2 with corresponding dependent variables, we found that the dependent variables corresponding to the 2 independent variable subgroups were not identical, as shown in Table 12. Therefore, H9 does not hold.

Table 12. High- and low-income groups and corresponding dependent variables of G1 and G2.

Dependent variable	Income	
	High (%)	Low (%)
X1[a]	84	84
X2[b]	82	78
X3[c]	88	94
Y1[d]	73	74
Y2[e]	69	72
Y3[f]	80	78

[a]X1: cognitive questionnaire overall correct response rate of judgment and recognition of the COVID-19 health rumor for G1.
[b]X2: cognitive questionnaire correct rate of judgment and recognition part 1 for G1.
[c]X3: cognitive questionnaire correct rate of judgment and identification of the COVID-19 health rumor part 2 for G1.
[d]Y1: cognitive questionnaire overall correct response rate of judgment and recognition of the COVID-19 health rumor for G2.
[e]Y2: cognitive questionnaire correct rate of judgment and recognition part 1 for G2.
[f]Y3: cognitive questionnaire correct rate of judgment and identification of the COVID-19 health rumor part 2 for G2.

Education

Based on the cognitive questionnaire, the independent variable education was divided into 4 segments, as shown in Table 4. First, 4 groups of the G1 independent variable education and corresponding intermediary variables were compared (Table 13). Through comparison and observation, we found that the higher the education level, the better the performance in the game, which demonstrates that the dependent variable education positively affects the intermediary variables. Second, the grouping and corresponding dependent variables of G1 and G2 based on academic qualifications are shown in Table 14. We found that education has a positive effect on the corresponding dependent variables. Therefore, H10 holds.

Finally, a thorough investigation of the selection tendency between the learning modes of serious games (M1) and traditional learning (M2) was conducted on G1 involving a comparison experiment of interest, help, and impression (Figure 15). The data showed that 76% (152/200) of the participants thought the serious game learning mode was more interesting than the traditional learning mode, indicating that G1 had a reasonable learning interest in games. Furthermore, 60%

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(120/200) of the participants thought that the serious game learning mode was more helpful than the traditional learning mode, and 65% (130/200) thought that the serious game learning mode was more impressive than the traditional learning mode. Therefore, from the perspective of the selection tendency of the participants, the serious game learning mode is more interesting, helpful, and impressive than the traditional learning mode, which strengthens the hypotheses.

Table 13. Proportion of game scores in different education segments.

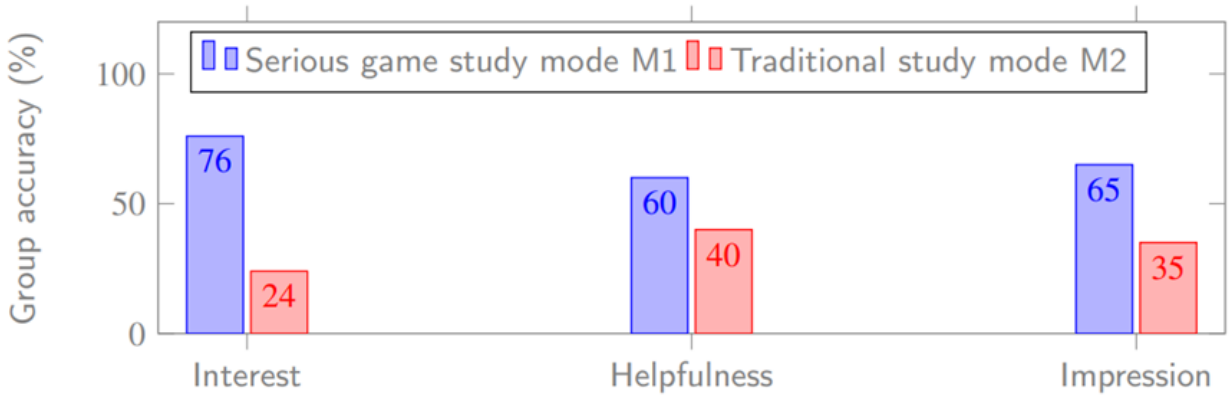
Segment	Intermediary variables			
	A (%)	B (%)	C (%)	D (%)
Less than high school	20	47	20	13
High school	28	44	20	8
College degree	45	40	15	0
Bachelor's degree and higher	59	23	13	0

Table 14. Education segments and corresponding dependent variables of G1 and G2.

Segment	Dependent variables					
	X1[a] (%)	X2[b] (%)	X3[c] (%)	Y1[d] (%)	Y2[e] (%)	Y3[f] (%)
Less than high school	83	72	94	72	76	77
High school	82	74	95	77	77	78
College degree	86	79	98	80	80	80
Bachelor's degree and higher	92	83	99	85	81	83

[a]X1: cognitive questionnaire overall correct response rate of judgment and recognition of the COVID-19 health rumor for G1.
[b]X2: cognitive questionnaire correct rate of judgment and recognition part 1 for G1.
[c]X3: cognitive questionnaire correct rate of judgment and identification of the COVID-19 health rumor part 2 for G1.
[d]Y1: cognitive questionnaire overall correct response rate of judgment and recognition of the COVID-19 health rumor for G2.
[e]Y2: cognitive questionnaire correct rate of judgment and recognition part 1 for G2.
[f]Y3: cognitive questionnaire correct rate of judgment and identification of the COVID-19 health rumor part 2 for G2.

Figure 15. Comparison between serious game learning mode and traditional learning mode.



Discussion

Principal Findings

Based on a self-made serious game, this paper investigated the health rumor phenomenon, and a study on the user behavior and willingness to disseminate health information among Chinese elderly WeChat users (SNS) was conducted during the early COVID-19 pandemic. After a survey, participants were chosen, and a COVID-19 health rumor was selected as the study content and the experimental platform with the self-made game was established. The UTAUT2 model was upgraded by adding parameters, several hypotheses were proposed, and a control experiment was designed. The experiment results show that the serious game is useful for health rumor prevention.

After collecting game data and the correct response rates of G1 and G2 in the cognitive questionnaire for the judgment and recognition of the COVID-19 health rumor, the game data and the cognitive questionnaire data were combined to determine the relationship between specific variables. Finally, the

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experimental hypotheses were tested and evaluated, proving that H1-H6, H8, and H10 hold, while H7 and H9 do not hold.

The findings affirm that serious games are a powerful tool to enhance learning and commonsense against health rumors in the context of elderly users of SNS. As Wu [43] argued, perceptions of rumor credibility affect the users' desire to find accurate information (*cognitive gratification*) because they use SNS for verifying the contents of rumors and for acquiring more knowledge and information. Equipping oneself with better knowledge and commonsense against health rumors could have a profound effect on the stability and harmony of society [58], minimize the chance of being misinformed [35], and help create effective control strategies against rumor spreading [45]. Furthermore, as serious games provide the means for people to receive direct feedback relative to their judgment of health rumors, using these games is considered a more humane and emotional approach [47]. In addition, it also provides a suitable channel for health care providers to increase awareness [49] since tackling COVID-19 requires everyone to follow medical advice. Based on the verification of our hypotheses, we found that the effect of serious games correlates with parameters such as education, which suggests that the future rumor management for the youth is perfectly suited to the use of serious games, especially in China, where the education level of the youth is much higher than that of the middle-aged and older populations.

Limitations

Given the seminal findings of this study, it has some limitations. First, the cognitive questionnaire was administered offline, and the midelder/elder participants were reluctant in terms of their willingness to cooperate with the research. As such, there was a risk of the sample distribution being uneven or biased. Second, strict epidemic prevention and control have geographically limited experimental samples. Third, the serious game design was restricted to the COVID-19 health information and had limited interactivity.

Conclusion

This experimental study on preventing new health rumors via serious games proves that the serious game learning mode can help research participants understand and learn about health and rumors. Furthermore, serious games make a more profound impression on people than traditional learning modes, while providing fertile ground for more comprehensive research in the future. In addition, serious games could provide suggestions and support in future research on rumor prevention and detection. In particular, the Chinese government ended the zero-COVID policy in December 2022, and many new health rumors related to the Omicron variant were found on the internet in China. This study could provide a method of challenging the new issue and the game could be updated for the current situation. More importantly, we discovered that serious games can act as an "informational vaccine" against rumors (if rumors are considered a kind of "informational virus or bacterium"), and in the future, we can conduct further research in this direction.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
A priori questionnaire for health rumor recognition.
[DOCX File , 16 KB - games_v12i1e45546_app1.docx]

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Abbreviations

GM: genetically modified
HCW: health care worker
IP: Internet Protocol
SNS: social networking service
TCP: Transmission Control Protocol
UDP: User Datagram Protocol
UTAUT: unified theory of acceptance and use of technology

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Original Paper

Pressure Ulcer Management Virtual Reality Simulation (PU-VRSim) for Novice Nurses: Mixed Methods Study

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Abstract

Background: Pressure ulcers (PUs) are a common and serious complication in patients who are immobile in health care settings. Nurses play a fundamental role in the prevention of PUs; however, novice nurses lack experience in clinical situations. Virtual reality (VR) is highly conducive to clinical- and procedure-focused training because it facilitates simulations.

Objective: We aimed to explore the feasibility of a novel PU management VR simulation (PU-VRSim) program using a head-mounted display for novice nurses and to investigate how different types of learning materials (ie, VR or a video-based lecture) impact learning outcomes and experiences.

Methods: PU-VRSim was created in the Unity 3D platform. This mixed methods pilot quasi-experimental study included 35 novice nurses categorized into the experimental (n=18) and control (n=17) groups. The PU-VRSim program was applied using VR in the experimental group, whereas the control group received a video-based lecture. The PU knowledge test, critical thinking disposition measurement tool, and Korean version of the General Self-Efficacy Scale were assessed before and after the intervention in both groups. After the intervention, the experimental group was further assessed using the Clinical Judgment Rubric and interviewed to evaluate their experience with PU-VRSim.

Results: The results compared before and after the intervention showed significant improvements in PU knowledge in both the experimental group (P=.001) and control group (P=.005). There were no significant differences in self-efficacy and critical thinking in either group. The experimental group scored a mean of 3.23 (SD 0.44) points (accomplished) on clinical judgment, assessed using a 4-point scale. The experimental group interviews revealed that the VR simulation was realistic and helpful for learning about PU management.

Conclusions: The results revealed that PU-VRSim could improve novice nurses' learning of PU management in realistic environments. Further studies using VR for clinical training are recommended for novice nurses.

(JMIR Serious Games 2024;12:e53165) doi:10.2196/53165

KEYWORDS

virtual reality; nursing; simulation; virtual training; pressure ulcer; simulation training; nurse; clinician; health care worker; ulcer; hospital; health care center; PU-VRSim; mixed methods study; health professional; medical education; training; games; gamification; learning; decubitus ulcer

Introduction

Pressure ulcers (PUs) refer to the skin damage caused by ischemia of the skin, subcutaneous fat, and muscles due to a continuous blood circulation disorder in a compressed body [1]. PUs result in a reduction of oxygen and nutrition delivered to the cells, which can contribute to the development of cancer and cardiovascular disease, ultimately amounting to high medical expenses [1]. The incidence of PUs is estimated at 12% in hospitals, representing a common but important health problem because it leads to high nursing burdens, increased

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medical costs, and mortality [2]. PUs are among the global health indicators and are included in the standard of nursing [3]. Most PUs are preventable by maintaining proper skin integration, and prevention is considered as important as treatment [3,4].

Nurses have a great responsibility in the well-being and safety of patients [5]. In addition, nurses are required to perform appropriate nursing for the prevention and management of PUs. However, they experience difficulties in performing clinical nursing and providing the necessary care to patients [6]. Novice nurses are those with less than 3 years of working experience based on the Benner novice-to-expert model; although they can recognize the basic order in nursing and take decisions, it is generally more difficult for novice nurses to establish priorities [7]. Particularly, novice nurses who have completed the regular curriculum do not have sufficient opportunities for practice during their training and thus experience difficulties in adapting to a new environment and changes in roles in the clinical field, leading to stress and anxiety [8,9]. Therefore, a program that can help novice nurses adapt to the clinical environment is needed.

Virtual reality (VR) is characterized by interaction, immersion, and imagination, and has been increasingly used in the curriculum for nursing with great potential for course development [10]. VR using a head-mounted display (HMD) provides the learning experience of communication between medical staff and patients, as well as simulations of standardized and controlled situations [11]. VR use has been easily accepted by learners in various medical environments and plays an essential role in improving their performance [11,12]. In nursing education, VR has been used in areas such as cardiopulmonary resuscitation, respiratory nursing, and delivery nursing, as well as for improving professional knowledge, clinical reasoning skills, and learning satisfaction [13,14]. In addition, as a learning method, VR meets the expectations and learning styles of the new generation of young learners [14,15].

In nursing education, teaching methods have shifted from traditional lecture-style education to simulation education [15]. Lecture-style education is effective in terms of knowledge transfer to novice nurses. However, there is a limit of this approach in improving nursing work skills in hospitals where various problems can occur [16]. Video-based education for novice nurses is a time-efficient and economically effective method owing to the heavy workload and lack of physical time; however, this format often lacks an appropriate feedback system [17]. Simulation education provides educational opportunities for clinical practice without putting patients or others at risk, and learners have the advantage of safely learning from experience [18]. VR is a representative technology for simulation education [15]. VR simulation can be used by novice nurses freely, which has been shown to improve their knowledge, critical thinking, and self-efficacy [13,18], thereby helping them transform into professional clinical nurses.

Simulation creates a learning environment in which learners can experience intervention and treatment in a safe manner, and various educational theories and structural models can be applied to achieve effective learning results [19].

The Analysis, Design, Development, Implementation, and Evaluation (ADDIE) instructional design model [20] is an effective and efficient development model based on the five steps of analysis, design, development, implementation, and evaluation. Kolb's experiential learning theory [21] states that learning is achieved through the process of "active experimentation," starting with a "concrete experience," "reflective observation," and "abstract conceptualization." Through the concrete experience of simulation, learners make reflective observations and abstract conceptualizations by trying and practicing new techniques in a safe environment, and they perform active experimentation to understand the patient's situation in an actual clinical environment and provide appropriate nursing practice.

This study aimed to develop a nursing PU management VR simulation program (PU-VRSim) and assess the feasibility of the novel virtual program for novice nurses. Toward this end, we applied the ADDIE instructional design model and Kolb's experiential learning theory. The first objective was to assess the feasibility of implementing PU-VRSim for nursing education on PUs. The second objective was to compare the effects of the VR program and video-based lectures on PU knowledge, self-efficacy, and critical thinking, and confirm the level of clinical judgment and experience of participants after undergoing PU-VRSim. The main research questions included: (1) Is implementing PU-VRSim for nursing education feasible? (2) What is the effect of PU-VRSim compared with that of video-based lectures? and (3) What are the participants' experiences with PU-VRSim?

Methods

Design

This study applied Kolb's experiential learning theory [21] based on the ADDIE model [20], which is a model of instructional design that was used to develop PU-VRSim for preventing and managing PUs using VR in a nursing education program. This was a mixed methods, pilot quasi-experimental study [22] including nurses with less than 2 years of clinical experience to confirm the effectiveness of PU-VRSim. PU-VRSim was created in the Unity 3D platform (Unity Technologies). Participants experienced the program through an HMD and hand controllers (HTC Corporation, VIVE pro).

Participants

For data collection, nurses with less than 2 years of clinical experience were notified of the purpose, period, conditions of participation, and benefits and disadvantages of participating in the study in the nurses' community bulletin boards. Recruitment for the preintervention survey, intervention, and postintervention survey was conducted through convenience sampling. Participants were categorized into the two groups based on the work schedule of the novice nurses, and participants were blinded to their group allocation. A total of 35 participants were recruited voluntarily from October 10 to December 31, 2022, with 18 assigned to the experimental group and 17 assigned to the control group from January 1 to March 31, 2023. In both groups, one researcher conducted a one-on-one survey and measured general characteristics, PU knowledge,

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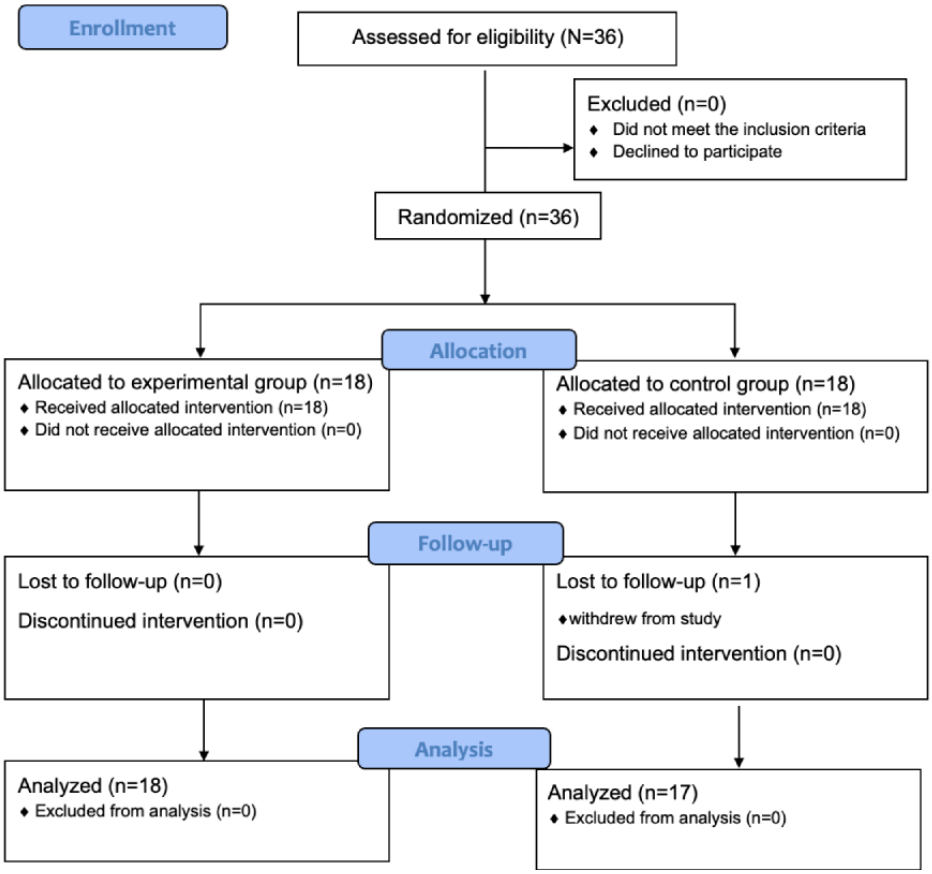
critical thinking, and self-efficacy using preliminary questionnaires, which were sent to the two groups before implementing the program. Regarding the intervention, the experimental group participated in the PU-VRSim program in the simulation room, whereas the control group participated in a video-based lecture on the prevention and care of PUs. After the program, PU knowledge, critical thinking skills, and self-efficacy were measured in both groups. The effectiveness of the program was further assessed with participants in the experimental group via interviews and the Lasater Clinical Judgment Rubric (LCJR) (Figure 1).

The sample size required to compare variables between groups with the *t* test was calculated using the G*Power 3.1 program according to the method of Polit and Sherman [23], using a significance level of α=.05, effect size (*f*) of 0.80, and power (1–β) of .90 [24]. Considering that the sample size satisfying the above conditions was at least 16 people per group, 36 participants were selected, including 18 in the experimental group and 18 in the control group, prior to data collection. One participant in the control group dropped out of the study. Finally, 35 participants were included in the analysis.

Figure 1. Flow diagram of participants' enrollment, allocation, follow-up, and analysis.



Ethical Considerations

Data collection began after obtaining approval from the Institutional Review Board (40525-202204-HR-016-03) of Keimyung University in Daegu City for the protection of the research participants. The purpose of the study, procedures, guarantee of anonymity and confidentiality, and assurance that there are no consequences in case of withdrawal from the study were explained to the research participants, and they were allowed to respond to the questionnaire only when they agreed to participate in the research. The researchers conducted the preintervention survey, application of programs, and postintervention survey. All data collected during this study were anonymized. Participants were compensated for their contribution with a beverage coupon worth 10,000 KRW (~US $8) after the postintervention survey.

Instruments

PU Knowledge

The Pieper–Zulkowski pressure ulcer knowledge test (PZ-PUKT), a PU knowledge tool developed by Pieper and Zulkowski [25] and modified and supplemented by Park [26], was used in this study. The PZ-PUKT comprises 39 questions, including 19, 9, and 11 questions on PU stage confirmation, wound assessment, and dressing methods, respectively. Each question was answered "yes," "no," or "don't know," with 1 point for correct answers and 0 points for incorrect answers. The total score ranges from 0 to 39, with higher scores indicating greater knowledge of PUs. The Cronbach α value was 0.80 and 0.70 in the studies by Pieper and Zulkowski [25] and Park [26], respectively, and was 0.69 in our study.

Critical Thinking

The critical thinking disposition measurement tool developed by Yun [27] and modified and supplemented by Shin et al [28]

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was used for evaluating the impact of the intervention on critical thinking skills. This tool comprises 27 questions divided into 7 subdomains: intellectual passion/curiosity (5 questions), prudence (4 questions), confidence (4 questions), systemicity (3 questions), intellectual fairness (4 questions), healthy skepticism (4 questions), and objectivity (3 questions). Answers are rated on a scale of 1 point for "not so" to 5 points for "very much so"; a higher score indicates a stronger critical thinking disposition. The Cronbach α value was 0.84 in the studies of both Yun [27] and Shin et al [28] and was 0.83 in our study.

Self-Efficacy

The Korean version of the General Self-Efficacy Scale developed by Schwarzer and Jerusalem [29] and adapted by Schwarzer et al [30] was used to determine general self-efficacy. The Korean version of the General Self-Efficacy Scale comprises 10 questions rated on a 4-point Likert scale ranging from 10 to 40, with higher scores indicating higher self-efficacy. The Cronbach α value was 0.90 and 0.88 in the studies by Schwarzer and Jerusalem [29] and Schwarzer et al [30] and it was 0.86 in our study.

Clinical Judgment Rubric

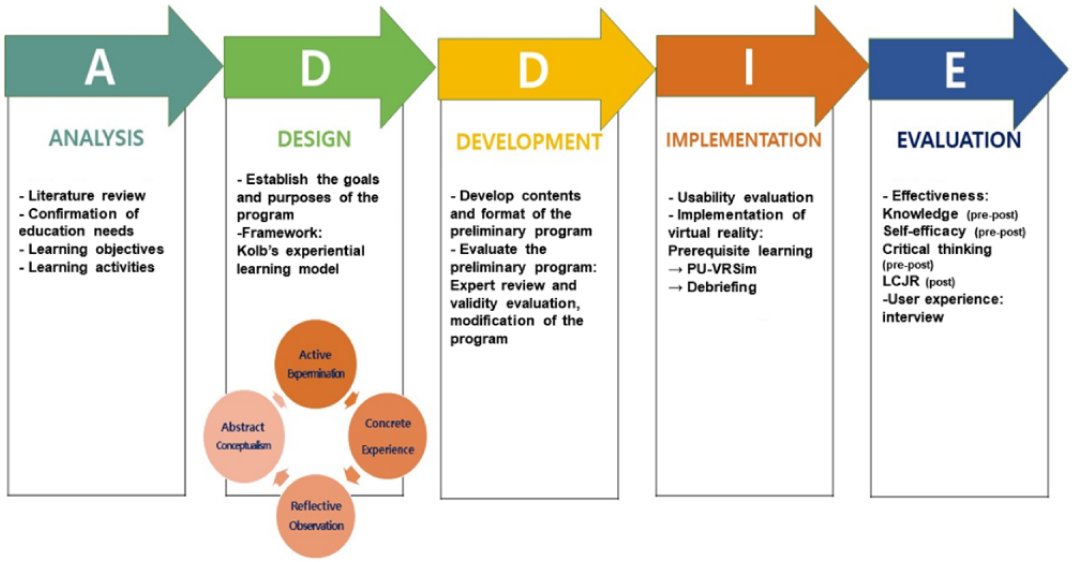
The LCJR, developed by Lasater [31], was used to evaluate the simulation experience. This rubric comprises 11 items based on the following four phases: noticing, interpreting, responding, and reflecting. The LCJR evaluates participants' performance as beginning (1 point), developing (2 points), accomplished (3 points), or exemplary (4 points). The total score ranges from 11 to 44, with a higher score indicating higher clinical judgment ability. The Cronbach α value was 0.83 in the study of Shin et al [32] and was 0.92 in our study.

Procedures

Development Overview

PU-VRSim was developed by applying Kolb's experiential learning theory to the ADDIE model (Figure 2).

Figure 2. PU-VRSim program development. LCJR: Lasater Clinical Judgment Rubric; PU-VRSim: pressure ulcer management virtual reality simulation.



Analysis Stage

The analysis stage identified learners' general and learning-related characteristics. Through a literature review [33], the importance of PU care, factors of PU occurrence, and prevention and management methods were confirmed, and the factors to be included in the development of the VR simulation were analyzed.

Design Stage

In the design stage, the teaching method for developing an effective educational program was determined. Kolb's experiential learning theory [21] was applied to the basic data collected during the analysis stage to determine the teaching method using the VR simulation (concrete experience) and debriefing (reflective observation). The design aimed to improve critical thinking, self-efficacy, and clinical judgment (abstract conceptualization). Using this approach, the learner would assist in performing PU prevention and nursing (active experimentation) well in actual patients.

Development Stage

In the development stage, a VR-based program was developed based on the educational topics selected in the analysis and design stages. A VR platform (Unity 3D, Unity Technologies) was constructed in collaboration with a professional company. A preliminary VR program was tested by five nurses with more than 5 years of clinical experience in scenarios and nursing care of patients with PUs. By checking and correcting errors in the VR program, operational problems were improved and addressed.

Implementation and Evaluation Stage

The implementation stage involved application and operation of the program completed in the development stage (Table 1).

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Table 1. Core contents and images of the virtual reality system.

Main contents	Components	Image
Login	Registration of users	
Objectives	Identifying learning objectives: • Assess the degree of risk of developing PUs[a] in the patient. • Classify the PU stage of the patient. • Apply a proper dressing to the patient's PU. • Provide prevention education and care for PUs to the patient.	
Patient case	• Patient hospitalization history • Patient information: name, sex, age, diagnosis, past medical history, social history	
Patient information	Identifying data: vital signs, results of blood test, x-ray findings, physical exam, medication	
Nursing intervention		
Risk assessment for PU prevention	Braden scale score; a lower score indicates a higher risk of developing PUs.	
Assessment and evaluation of PUs	• Assessment of PUs: size and stage • Evaluation of PUs: writing a report	
Management of PUs	Dressing on PUs • Stage 1: film dressing • Stage 2: foam dressing	
Patient education	PU prevention and management education: • Skin care, urinary and fecal incontinence management • Support surfaces • Repositioning • Nutrition	
Final confirmation	• Running times • Feedback (recording)	

[a]PUs: Pressure ulcers

Assessments

Overview of Study Design

The program was used during the evaluation stage. PU knowledge, critical thinking, and self-efficacy in the experimental and control groups were measured once before the start of the study and then again after the program. For the experimental group only, assessment using the LCJR was performed after the program and the effect of PU-VRSim was evaluated through an interview.

Preintervention Survey

The preintervention survey of the experimental group was conducted from October 1 to November 30, 2022, and that of the control group was conducted from January 1 to March 1, 2023. After the participants signed a consent form to participate in the study, their PU knowledge, self-efficacy, and critical thinking were measured using structured questionnaires as described above.

Implementation

The experimental group received the VR simulation program, comprising a prebriefing session (15 minutes) where participants briefly learned about the definition, classification, prevention, and wound management of PUs. Participants were then exposed to PU-VRSim (10 minutes), including PU assessment, nursing care, and education to patients through VR. This was followed by a debriefing session (20 minutes), in which participants were assessed using the LCJR after the simulation.

The control group received a video-based lecture. The video format was selected to reduce the time burden on participants who work in shifts and to ensure safety from SARS-CoV-2 infection, according to the participants' hospital work. In total, 17 participants in the control group received lecture materials and a 30-minute video-based lecture on the definition, classification, prevention, and management of PUs.

Postintervention Survey

After the program, PU knowledge, self-efficacy, and critical thinking were assessed in both groups. The experimental group was further assessed using the LCJR and an interview was conducted to confirm their experience.

Interview

To discuss the experience of participating in PU-VRSim, which could not be verified using objective data, the participants were

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interviewed after the program. The interview included a self-introduction by the researcher and participant, recording of the interview, guaranteeing anonymity, and explaining that the research results were used only for research purposes and that the interviews were conducted with the participants' voluntary consent. One-on-one interviews were conducted in all cases in a quiet seminar room. Before conducting the interviews, the questions were drafted based on the purpose of the study and proceeded in the order of introduction, transition, and main questions, as shown in Textbox 1.

Textbox 1. Interview question structure.

Introduction question: Thank you for taking the time after work to participate in the virtual reality (VR) program. Can you briefly describe your feelings?

Transition question: Now, we would like to take the time to talk freely about the program's effectiveness and improvements.

Main question: What helped you with the program? What do you think about the content and methods of the VR program in which you participated? What do you need to improve or add to this program?

Data Analysis

The data collected in this study were analyzed using IBM SPSS 23.0, and a two-tailed test was performed at a significance level of .05. The normality of the dependent variable was verified using the Shapiro-Wilk test. The homogeneity of the data in the experimental and control groups was verified using the χ^2 test and independent *t* test. General characteristics and performance on the LCJR aspects of the participants were presented as means (SDs) and n (%), respectively. Wilcoxon signed rank and Mann-Whitney *U* tests were used to verify differences in PU knowledge, critical thinking, and self-efficacy between the experimental and control groups.

The data collected through the interviews were analyzed using an inductive approach, which is one of the content analysis methods suggested by Elo and Kyngäs [34]. For the data analysis, the researcher repeatedly read the transcripts of the interviews, interpreted the meaning of the key statements, and created categories by assigning titles. After data analysis, the authors discussed their interpretations to reach a consensus. Subsequently, the semantic units identified were grouped into higher-level categories, the properties were stated, and the keywords were derived by coding the contents accordingly.

Results

Feasibility of PU-VRSim

Our first objective was to assess the feasibility of implementing the PU-VRSim program for nursing education on PUs in the implementation and evaluation stages.

The general characteristics of the participants are presented in Table 2. The average age and work experience of the 35 novice nurses was 24.8 years and 14 months, respectively. The experimental group comprised 18 (100%) women, whereas the control group comprised 2 (12%) men and 15 (88%) women. We analyzed the homogeneity of the two groups in terms of general characteristics such as age, educational level, VR experience, and PU education experience; no significant difference was observed between the two groups (all $P>.05$) and thus homogeneity between the two groups was confirmed.

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Table 2. Characteristics of participants (N=35).

Characteristics	Experimental group (n=18)	Control group (n=17)	χ^2 or t[a]	*P* value
Age (years), mean (SD)	24.11 (1.32)	25.53 (2.72)	–1.98	.06
Sex, n (%)			1.46	.16
Male	0 (0)	2 (12)		
Female	18 (100)	15 (88)		
Work experience (months), mean (SD)	14.06 (7.75)	14.65 (7.17)	–0.23	.82
Education, n (%)			1.852	.83
College	0 (0)	3 (18)		
University	18 (100)	14 (82)		
PU[b] education, n (%)			1.00	.33
Yes	17 (94)	17 (100)		
No	1 (6)	0 (0)		
VR[c] experience, n (%)			0.882	.38
Yes	3 (17)	7 (41)		
No	15 (83)	10 (59)		

[a]*df*=17 for the experimental group and 16 for the control group.

[b]PU: pressure ulcer.

[c]VR: virtual reality.

Effect of PU-VRSim on Outcomes

Our second objective addressed the effects of the VR intervention on PU knowledge, self-efficacy, critical thinking, and critical judgment.

As shown in Table 3, in the experimental group, the PU knowledge score increased by 2.88 points and the self-efficacy score increased by 0.56 points compared with those in the preintervention survey. In the control group, the PU knowledge score increased by 4.12 points, the critical thinking score increased by 4.0, and the self-efficacy score increased by 0.76 points. Each group showed significant improvements in PU knowledge after the intervention. However, there were no significant differences in critical thinking and self-efficacy in either group. There were no significant differences in the change in PU knowledge, critical thinking, and self-efficacy between the two groups.

The results for the clinical judgment assessment are summarized in Table 4. In the experimental group, after PU-VRSim, the overall clinical judgment of novice nurses was 3.23 points. When evaluated in the four phases to confirm whether all phases reached the level of “accomplished,” out of a total of 4 points, the mean scores for noticing, interpretation, responding, and reflecting were 3.27, 3.31, 3.32, and 2.91 points, respectively. The items “well-planned intervention/flexibility” and “skill proficiency” in the responding phase scored the highest, with 3.67 points, whereas “commitment improve” in the reflecting phase scored the lowest, with 2.78 points.

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Table 3. Effect of the pressure ulcer management virtual reality simulation on outcomes.

Variable	Preintervention, mean (SD)	Postintervention, mean (SD)	*Z*	*P* value[a]	Difference		
					Mean (SD)	*Z*	*P* value[b]
Knowledge						–0.81	.42
Experimental (n=18)	24.39 (4.79)	27.28 (4.43)	–3.45	.001	2.88 (2.40)		
Control (n=17)	24.71 (5.42)	28.82 (3.41)	–2.78	.005	4.12 (4.74)		
Critical thinking						–1.51	.13
Experimental (n=18)	99.00 (10.70)	98.61 (8.51)	–0.13	.896	–0.39 (5.95)		
Control (n=17)	94.82 (7.24)	98.82 (9.36)	–1.40	.163	4.00 (9.01)		
Self-efficacy						–0.57	.57
Experimental (n=18)	29.11 (3.41)	29.67 (3.24)	–1.45	.148	0.56 (1.69)		
Control (n=17)	25.59 (4.18)	26.35 (3.98)	–1.16	.247	0.76 (3.40)		

[a]Wilcoxon signed rank test.
[b]Mann-Whitney *U* test.

Table 4. Clinical judgment scores.

Clinical judgment phase	Score, mean (SD)
Overall	3.23 (0.44)
Noticing	
Total	3.27 (0.45)
Focused observation	3.17 (0.51)
Recognizing deviations from expected patterns	3.06 (0.54)
Information seeking	3.61 (0.50)
Interpretation	
Total	3.31 (0.60)
Prioritizing data	3.28 (0.67)
Making sense of data	3.33 (0.59)
Responding	
Total	3.32 (0.46)
Clear communication	3.11 (0.58)
Well-planned intervention/flexibility	3.67 (0.49)
Being skillful	3.17 (0.62)
Reflecting	
Total	2.91 (0.62)
Evaluation/self-analysis	3.06 (0.64)
Commitment to improvement	2.78 (0.73)

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Qualitative Outcomes of the PU-VRSim Experience Among Novice Nurses

Overview of Themes

For the third objective, the interviews were grouped into five main themes: (1) realistic VR scenarios, (2) helpfulness of VR learning, (3) usability, (4) satisfaction, and (5) limitations of VR equipment (Table 5).

Table 5. Qualitative outcomes of the pressure ulcer (PU) management virtual reality (VR) experience in novice nurses.

Themes and subthemes	Description
Realistic VR scenarios	
Real environment	There was a sense of presence in the hospital
Real experience	Actual practice in nursing on PUs
Helpfulness of VR learning	
Improving knowledge	Remember the concept and care of PUs well
Improving skills	Perform overall practice (assess-evaluate-manage) for PUs
Usability	
Safety	Safe from infection due to low contamination
Accessibility	Able to participate freely regardless of time and place
Satisfaction	
Joy and fun	It was more like playing games than learning
New experience	It was a new and interesting learning experience
Limitations of VR equipment	Inconvenient to use equipment

Theme 1: Realistic VR Scenarios

The participants gained practical experience through VR scenarios. The subtopics related to this were “real field” and “real experience.”

> *When I experienced it myself, it was lively and felt like a real clinical environment.* [S1, S8, S10, S16]
>
> *It was realistic to be able to assess and manage wounds about which I learned from books using VR* [S4]
>
> *Although it is VR for pressure ulcer nursing, which is difficult to understand only through lectures, it was good to apply it as a direct action* [S11]
>
> *I only practiced with lying mannequins, but it felt more realistic when I experienced it with patients in VR like a real clinical environment.* [S13]

Theme 2: Helpfulness of VR Learning

The participants expressed that VR was helpful for learning. Subtopics related to this theme were “improvement of knowledge learning” and “improvement of skills.”

> *I was able to learn the stages of PUs and the types of dressings.* [S6]
>
> *I was able to learn about PU care.* [S8]
>
> *When applying nursing care to patients with PUs through VR, it seems to be more memorable.* [S9, S15, S16]
>
> *I was able to confirm the PU classification concept.* [S12]
>
> *There were no bedsore patients in the ward where I worked, and through this virtual reality program, I was able to evaluate, intervene, and evaluate PUs.* [S2]
>
> *I was able to perform overall nursing activities for patients with PUs.* [S6]

Theme 3: Usability

The participants expressed the feeling of using VR learning as “safe” and “easy to access.”

> *There were times when the mannequins were dirty in nursing practice, but it was nice that the virtual patients were not contaminated.* [S13]
>
> *It was nice to be able to participate without the burden of time and place.* [S5]

Theme 4: Satisfaction

The participants expressed their satisfaction of using VR learning as “pleasure,” “fun,” and “new experience.” They showed interest in VR and experienced fun and enjoyment through learning.

> *It feels more like playing a game than learning something. Enjoyed it.* [S4]
>
> *It was my first time using virtual reality, and I was able to enjoy it. I want to try again.* [S5, S13, S17]
>
> *It was a new experience, and I enjoyed it.* [S8, S14, S17]

Theme 5: Limitation of VR Equipment

The participants expressed limitations in terms of the equipment used in the VR program.

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When I put the equipment on my head, I took off my glasses and put it on, so it was difficult to read the text because my vision was not clear. [S5]

It was a bit heavy to wear on my head. [S8]

The preparation for running the program was complex and took a long time. [S12]

It took a long time when the focus was not good, and the text looked blurry and the controller was not recognized well in VR. [S13]

Discussion

Principal Findings

In this study, we developed PU-VRSim by applying the ADDIE model and Kolb's experiential learning theory [20,21]. PU-VRSim was designed as a PU prevention and nursing simulation program for novice nurses with less than 2 years of clinical experience. The participants of the PU-VRSim group showed significant improvements in PU knowledge. They reached the accomplished phase of clinical judgment. They commented that it was realistic and helpful for learning about PU management.

PU-VRSim was developed by applying an analysis-design-development-implementation-evaluation method according to the ADDIE model [20]. In the analysis stage, a literature review [33] confirmed that PU care was an important indicator of the quality of nursing services, which is becoming increasingly important [35]. PUs are caused by immobility, pressure, and friction. Factors to be included in education were analyzed by evaluating the methods for preventing and managing PUs through support surface management, position change, and dressing application to relieve pressure on the skin surface. Previous studies [36,37] have confirmed the improvement in PU knowledge and nursing performance of nurses through PU nursing education, thereby suggesting that continuous education on PUs for nurses is needed.

Kolb's experiential learning theory [21] applied at the design stage of PU-VRSim connects theory and practice in VR simulation. Through concrete experience and reflective observation, an abstract conceptualization of theories in realistic situations can help to acquire the knowledge and skills that can be used in real situations. Kolb's theory has also been applied in simulation education in various health fields [38], and VR provides learners with experience-based learning in a real environment by which the learners make decisions and take appropriate actions in real situations [10]. Through PU-VRSim, novice nurses freely apply the theoretical knowledge acquired through existing knowledge and prior learning materials to the process of solving problems encountered by patients in a safe virtual clinical environment. Ultimately, positive results can be expected by applying the improved nursing capabilities in actual clinical trials.

After novice nurses underwent the program, they showed improvement in PU knowledge and reached the "accomplished" stage of clinical judgment. PU knowledge scores increased on average in both the experimental and control groups after the educational program. This shows that the effect of knowledge transfer [16] can be confirmed via both traditional teaching and lectures and with the new VR simulation method. According to Kolb's experiential learning theory, during knowledge transfer via VR, learners can improve their knowledge by reapplying it through concrete experiences and reflections, as well as learn how to utilize what they have learned and gain new knowledge. PU knowledge is the basis of PU care, and professional nursing can be performed through critical thinking and improvement of clinical performance skills. Furthermore, clinical judgment is a particularly important skill in nursing that has also received recent attention. VR has a positive impact on clinical judgment in nursing education [39]. Therefore, positive effects and acquisition of new skills can be expected if field-tailored simulation [40] is applied to nurses to reproduce clinical situations.

Interview contents were analyzed to confirm the experiences of the novice nurses participating in the PU-VRSim program. The analysis revealed that the realistic scenarios of PU-VRSim help in learning, with usability of safety, easy accessibility, and satisfaction being expressed as positive experiences. However, inconveniences in using the equipment to implement VR programs were expressed as negative experiences. This is consistent with the findings of Adhikari et al [41] on the experience of VR programs in terms of acceptability, applicability, areas of improvement, and limitations. VR can be safely and repeatedly applied in situations that can be dangerous to patients; however, it is expensive and has usage limitations [42]. VR was deemed to be a safe and effective educational method for use during the COVID-19 pandemic [43]. The development of a VR program that reduces the inconvenience and cost burden of equipment is expected to increase the use of VR in nursing education.

Our participants confirmed that PU-VRSim was helpful for learning because it could be used repeatedly to access disease-focused nursing problems. There is a need for education about various clinical situations in which nurses can apply nursing interventions according to the situation and an overall assessment of the patient [44,45]; PU-VRSim reflects the clinical situation of PUs and requires nursing education. In addition, it was confirmed as a positive experience, suggesting that improvement in nursing knowledge and clinical performance ability as well as repetitive learning are possible through the promotion of spontaneous thinking and immediate feedback of learners, which were evaluated as advantages of simulation in previous studies [46,47]. These results confirm the possibility of using PU-VRSim as an educational program in clinical practice.

In nursing practice using mannequins during the COVID-19 pandemic, the participants expressed concerns about infection via contamination of the mannequins from multiple contacts. Using VR, they felt safe as the risk of infection could be avoided. In previous studies, VR simulation was suggested and used as a nonface-to-face practice method when clinical practice was not possible due to the prevalence of COVID-19 [43,48]. In addition, participants did not feel the burden of time and space when participating in VR education. This is an advantage of VR, in which one can experience the actual medical field using only computers and equipment. Furthermore, individual

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learning is possible; therefore, it can provide optimal learning to individual learners and help them overcome obstacles in the physical environment [49]. VR may be an appropriate training method for shift workers, because nurses who work shifts can access the education without experiencing a time burden.

Novice nurses in this study regarded VR education as a new experience and evaluated it as enjoyable. A VR learning environment enhances immersion and activates learners' imagination to simulate the real world [50]. The VR program is a teaching method that incorporates the latest technology and meets the learning needs of a new generation. Educational programs are being developed on various topics for nursing students and novice nurses, and the effects of enjoyment and fun have been confirmed [13]. Learning satisfaction through the enjoyable and fun VR improves learners' learning motivation and confidence, and they experience reduced fear in real situations [14]. Because enjoyment and fun in learning are factors that stimulate learning motivation and interest, gamification can be applied when developing programs so that learners can enjoy various experiences in the virtual world.

When implementing the VR program, participants had difficulty in using an HMD; in particular, participants wearing glasses experienced inconvenience when wearing the device along with their glasses. As in previous studies, most of the participants experienced technical difficulties [41]. A VR program is typically executed using a computer program, an HMD, and a controller; however, the HMD and controller devices do not recognize the participants' fine movements, making it difficult to proceed [42]. In the future, the development of a convenient version of the HMD, with a clear field of view, ease of wearing, and usability, may lead to an increase in the use of VR education.

PUs are common health problems in hospitals, and novice nurses experience difficulties in treating PUs. Education of nurses has been regarded as an integral component of PU prevention [51]. VR is an ideal educational technology, and the number of educational programs applying VR in nursing education has been increasing recently [52]. For the VR education program, we confirmed the improvement in knowledge of the participants through the experience in prevention and nursing interventions for patients with PUs. Improvement in clinical performance can be expected with improved knowledge. In addition, the novice nurses in this study expressed satisfaction with VR education as a new experience and a safe learning method. Considering the limitations of VR equipment, it is necessary to develop and utilize a popular simulation program that is more user-friendly and can be manipulated easily. Based on this study, we suggest the development of VR nursing education programs focusing on the educational needs of novice nurses and including new technology such as artificial intelligence with the development of technology.

Conclusion

The PU-VRSim program developed in this study was found to be effective in improving novice nurses' knowledge of PUs and was positively evaluated as a pleasant experience conducive to learning in an actual hospital-like environment. Therefore, PU-VRSim can be used as an effective educational method for novice nurses, as well as for nursing students and clinical nurses. In addition, a synergistic effect can be expected when the content used incorporates various software programs, including VR simulation programs.

Limitations exist in understanding and generalizing the effects of nonrandomized control-group experiments targeting novice nurses. To supplement this, we propose a follow-up study that applies the PU-VRSim program to nursing students and clinical nurses, as well as a randomized control group experimental study of novice nurses. All participants in the experimental group were women; therefore, we propose a further study with a more heterogeneous group of participants by including male and female nurses. In addition, we suggest the development of a field-tailored VR simulation for health professionals, including novice nurses, and study of its educational effect. Finally, developing a program for VR simulation is expensive and wearing an HMD when implementing the program is uncomfortable. We propose the development of software and VR simulations using technology such as smartphone apps, which are inexpensive, comfortable, and easy to use. In conclusion, we propose the continuous development and improvement of VR nursing education programs for novice nurses applying new technologies.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

ADDIE: Analysis, Design, Development, Implementation, and Evaluation
HMD: head-mounted device
LCJR: Lasater Clinical Judgment Rubric
PU: pressure ulcer
PU-VRSim: pressure ulcer management virtual reality simulation
PZ-PUKT: Pieper-Zulkowski pressure ulcer knowledge test
VR: virtual reality

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Original Paper

An Escape Game on University Students' Mental Health During the COVID-19 Pandemic: Cocreation Study

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Abstract

Background: The COVID-19 pandemic has had a severe impact on students' mental health. Interventions are needed to promote their psychological well-being and prevent mental illnesses in the aftermath of this unprecedented situation. Digital escape games can be an effective tool to support students' mental health. A cocreation approach can improve the acceptability of these interventions by involving different stakeholders (eg, end users, game designers, and health professionals) to obtain audience-specific games.

Objective: This study aims to describe the process of testing and optimizing the game "EscapeCovid" on students' mental health, to serve as a model for the cocreation of future similar interventions.

Methods: The PRODUCES (Problem, Objective, Design, End Users, Cocreators, Evaluation, Scalability) framework was used. Cocreation steps (test and optimization) were detailed for replicability. A total of 45 students tested a pilot version of the game, with 10 undergoing a semistructured interview. Meetings with a group of stakeholders and brainwriting were organized to optimize the game.

Results: We produced a new version of the game incorporating the suggestions provided by student testers and following the stakeholders' guidelines. Improvements were made to both the content and the form of the new version of the pilot game. The storyline, including the protagonist and the scenes, was adapted to the student population.

Conclusions: Our results suggested that cocreation can contribute to the design of more widely accepted interventions aimed at promoting mental health and preventing psychological disorders. Results also suggest that an end user–centered approach can facilitate intervention tailoring. When conceiving a health-related escape game for students, we recommend using the cocreation approach to enhance players' experience, thus positively influencing their learning process and overall well-being.

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KEYWORDS

students; game; mental health; COVID-19; cocreation; university student; promote; psychological well-being; effective tool; tool; acceptability; testing; questionnaire; learning; motivation; user centered

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Introduction

University Students' Mental Health and the COVID-19 Pandemic

University students are often likely to experience serious mental health problems during their studies because they are exposed to several stressors including academic pressure, taking on more adult-like responsibilities, or having limited financial resources [1].

The COVID-19 pandemic has exacerbated students' mental health, as demonstrated by a skyrocketing incidence of mental health disorders during the repeated lockdowns between 2020 and 2021 [2,3]. Shifting to online courses, uncertainty about academic and professional future, and a dramatic reduction of social interactions have largely contributed to compromising the mental health of the student population [4]. Restrictive measures, in particular, were associated with high levels of depression, anxiety, and stress in students [5-7]. In 2020, nearly one-fifth of students experienced suicidal ideation as a result of COVID-19 [8]. The prevalence of these mental health problems was more than 50% higher among students than in the general population [9]. Students' mental distress due to the COVID-19 pandemic persisted in the aftermath of the peak of the pandemic [10].

Against this background, there has been a high demand for mental health prevention programs addressed to students during and after the lockdowns [11]. Several studies have described the development and application of interventions aimed at supporting students during the health crisis. In particular, digital psychological interventions have produced positive effects on students by promoting resilience and well-being [12]. During the lockdowns, when face-to-face contact was limited, digital interventions had the advantage of reaching a larger audience with no time or space limit. Examples of interventions were video clips, online booklets, mobile applications, virtual doctor appointments, etc. University students, in particular, actively sought this type of online help and interventions, probably because they are digital natives [13].

Gamification in Mental Health–Related Interventions

To optimize interventions, gamification is considered an essential strategy, including in the mental health field [14]. Gamification relies on the full involvement of the player and exploits several psychosocial determinants affecting the learning process (eg, self-efficacy, social interaction, and a positive learning environment) [15]. Enhancing these factors can facilitate the recall of abstract concepts, such as the concept of mental health [16]. Introducing gamified elements (eg, step-by-step sequencing, rewarding systems, and puzzle-solving activities) in a health promotion and prevention tool can influence the aforementioned psychosocial determinants and, consequently, stimulate participants' learning loop and their cognitive capacity [17].

Over the last few years, increasing attention has been paid to the possibility of games improving well-being [18]. Games can engage players, especially young target populations, in understanding and retaining information in a more attractive and acceptable way [19]. This means that they can increase their mental health literacy and their knowledge of both the symptoms of psychological problems and the different solutions to overcome them. By providing tips and skills to face psychological difficulties, games might also contribute to positive changes in individuals' behaviors and attitudes.

Escape Games as a Tool to Improve Psychological Well-Being and Prevent Mental Disorders

Escape games are a type of digital intervention based on gamification where players collaborate to find clues, complete tasks, and solve puzzles with the aim of achieving a specific, time-bound goal, which is usually to escape from a room. Previous research corroborated the constructive impact of escape games in improving health-related knowledge in players [20,21] using a learning-by-doing approach [21].

Escape games can contribute to delivering health-related messages by fostering motivation for behavioral change through an enjoyable and playful approach, according to the PRIME (Plan, Response, Impulses, Motives, and Evaluation) theory of motivation [22]. Based on this theory, a decision to engage in an activity will not result in action unless it generates the desire and the impulse to do it at the relevant moment. Thus, the stimuli generated from the act of playing a game—including different tasks, lights, sounds, and colors—trigger feelings, ideas, and brain activities for positive decision-making. In other words, the game gives the input to change.

Additionally, gamification has the potential to increase motivation, engagement, and self-awareness, and even diminish symptoms of diseases such as depression and anxiety [23]. Indeed, gamification stimulates several components of good mental health. As an example, achieving goals in a game can result in a sense of satisfaction, accomplishment, and increased self-esteem, all of which improve overall well-being. Furthermore, game enjoyment is associated with positive well-being and social and emotional support [24].

The Cocreation of Escape Games

Cocreation occurs when end users and service providers, often along with other participants, work together in the early phases of the development of an intervention cycle [25]. Cocreation is a process facilitating the acceptability of an intervention because it primarily considers the needs and preferences of end users during the intervention development. Thus, the benefits of gamification tend to increase when cocreation is used [26], and cocreating an escape game can foster its adoption [27]. Based on this approach, game producers and end users must first exchange views to achieve a shared goal [28,29]. Indeed, when developing a public health–related game, players' experience and needs are relevant for enhancing its effectiveness in promoting health and prevention. Ideally, players work alongside designers, health professionals, and researchers, to produce the intervention. The cooperation of players and other stakeholders is therefore essential to maximize end users' acceptability and adherence to the game. As a result, cocreation is usually recommended to produce a successful game, including in the mental health field. Accordingly, sensitive topics and taboos should be addressed using players' words and taking into

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account the levels of empathy and sympathy players display during the cocreation process. Including end users with lived experience of mental health disorders promotes a deeper understanding of the game topic [30].

The PRODUCES Framework

PRODUCES (Problem, Objective, Design, End Users, Cocreators, Evaluation, Scalability) is among the different existing frameworks facilitating the cocreation of health-related interventions [27]. It is well-known for using a systemic approach to participatory methodology. According to this framework, the *problem* is a narrowed-down behavioral issue that the researchers and the designers wish to address. The cocreation process has an *objective* ("what" and "how") and follows a specific predefined *design*, engaging *cocreators* who represent end users (ie, a specified target population). For the latter, all characteristics must be considered, from age to socioeconomic status, to tailor the intervention coherently. Cocreated interventions can also be *evaluated* and their *scalability* can be assessed. The satisfaction of the end user as well as the effectiveness of the intervention are elements to consider for the final evaluation. A successful intervention can be scaled up to reach a wider public. Thus, the PRODUCES framework helps to guide the participatory methodology by providing specific instructions.

Objective

The objective of this study was to describe the process of cocreation of the escape game "EscapeCovid". The end goal of the game was to promote university students' mental health literacy, their beliefs about mental health, management of emotions, and positive coping strategies during the COVID-19 pandemic. An applied methodology is presented here to be used as a model for cocreating an acceptable gamified mental health intervention addressed to young people. Providing this example also has the aim to illustrate one cocreation process for the benefit of other researchers and designers.

Methods

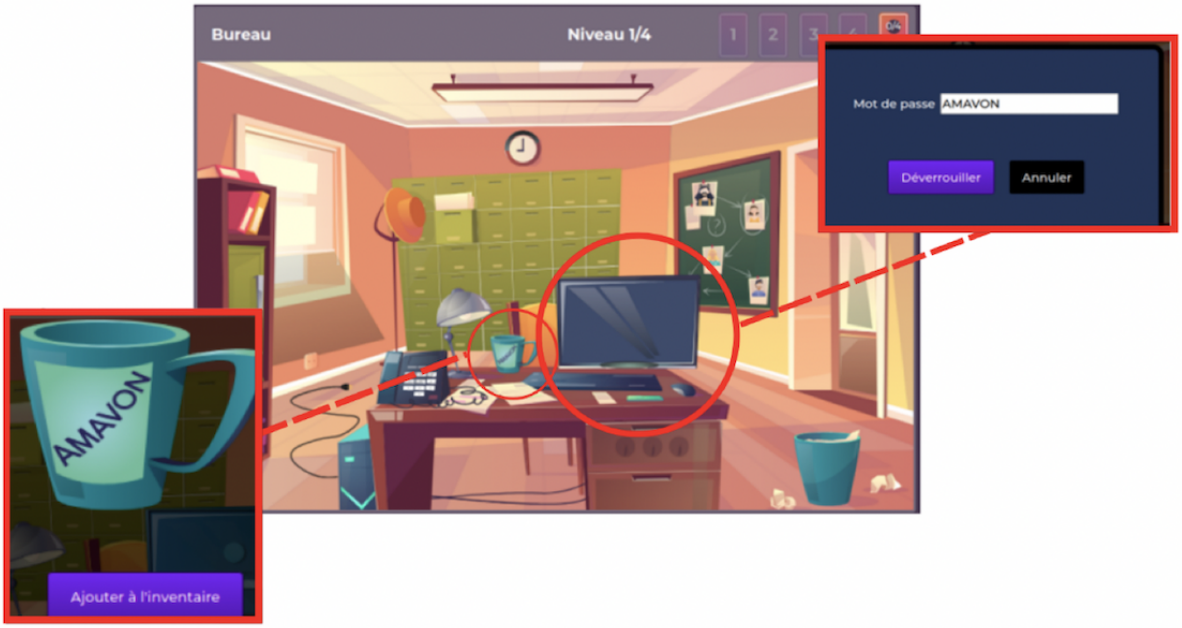
The First Pilot Version of "EscapeCovid": The Escape Game "Manage Your Emotions"

"EscapeCovid" was based on an existing escape game that was used as the skeleton of the final game. "Manage Your Emotions" was created in 2021 during the pandemic by a start-up based in Bordeaux, France, specializing in producing both real-world and online escape games. Creators were game designers, programmers, and health care professionals aged under 35 years.

The game "Manage Your Emotions" is set in Tony's room, a fictional university student living in a shared flat and experiencing the difficulties of the first lockdown. The goal of the game is to collect several tools to disclose emotion cards and combine them. The game session involves 4 players and a game guide. The role of the game guide is to coordinate the whole game, to give clues if the players are stuck, and to animate the debriefing session. The game lasts in total 2 hours: 45 minutes of play and 1 hour and 15 minutes of debriefing. During the debriefing, the game guide and the players discuss in more detail the concept of emotions (ie, how to identify and manage them). The game guide follows a predefined plot facilitating the interactions between participants.

During the game, players follow Tony during a typical day through 3 rooms of his apartment (his home office in the bedroom, living room, and bedroom). By doing so, players discover his emotions and their consequences on his daily life. Figure 1 illustrates Tony's home office in the bedroom with a set of clues for the players.

Figure 1. Tony's office in the escape game "Manage Your Emotions."



Players solve puzzles by clicking on the elements on the screen to uncover emotion cards. The definition of the different emotions is based on Plutchik's wheel of emotions [31] (Figure 2) which is the theoretical framework of the game.

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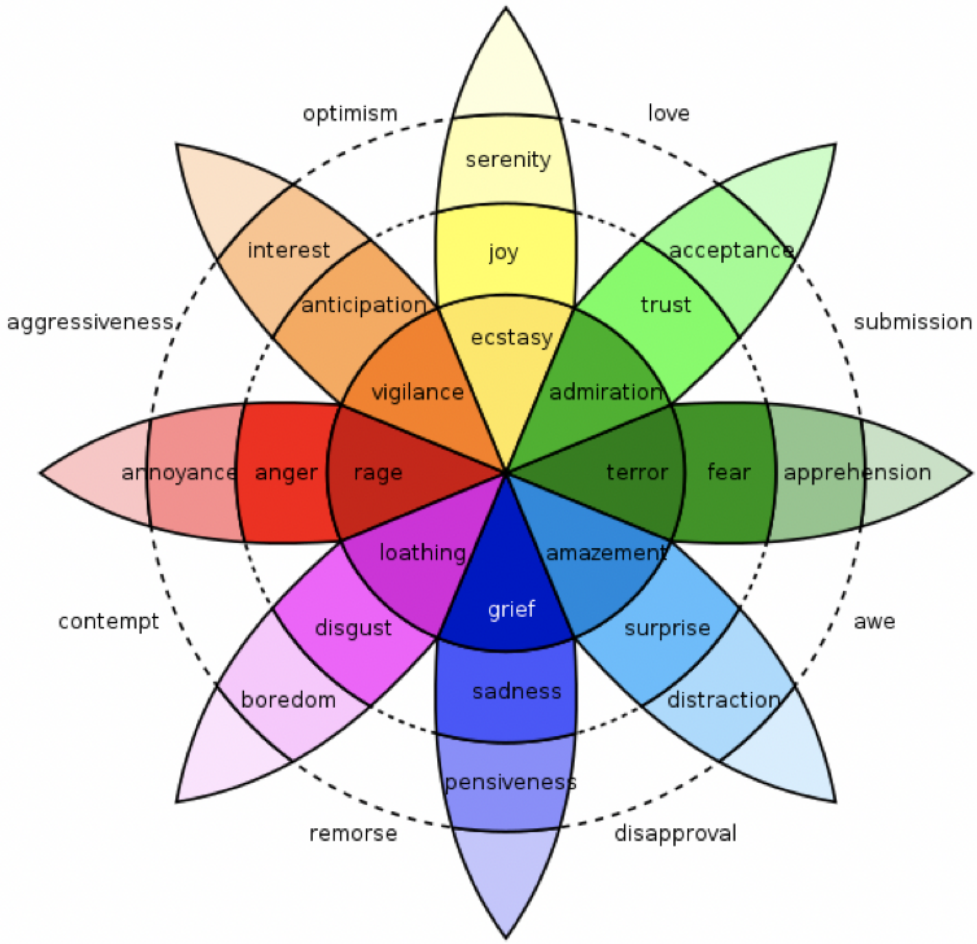
Figure 2. Plutchik's wheel of emotions.



Plutchik's wheel of emotions covers 8 primary emotions: joy, trust, fear, surprise, sadness, anticipation, anger, and disgust. They can be combined into more complex secondary emotions—for example, the combination of joy and trust can result in love. In the wheel, darker colors correspond to more intense emotions. All combinations and intensities are explained in the cards. Plutchik's theory posits that the more we know about emotions, the better we understand how various emotions are interlinked and how they can change over time. Plutchik's wheel of emotions has been used in several studies as a scientific instrument to interpret emotions [32,33]. In this escape game, playing cards had to be associated to identify Plutchik's emotions.

As the name suggests, the game "Manage Your Emotions" exclusively focused on emotions and therefore did not cover the full range of features of mental health (eg, mental health literacy and positive coping strategies). Furthermore, the software presented several bugs and the scenarios did not reflect the real-life conditions of a student during the pandemic.

Cocreating "EscapeCovid": Test and Optimization

Our cocreation process followed the PRODUCES framework [27]. The problem we chose was students' mental health during the COVID-19 pandemic. We particularly focused on mental health literacy, beliefs about mental health, management of emotions, and positive coping strategies as the levers to act upon for increasing students' psychological well-being. We addressed all types of mental health problems, but specifically anxiety and depression, among the most common troubles in young people [34]. These problems were exacerbated during the repeated COVID-19–related lockdowns [35].

Our objective was to develop the "EscapeCovid" game. The project was born during the third lockdown in France (from April 3 to May 3, 2021 [not included], ie, 29 days), where students were especially penalized because all educational institutions, but universities, were open. At that time, the plight of university students was prominently featured in the French media, which in turn heightened the pressure on French politicians [36].

As for the design aspect, we used a 2-step participatory methodology approach (test and optimization), as described below. Both steps involved students as players of the game before and during its improvement. Thus, through direct experimentation, cocreators were a sample of students representing all university students referred to as end users.

The evaluation was performed through questionnaires and semistructured interviews using a mixed methods approach. Students reported their opinions on the game allowing for an assessment of its qualities and defaults. In this sense, the design and the evaluation were strictly related.

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In terms of scalability, our objective was to distribute the new game among additional universities catering to French-speaking students (eg, France, Africa, and Québec).

Table 1 reports the components of our study corresponding to the PRODUCES framework, including the phases and steps of the project.

Table 1. The PRODUCES[a] framework applied to the "EscapeCovid" study.

PRODUCES framework	Application in "EscapeCovid"	Corresponding element/phase
Problem	To address students' mental health during the COVID-19 pandemic	N/A[b]
Objective	To develop the "EscapeCovid" game	N/A
Design	Participatory methodology approach	Cocreation (test + optimization)
End users	Students	Optimization
Cocreators	45 health care students + 2 game guides + 1 developer + 1 project manager + 1 student intern + 1 designer+ 1 developer + 1 medical doctor + 1 researcher	Cocreation (test + optimization)
Evaluation	45 questionnaires and 10 semistructured interviews (mixed methods)	Test
Scalability	Disseminate the new game to other French students	Optimization

[a]PRODUCES: Problem, Objective, Design, End Users, Cocreators, Evaluation, Scalability.

[b]N/A: not applicable.

In practice, referring more specifically to design, cocreation was implemented following 2 steps: the test and the optimization. In the first step, the escape game "Manage Your Emotions" was tested by a sample of health care students, 2 game guides (both public health experts), and 1 developer (a computer scientist). Game guides trained with colleagues and friends to annotate their first impressions of the game flow. They commented on the difficulties encountered while animating the game, including interactions with players and technical issues. The collected information was used to improve the debriefing and to solve bugs in collaboration with the developer.

Then, the official test was launched. Health care students played the game in groups of 3 or 4, each group supervised by 1 game guide. At the end of the game session, health care students were asked to complete an online questionnaire to rate their experience and provide feedback for improvement. Semistructured interviews were conducted with some voluntary respondents to obtain more in-depth advice (for improving the game).

In the second step, the game was optimized using the data collected from the test with the collaboration of a group of stakeholders. The latter included 1 project manager from a public health research center, 1 student intern completing a degree in cognitive engineering, 1 game designer, the developer of the test step specialized in computer science, 1 medical doctor, and 1 psychology researcher. Meetings were organized to reshape the pilot game and brainwriting techniques were used to collect ideas and pass them on to stakeholders. The brainwriting technique involves the written generation of ideas by different individuals on separate sheets, which are then collated by the project manager in the same shared file. Ideas are categorized and synthetized in the shared document where stakeholders can discuss them with written comments and paragraphs. Then, the team meets in person to agree on a common solution. Meetings and brainwriting were done in an iterative loop [37]. Figure 3 illustrates the cocreation process we adopted.

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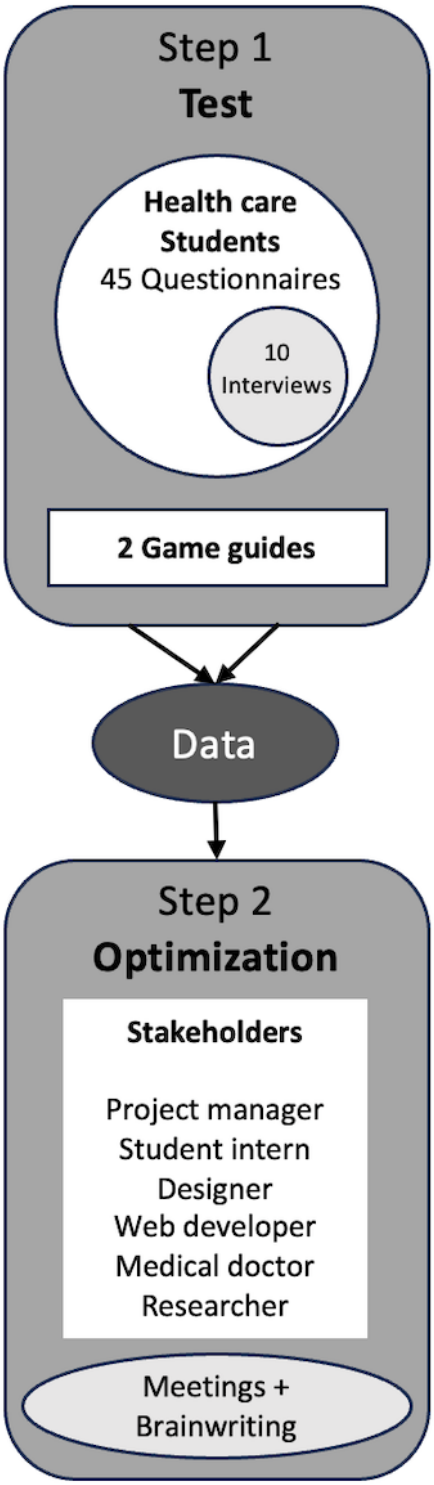
Figure 3. The cocreation process.



The Testers of "EscapeCovid"

The students testing the game were included exclusively if they were health care students registered at the University of Bordeaux (France). We accepted all specific health-related fields of study (eg, medicine, midwifery, speech therapy), genders, and ages. We opted for health care students to assess the relevance of the contents of the game given their expertise in medical and paramedical care. Furthermore, previous studies have shown that health care students are a population at risk of mental illness [38] and, as a consequence, tend to be more sensitive to this topic. Recruitment was conducted from April 27 to May 17, 2022. We used a snowball sampling approach starting with health care students doing their internship at the public health research center where the study was based. Additionally, health care–related student associations were asked to post a recruitment announcement on their social media pages. We aimed to recruit between 30 and 50 health care students, as this number would guarantee the feasibility of the study and the interactions required during the game. Thus, the recruitment was stopped when we reached a sample of 45 health

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care students and the recruitment strategies seemed to be no longer efficient (ie, no further responses). The final number of health care students who took part in the study was 45.

Through an email or by clicking on a link on the association's social media posts, participants in the study were directed to a form to schedule the game session and then randomly allocated to a session including 4 players each.

All 45 health care students received a €20 (US $22) gift card. Among them, 10 also volunteered to take part in a semistructured interview and received a supplementary €20 (US $22) gift card.

In addition to health care students, testers included 2 game guides and 1 developer employed by the start-up producing the game. No inclusion or exclusion criteria were considered for these testers who were all females and aged between 25 and 30 years.

The overall aim of the project was to coproduce a game and not to measure its impact on the mental health of health care students playing the game. Students were in charge of testing the intervention, as opposed to being on the receiving end. In other words, they were not the research sample but were actively engaged in designing and implementing the research process [39]. Nonetheless, they were provided with a list of mental health care services they could refer to if needed. The medical doctor and the researcher in psychology from the stakeholders' group were also available upon request. Finally, respondents were asked to electronically sign a consent form stating that their answers were completely anonymous without tracing. Interviewees also signed a form assuring that the recording of the interview would be deleted after 5 years until the final report and the last published paper, according to the policy of the involved research center.

Data Collection Instruments and Analysis During the Test

A mixed methods approach was applied using both questionnaires and semistructured interviews which were administered to our sample. The satisfaction questionnaire was sent by email to students 1 day after having played the game. It was created ad hoc by IM for this study and tested with 3 public health interns at the research center where the project was conducted. The interns played the escape game and answered the questions reporting to IM if they were adapted and appropriate, and whether it was easy to answer them. Some adjustments to the original items were made after this pilot testing. The final satisfaction questionnaire included 12 items on the degree of appreciation and relevance of the intervention. On a visual analog scale from 0 (not at all) to 10 (a lot), students had to rate the game in terms of how enjoyable it was, the quality of its content, its level of difficulty, the graphics, and the clarity and relevance of the objective. Students were also asked to state to whom they would recommend the game, whether they would pay to play it, whether they had understood the importance of talking about mental health, whether the game increased their knowledge about mental health, whether the game helped them speak more freely about mental health, and whether they felt the game destigmatized mental health. Participants were also asked to rate the game from 1 (very bad) to 5 (very good) stars. We included these specific questions because they provided concrete hints for improving the game. The start-up appraised the features with the lowest scores as the most important to consider when reshaping the game. For instance, they chose to work first and foremost on the graphics if players rated them low (ie, <5 points). Some questions helped understand if the game could have its own business model, with players advising and paying for it. Finally, the questions were aimed at assessing the impact the game had on students' mental health literacy, ranging from destigmatization to readiness to seek help [40]. The items of the satisfaction questionnaire are available in Multimedia Appendix 1. Sociodemographic characteristics were also collected, including students' gender, age, and year of study. Variables were described as counts and percentages. The questionnaire allowed us to obtain a large number of answers in a short time from a young population that is often difficult to reach [41].

Semistructured interviews were based on a grid composed of 3 macro themes and related 13 subthemes. The first macro theme, called "General Description of the Participant" included the following 3 subthemes: students' profile (sociodemographic characteristics), any previous experience with escape games, and the reason for participating in this study. The second macro theme was a "Brief Account of Participants' Experience" during the game session of "Manage Your Emotions," focusing on 5 subthemes: whether students enjoyed it, their satisfaction with the design and scenarios, the feasibility of the game, the learning outcomes, and any advice to improve the game. The last macro theme, "The Impact of the Game," included questions on the effectiveness of the game in teaching 5 topics (each corresponding to a specific subtheme): mental health, stigmatization, understanding and managing emotions, the importance of help-seeking, and techniques for mental health promotion. All subthemes were applied deductively, meaning they had been determined before the interviews.

Then, individual students' speeches were generalized to obtain an overall assessment of the game. Interviews were recorded, fully transcribed, and analyzed through qualitative coding. The framework method was used to cross-check results among individuals and within individuals to report common and consistent concepts [42]. This approach allowed us to list the guidelines for the optimization step.

Ethics Considerations

As the goal of the project was to collect satisfaction data with no repercussions on participants' health, no ethical approval was needed, in line with the French law for health-related research (Délibération n° 2018-155 du 3 mai 2018).

Results

Sociodemographic Characteristics

The quantitative sample of 45 students was purposely limited for a small-scale test. Among them, 34 were female students, 10 male, and 1 nonbinary. Their average age was 22 years (range 18-27 years). The years of study ranged from first-year students to PhD candidates, with the majority attending their fourth year

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(n=16). The qualitative sample (n=10) was composed of 7 female students and 3 male students. In the qualitative study, one-half of the sample declared having experienced a mental health problem and having seen a mental health specialist.

Students' Gaming Experience

The sample of 45 students who answered the questionnaire and the sample of 10 students interviewed reported enjoying the game session.

> *We discuss between us, why and how it is this emotion and not another [...] it was really good.* [B, female PhD candidate, Public Health, first year]

> *Yeah, I really liked the associations of emotions [...] frankly, we spoke with people we didn't know, so frankly it went well, it was cool.* [D, male students, Pharmacy, fourth year]

The majority of the sample (30/45, 67%) gave a high score (between 8 and 10) when asked whether they enjoyed the game. For 34/45 (76%) it was interesting (scores from 8 to 10). Twenty-one students considered that the game was easy. The most frequent overall score given to the game was 4 out of 5 stars (25/45, 56%).

In line with this finding, 21/45 (47%) respondents gave a positive score between 8 and 10 regarding the appeal of the graphics. Concerning the visual staging of the game, 1 student declared that the storyline was not coherent:

> *Tony's apartment is too big for being a student flat.* [MA, female student, Speech Therapy, second year]

Tony's character was also discussed, with some students questioning his relatability:

> *When Tony was talking, I didn't really get into the thing, in the end I found it very tricky, too tricky, a bit like a fake student.* [L, female student, Speech Therapy, third year]

Regarding the overall content of the game, 27/45 (60%) participants found the objective of the game clear (scores from 8 to 10) and 30/45 (67%) considered the content of the game suitable for students (scores from 8 to 10).

Half of the sample (24/45, 53%) would recommend the game to their close friends and family, especially their friends attending university (43/45, 96%). However, the vast majority of students (36/45, 80%) would not pay to play it.

The Knowledge Acquired During the Online Game Session

For 27/45 (60%) of the respondents, the game made them understand the importance of talking about mental health and 38/45 (84%) thought that the game was likely to increase their knowledge about mental health. However, interviewed students reported that knowledge about mental health was addressed in an unsuitable way.

For students, the game enabled users to better understand and identify different emotions, but the general concept of mental health was missing:

> *It was really more about identifying emotions, and self-reflection.* [L, female student, Speech Therapy, fourth year]

> *There would be a wealth of important information to address on mental health.* [A, female student, fourth year of international health]

The Development of the "EscapeCovid" Game

Quantitative and qualitative data from the test (step 1) informed the optimization of the game "Manage Your Emotions" (step 2) to produce the new game "EscapeCovid". Data were collated and analyzed by the stakeholders working on the development of the game. All results were considered to reshape the new escape game accordingly. The results of the mixed methods analyses were shared among stakeholders. This group of experts met 3 times to summarize the most important suggestions provided by the testers. Each meeting lasted from 3 to 4 hours. Then, 1 shared document was prepared and the stakeholders were asked to provide solutions for each suggested change. This was the beginning of the brainwriting process, where stakeholders updated the document once per week and met regularly every other week. Ideas were incorporated into a new working document, which was the basis for a new round of discussions (ie, five 2-hour meetings). Once consensus had been reached, the web developer revised the game following the guidelines written by the stakeholders on an online document and Figma (Figma, Inc.), a collaborative web application for interface design. Both the contents and the designs were discussed and modified.

Table 2 reports the modifications made from the first version of the game to the final one (also see Textboxes 1 and 2 for the topics addressed and educational content of versions 1 and 2).

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Table 2. Comparison of features from the 2 versions of the game.

Features	Version 1: "Manage Your Emotions"	Version 2: "EscapeCovid"
Objectives	• To teach players to name, identify, and manage their emotions.	• To increase students' knowledge of mental health by familiarizing them with a range of emotions and symptoms of depression and anxiety.
Game flow	• 45-minute game session (3 rooms: home office in the bedroom, living room, and bedroom) + 45-minute debrief.	• Alternating game/debrief sessions in each room (home office in the bedroom, living room, and bedroom) and evaluation questions.
Topics addressed and educational content	• See Textbox 1.	• See Textbox 2.
Character(s)	• Tony, a confined student.	• Thomas, a confined student. • Thomas' roommate, "Hana." • A researcher who appears on the screen to give instructions and clues if the players need them.
Team competition	• Accumulation of points assigned according to the speed with which the player solves puzzles.	• Accumulation of points based on different criteria: speed in solving a puzzle, number of clicks used, time spent in each room and in the entire game, and correct answers to evaluation questions. Teams can also lose points if they choose to access clues to solve puzzles or if they answer assessment questions incorrectly.
Storyline	• Tony is a student living confined in his shared flat during the first lockdown. Game users follow him and the emotions he felt throughout lockdown. • Players must solve puzzles to access emotion cards.	• The same story plot as version 1. The presence of a new character changes the transition from 1 room to the other. • Players must solve puzzles to access emotion cards.
Game setting	• The graphics of the game are similar to an apartment of a young worker and not a student. • The vocabulary used by Tony is not adapted to the target audience.	• A student flat share; instead of having a home office in the bedroom and a separate 2-bedroom flat, the home office in the bedroom is on one side of Thomas' room. • Thomas' voice and vocabulary have also been adapted to meet the expectations/requests of the target audience.

Textbox 1. Topics addressed and educational content of version 1: "Manage Your Emotions."

1. Game
   - This involved knowledge, identification, and management of emotions.
2. Debriefing Session
   - This involved tips and resources to identify and manage emotions.
   - In addition, the emotions felt during the examination period were discussed.

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Textbox 2. Topics addressed and educational content of version 2: "EscapeCovid."

1. Game (examining symptoms of depression through emotions):
   - Stress and anxiety: other emotions, fear.
   - Anhedonia: sadness.
   - Self-devaluation: disgust.
   - Other topics related to mental health that were addressed, including the following:
     - Names of some mental health illnesses.
     - Stigmatization of mental health and mental illness.
     - Resources
2. Debriefing session
   - Room 1: Home office in the bedroom within the bedroom
     - Stress and anxiety: definitions and differences. Link with depression.
   - Room 2: Living room
     - Relationship between mental health and anhedonia. Link with depression.
   - Room 3: Bedroom
     - Relationship between mental health and self-devaluation. Association with depression.
3. Debriefing/end of the game
   - Emotions not previously addressed during the game.
   - Experienced symptoms and depression.
   - Stress on the importance of having good mental health.
   - Resources available in the case of a mental health problem.

In particular, substantial modifications concerned the introduction of mental health–related information in the game. Students had confirmed that the first version of the game was exclusively oriented toward emotions and their management. There were no specific elements of mental health described as either mental diseases or psychological well-being. In "EscapeCovid," the terms "depression" and "anxiety" were used by the main character. The symptoms and consequences of these mental health diseases were presented in the story. Depression and anxiety were selected because they are the most frequent psychological issues among young adults [43]. Players were supposed to learn more about mental health problems (mental health literacy), to destigmatize them (positive beliefs about mental health), and be able to tackle them (positive coping strategies). Puzzles and enigmas were used to teach these concepts with debriefing sessions to reinforce the learning process. Given their expertise in the field of health care, interviewees (health care students) helped with the writing of the plot, from the enigmas to the summary sheets. An example of a cocreated scenario within the story is available in Multimedia Appendix 2. Thanks to a cocreation approach, the game content could be revised by all public health stakeholders who were experts in public health and psychology. The graphics were also modified as shown in Figure 4.

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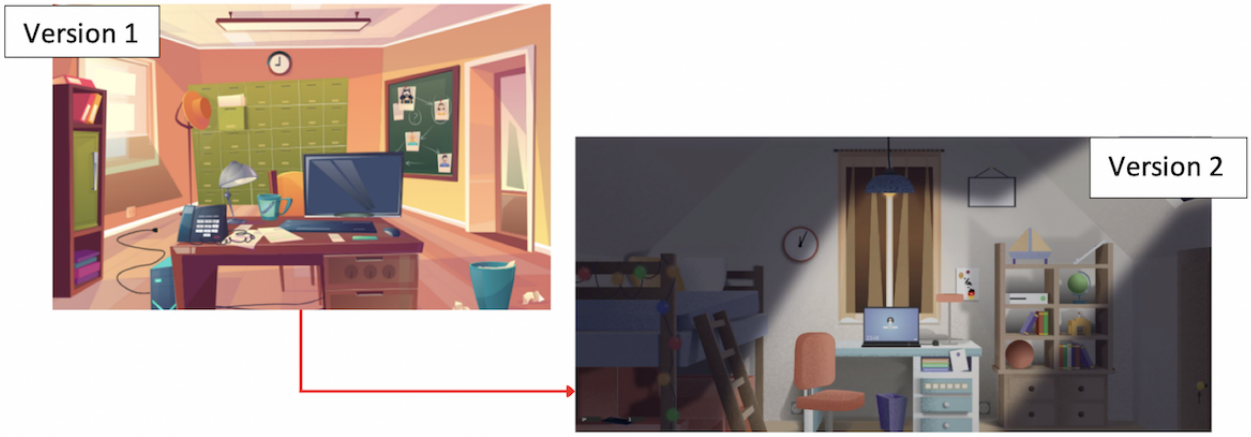
Figure 4. Evolution of the graphics of the first room of "Manage Your Emotions" versus "EscapeCovid".



Playing the "EscapeCovid" Game

The escape game takes place in Thomas' apartment which he shares with another student, Hana, during the first COVID-19 lockdown. Thomas is a university student and is taking his classes remotely. Throughout the game, we follow him during a typical day in lockdown. There are 3 rooms in Thomas' apartment—a home office in the bedroom, a living room, and a bedroom. To move from 1 room to another, players must solve all the puzzles by clicking on the objects spread out in Thomas' room. When players click on an object, a riddle appears and must be solved to move on to the following riddle. Players can only move to another room if they have solved all of the enigmas by uncovering clues or cracking the codes hidden in the sofa, among books, on the floor, etc. There is a limited number of clicks per participant.

At the end of each room scenario, a set of cards is shown, with each card containing a mental health–related message linked to the puzzles. For instance, in the living room, Hana is sleeping on the sofa in the dark and the books around her have titles containing the words "depression," "pain," etc. By solving clues and clicking, players can switch the light on and tidy up the room to make her recover strength. The cards synthesize the messages transmitted through the puzzles in the room. In this case, they explain the symptoms of depression and give tips for coping with distress.

"EscapeCovid" can be played in groups of 4-6 players who help each other and discuss using their computer cameras and headphones. This encourages team spirit and mutual aid, which can be the reflection of real life in the case of mental suffering. All along the game, the group of players is guided by a game guide who explains the rules and answers any questions. The same guide concludes the game session with a final debrief where all participants share their experiences. This final stage is essential for understanding and retaining the mental health–related takeaway messages.

Discussion

Principal Findings

We described the process we used to cocreate a digital game promoting students' mental health during the COVID-19 pandemic. We followed a 2-step procedure. First, we collected quantitative and qualitative data from a manageable sample of students testing a preexisting game. Second, a group of stakeholders used these data to refine and optimize the game to obtain the final user-centered version.

The cocreation approach was very informative for developing the "EscapeCovid" game. In particular, during the test, students felt free to express their opinions openly and give feedback. They mostly appreciated the fact that they could support the development of an intervention addressed directly to them and their peers. Students were also motivated to cocreate the game because it was in line with their values. Students' contribution to the design process nurtured new ideas following a collective creative approach [44] from the testing phase to the final optimization phase. Stakeholders' work was facilitated by students' guidelines while being creative and innovative.

The Rationale and the Usefulness of "EscapeCovid"

During the COVID-19 crisis, several mental health diseases emerged in the young, and digital games were among the most accepted solutions to overcome psychological difficulties [45]. With this rationale, we conceived "EscapeCovid". This game was designed to alleviate anxiety and depression by encouraging interaction with peers and fostering empathy. Participants in this study also confirmed the usefulness and appreciation of digital games during and after the COVID-19 crisis. Previous studies have shown that playing games is helpful in dealing with trauma and improves well-being [46]. This has also been observed in the context of the pandemic [47]. For this, "EscapeCovid" combines the pleasure and the entertainment of games, with a positive psychological effect. This might be due to teamwork, engagement, learning of coping strategies, and creativity, which are all at the root of our game. Indeed, the objective of "EscapeCovid" was to trigger the need to speak out about mental health after having experienced the psychological difficulties of COVID-19. "EscapeCovid" pioneered the discussion of mental health, making it a common topic, and provided advice on how to improve one's mental health, especially in the aftermath of the crisis.

Guidelines for Successful Escape Games on Young's People's Mental Health

First, we confirmed that students enjoy playing escape games, which are linked to mental health. This was also found in other

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studies where health-related serious games were proven to facilitate experiential learning through an entertaining approach [21,48]. Thus, resorting to this type of intervention could be a good strategy to convey messages aimed at improving players' mental health. Engaging in playing games has been reported to promote the potential to enhance life satisfaction and improve individuals' mental well-being [18].

We observed that the plot was essential in capturing players' attention. During the game, testers were attracted by the messages and the scenario, feeling interested in following Thomas' story. They considered this aspect as crucial to transmit educational content, helping to convey new health-related topics, as shown in a previous study [21]. A meta-analysis on the gamification of learning confirmed that the use of personified narrative components is particularly effective in promoting behavioral learning [49].

Playing in groups was also a strategy to make connections and combat isolation, particularly experienced during the COVID-19 lockdown. The notion of interrelationship and mutual aid is a component to consider when developing games, even if they have a digital format.

According to testers, the "EscapeCovid" game had to be user-friendly, fun, and pedagogical. It had to present supplementary contents on mental health, with more specific details on mental health disorders and advice for preventing or treating them. We recommend that future game creators use precise and detailed content, providing accurate and uncensored mental health information and avoiding stigmatizing psychological disorders.

The Challenges of Cocreating Mental Health–Related Games With and For Young People

The involvement of end users entails a large proportion of subjectivity. This is especially true when handling topics such as mental health where feelings and emotions are at stake. End users give their opinions without any specific framework [50]. To mitigate this issue, the sample answering the questionnaire should be large enough to be representative of the target population. However, for the sake of feasibility in terms of time and financial efforts, it is not always possible to question more than 50-100 people. Qualitative interviews are meant to provide further information corroborating the quantitative data, but they still imply subjectivity. Per se, interviews cannot be representative [51]. The limited number of stakeholders has its share of arbitrariness. Nonetheless, regardless of their number, cocreators are the bridge between the whole target population and the stakeholders [27].

Cocreation is time-consuming. The 2-step development demands at least twice as long as the standard time to produce a game. Data collection and analysis add work to the producers who need to incorporate the results into their creative process. Discussions among stakeholders and brainwriting also slow down the production process. This is a limit of cocreation which cannot be overcome while being the best solution for producing an intervention that is well-tailored to the needs of the end user. Qualitative interviews in particular require time and effort, but they are a crucial tool for an in-depth analysis.

Technological issues should also be considered. Players' expectations might not be easily met because of software limitations. This could result in frustration from both parties and decrease adherence to the game. Start-ups and game industries should therefore keep up with new technologies and continuously update their services.

The Advantages of Cocreation

Cocreation has the advantage of considering the viewpoint of the end user, which might not be the case in classical processes of game development using a top–down approach. Collecting students' opinions before the development of the game allowed us to obtain several inputs and ideas that a limited number of web developers and project managers could not provide. The filter of expert health care professionals was also essential during the process. New knowledge was produced through sharing among parties.

The consultation with students having experienced mental health disorders allowed us to address the escape game's topic through a different lens. By considering their opinion, the game could be made more realistic and engaging. The disclosure of emotions and opinions can be facilitated through anonymous questionnaires and qualitative interviews, with students knowing that they are contributing to an intervention beneficial to them and their peers. The feeling of being useful to the community is another added value in the cocreation process [52].

Two different teams—one from an academic environment and the other from a start-up—collaborating to develop the game was also an asset. Indeed, researchers' scientific point of view informed the business goal of the start-up with the common will of creating an evidence-based marketable product.

Finally, cocreation provided useful information for the improvement of both the content and the format of the game. The latter was more contextually specific, adapted to a young population, namely, students, and bridging the gap between the preconceived ideas held by the start-up team and the real-world implementation of the game.

Recommendations for Researchers and Designers

The "EscapeCovid" game is an example of a digital game on mental health, which could be cocreated with young users. The guidelines we present might be applied to other similar interventions.

A 2-step approach is recommended with (1) an initial collection and analysis of combined quantitative and qualitative data, followed by (2) the integration of these data into the reflective and creative work of a group of experts and stakeholders. This approach, similar to a market survey, allows us to obtain clearer game instructions and broader insights, resulting in a more targeted and audience-specific final product.

We suggest basing the coconstruction process on an already existing pilot version because it facilitates the development of the final game. Although the game can be completely re-created, preliminary mock-ups will allow to save time and money. In our study, students were not required to design the game from scratch, and working on the first version of the game was an

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advantage for providing relevant, concrete, and realistic comments based on an existing version.

Stakeholders are also advised to take into account testers' opinions seriously and implement them accordingly. Testers represent the end users and their preferences must be carefully considered to obtain a fully satisfactory end product. For this reason, it is essential to collect as much information as possible during the testing stage.

We suggest to try out the game again once it has been modified. An iterative loop of test-optimization-test will increase the quality of the game. However, it must be pointed out that this process is expensive and time-consuming, despite being extremely informative. It is therefore recommended to end the loop once the comments are saturated, which effectively means limiting the number of additional changes suggested by users and resulting work for developers. This approach can serve as a blueprint for future work on creating gamified interventions on health-related topics addressed to students. Successfully cocreated games can have a wide outreach and improved scalability.

Study Limitations

Testers were mostly student interns at the research center where the study was conducted. This might have biased the results because participating students were already made aware of the project and willing to contribute to its progress as members of the same research laboratory. The test was performed by health care students, meaning that the modifications of the game might be relevant to them and not to students of other subjects. This particular student population also faces specific forms of stress not experienced by their peers. However, we considered their opinion to be of paramount importance in terms of the contents of the game, which benefited from their skills and experience with stress. The game was more realistic and other students could relate to Thomas' story imagined by young people their age.

Another limitation is that the students participating in the study were rewarded with a gift card, which could have significantly influenced the answers due to desirability bias. This phenomenon was even more likely in the case of interviewees who had received 2 gift cards. The gender balance among the participants was skewed in favor of female students, which may have influenced the results of the test.

Finally, we were not able to retest the game after its modification. Because of money and time constraints, we only produced a new version of the game without further refinement.

Conclusions

Our results suggest that cocreation contributes to improving the suitability of a health promotion and disease prevention intervention and that an end user–centered approach can facilitate intervention tailoring. When conceiving a health-related escape game, we recommend using a 2-step approach, including an initial collection of quantitative and qualitative data from end users testing the game (test), followed by the integration of these data into the development of the game by a restricted number of experts (optimization). This approach can serve as a model for future work on creating gamified interventions on health-related topics addressed to students.

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Authors' Contributions

DL was responsible for conceptualization, investigation, and writing—reviewing. CV performed data curation and writing—original draft preparation. DT collected and analyzed the quantitative data. HH and CT took part in data curation and writing. IM contributed to conceptualization, methodology, investigation, writing—reviewing and editing, and supervision.

Conflicts of Interest

DL, HH, and DT are employees of the start-up Tricky, which developed the game described in this paper. Their jobs are paid by other projects, and they did not take any financial benefit from the development of "EscapeCovid." The game was developed for business, but data collection, analysis, and observation for this manuscript were conducted by CV, CT, and IM who are totally independent from Tricky. The study results are completely transparent and based on scientific integrity.

Multimedia Appendix 1
Satisfaction questionnaire.
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Multimedia Appendix 2
Example of a cocreated scenario in "EscapeCovid".

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[DOCX File , 329 KB - games_v12i1e48545_app2.docx]

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Abbreviations

PRIME: Plan, Response, Impulses, Motives, and Evaluation
PRODUCES: Problem, Objective, Design, End Users, Cocreators, Evaluation, Scalability

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Original Paper

Enhancing Serious Game Design: Expert-Reviewed, Stakeholder-Centered Framework

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Abstract

Background: Traditional serious game design methods often overlook stakeholder needs. This study integrates stakeholder theory and enterprise architecture (EA), along with the Architecture Development Method, to propose a novel framework for serious game design. Crafted to aid practitioners, researchers, and specialists in leveraging resources more effectively, the framework is validated through a design science research methodology. Expert reviews have further refined its features, making it a robust tool for enhancing serious game design and implementation.

Objective: This paper introduces a framework for designing serious games, covering stakeholder analysis, requirements gathering, and design implementation planning. It highlights the importance of expert review in validating and refining the framework, ensuring its effectiveness and reliability for use in serious game design. Through critical assessment by experts, the framework is optimized for practical application by practitioners, researchers, and specialists in the field, ensuring its utility in enhancing serious game development. The next step will be to validate the framework empirically by applying it to a serious game development project.

Methods: We developed and validated a conceptual framework for serious game design by synthesizing stakeholder theory and EA through literature review, concept mapping, and theory development by way of a design science research approach. The framework is iteratively refined and validated via expert review, drawing on insights from professionals experienced in serious games, stakeholder theory, and EA. This method ensures the framework's practical relevance and effectiveness in addressing real-world design challenges.

Results: An expert review by 29 serious game practitioners validated the framework's success in stakeholder management, confirming its stakeholder-centered effectiveness. Although the experts praised its structured approach, they suggested clearer guidance for game design elements. In addition, the experts, while acknowledging the framework's complexity, saw its depth as valuable for efficient management. The consensus calls for a refined balance between detailed functionality and user-friendly design, with the framework's impact on stakeholder capabilities revealing a spectrum of professional needs.

Conclusions: This paper presents a framework for creating effective and organizationally aligned serious games. Evaluated across execution, practical, and EA levels, it is logical but varies in ease of understanding, with experts calling for more accessibility at the EA level. It enhances stakeholder efficiency and management but is criticized for rigidity and a need for flexibility. Recommendations include streamlining the framework, enhancing clarity, reducing administrative tasks, and incorporating clear guidelines on technology use, motivational elements, and operational tools. This aims to help stakeholders produce more targeted and adaptable game designs. The next iteration will be developed after application to a project and team feedback.

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KEYWORDS

serious games; stakeholder theory; enterprise architecture; serious game development; design framework

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Introduction

Background

This paper articulates a stakeholder-centered framework for serious game design in various stages before, during, and after various methods have been applied to develop it. The research presents the framework—informed by stakeholder theory and enterprise architecture (EA)—as it evolved through various stages of development. It underscores the need for a structured approach that focuses on stakeholders throughout the design process to enhance the success of serious game production efforts. This research reflects 3 cycles of the design science research (DSR) paradigm, aiming to balance domain-specific needs with generalizable solutions. The framework emphasizes alignment with stakeholder needs and effective communication among different groups, recognizing the complexity of serious games and the importance of their relevance to users.

This work also presents findings from an expert review questionnaire that used a qualitative methodology to assess the framework's effectiveness. The review gathers feedback from practitioners and specialists in the field, guiding enhancements to the framework's clarity, structure, and usability. The paper concludes with insights into the framework's current state of development and recommendations for its refinement, emphasizing the need to simplify its complexity and communicate its components more effectively for real-world application.

Framework Requirements

Several key requirements for the initial framework emerged from a comprehensive integrative literature review. A conceptual framework is indispensable for comprehending the complex phenomena explored because it provides a structured and systematic method for organizing, analyzing, and interpreting data. Several essential components of a conceptual framework contribute to its efficacy, including clarity, relevance, coherence, simplicity, testability, and generalizability. As such, the following characteristics of the framework that has been developed serve as guiding principles. First, a conceptual framework should be clear and straightforward for its intended audience to comprehend. It should define its key concepts, variables, and relationships as well as provide a thorough overview of the subject under investigation. Second, the framework should be pertinent to the research problem or question being addressed. It must thus be tailored to the context and objective of the study. Third, the framework must have logical coherence, a clear structure, and internal consistency. The framework's concepts, assumptions, and relationships should be logically connected and consistent with one another. Fourth, a good conceptual framework should be as simple as possible while capturing the essential characteristics of the studied phenomenon. Fifth, the framework must be susceptible to empirical testing, with testable hypotheses and predictions that can be evaluated through observation and data analysis. Sixth and last, such a framework should be applicable to other settings or situations and be generalizable beyond the specific context of the study. It should therefore serve as a foundation for the development of broader theoretical insights and generalizations about the subject of study.

Our framework prioritizes stakeholder engagement and management within serious game design, addressing a gap often overlooked in conventional design literature. While incorporating established design elements—such as learning objectives [1-4], game mechanics [5-9], narrative [10,11], user interface and experience [12], and evaluation [13,14]—the framework's novelty lies in its stakeholder-centered approach. It is tailored to align with educational or training standards, drive engagement, and provide meaningful feedback. However, the primary focus is not solely on game design; instead, the framework is rooted in stakeholder theory and EA, which have been the fulcrum of our extensive literature review. By doing so, we address the intricacies of organizational and stakeholder dynamics, ensuring that serious games are developed within a context that appreciates the diverse roles and impacts of various stakeholders.

Products of the Integrative Literature Review

Overview

The integrative literature review presents a taxonomy of serious games; the phases of serious game production; the stakeholders involved in serious game production; stakeholder identification, analysis, and management procedures; and The Open Group Architecture Framework (TOGAF) Architecture Development Method (ADM). These concepts are briefly outlined in the following subsections because they inform the construction of the conceptual serious game framework.

What? Classifying Serious Games

Serious games are edifying artifacts, tools, and games created by development teams that use ludic activity for a specific purpose, format, genre, interaction style, and application area. Serious game taxonomies classify games by *purpose*. This classification can help identify the functions of a serious game and guide the selection and development of educational and training games. The following are some serious game categories:

- Simulation games simulate real-world situations to give learners practical experience and practice in complex or high-risk situations (eg, flight simulators for pilot training and medical simulators for surgery [15]).
- Educational games teach specific knowledge or skills, such as language, math, or history. Game mechanics such as rewards and feedback encourage learning and participation [16].
- Training games teach practical abilities such as customer service, leadership, and teamwork. To track progress and facilitate learning, they may include simulations or role-playing scenarios as well as feedback and assessment [17].
- Health games promote healthy behaviors such as exercise, healthy eating, and disease management. Game mechanics such as rewards and challenges may encourage behavior modification and participation [18].
- Persuasive games aim to influence players to adopt certain behaviors, such as environmental conservation, social

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justice, or political activism. Story elements often emotionally engage and motivate players [19].

By classifying serious games by their intended function, a functional taxonomy can help find the best games for learning or training needs and guide their development. These serious game classifications are relevant to this research and accepted under the serious game banner.

Serious games, gamification, and game-based learning differ greatly. These terms all refer to using games or game elements in learning or training, but serious games are games with a specific goal. They usually teach players a skill [20]. Serious games differ from entertainment-focused commercial games. Gamification, by contrast, uses game elements such as points, badges, and leader boards to motivate and engage nongame users [21]. A fitness app, such as *Strava*, that rewards users for reaching fitness goals uses gamification. Game-based learning uses games to teach or train, but, unlike serious games, its main goal is not to achieve a learning outcome [22]. *Civilization* may be used by a history teacher to teach about historical events and civilizations, but it is not meant to teach history. Game-based learning uses games to teach or train without a specific goal.

Who? Serious Game Production Stakeholders

Different stakeholders from varying fields are involved in serious game production and development. Common stakeholders include the following [16]:

- Game developers are responsible for designing and developing the game. They create captivating game mechanics, visuals, audio, and more.
- Subject matter experts (SMEs) are knowledgeable about the serious game topic. They provide content and knowledge for game accuracy and effectiveness.
- Teachers and trainers can use serious games as a teaching or training tool for students or employees. They demonstrate how the serious game can meet learning goals.
- Game publishers distribute serious games to a wider audience. They market, distribute, and sell the game.
- Players are serious game consumers. They play the game and give feedback to improve it.
- Funders and sponsors are individuals or organizations that provide financial support for the development of the serious game (eg, government agencies, private foundations, or businesses).

When? Phases of Serious Game Production

Serious game production follows a similar process to traditional game development but with educational or training goals. The following are the five main serious game development phases:

1. The first step in serious game development is to identify the game's learning objectives, audience, and context. This usually involves a needs assessment or curriculum analysis to identify gaps or areas where game-based learning could be beneficial [15].
2. A detailed plan for game mechanics, story, user interface, and learning content is created during the design phase. This phase may include storyboarding, prototyping, and playtesting to ensure that the game is engaging and meets learning objectives [16].
3. Development includes creating the serious game, including programming, artwork, audio, and multimedia assets. Game developers, instructional designers, SMEs, and other stakeholders work together to ensure that the game meets educational or training goals [23].
4. After creating the serious game, it is tested and evaluated to ensure that it meets its learning objectives. User testing, focus groups, and other student and stakeholder feedback methods may be used [24].
5. The serious game can be deployed for use in educational and training settings in the deployment and maintenance phase and should be supported and updated to ensure that it remains relevant and effective over time.

Serious game developers use the aforementioned steps to create outcome-aligned educational and training games. Such a framework supports agile game development and various development methods.

Where? TOGAF ADM

Serious games can make use of TOGAF ADM. Serious games with multiple stakeholders and complex systems require a structured EA development process. TOGAF ADM can also be customized for different industries and organizations. Such a broad view ensures that the game aligns with organizational goals, making it a good choice for serious game creators. TOGAF ADM is a nine-phase, sequential process for EA [25]:

1. Architecture vision: the EA team creates a high-level vision of the organization's desired future architecture state. This phase determines the architecture development's business drivers, stakeholders, and scope.
2. Business architecture: phase 2 involves understanding the organization's business processes, objectives, and strategies. This phase produces business architecture artifacts that describe the organization's business capabilities, value streams, and structure.
3. Information systems architecture: this phase focuses on understanding the organization's information systems and technology infrastructure. This phase creates architecture artifacts for the organization's application, data, and technology architecture.
4. Technology architecture: phase 4 focuses on selecting and defining technology components for implementing the organization's architecture. This phase creates architecture artifacts for the organization's technology infrastructure's hardware, software, and networks.
5. Opportunities and solutions: phase 5 evaluates architecture solutions that meet business goals and objectives. This phase creates architecture artifacts that describe proposed solutions and their organizational impact.
6. Migration planning: in this phase, a plan is created to transition the organization's architecture to its desired future state. This phase produces architecture artifacts that describe transition activity sequence and timing.
7. Implementation governance: phase 7 oversees the implementation of architecture solutions and ensures alignment with organizational objectives and goals.

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Governance framework architecture artifacts are produced in this phase.

8. Architecture change management: this phase manages ongoing changes to the organization's architecture, aligning them with its goals and objectives. This phase produces architecture artifacts that describe change management.
9. Architecture evaluation: this phase evaluates the effectiveness of the architecture solutions and ensures that they meet the organization's goals and objectives. This phase creates architecture artifacts that describe the evaluation process and results.

Interest groups can create EA solutions that meet their business goals by following TOGAF ADM. Moreover, TOGAF application to serious game development requires several crucial steps. First, an architecture vision is created to describe the game's goals, objectives, target audience, and learning outcomes. Stakeholder analysis is then performed to identify the game development stakeholders and their needs and expectations. This ensures that the game is designed with stakeholders in mind. Architecture requirements describe the game's functional and nonfunctional needs. The architecture development phase designs the game's architecture based on the previous step's requirements. This includes game mechanics, visual and audio assets, user interface, and layout design, that is, build, code, integrate visual and audio assets, and test the game's usability and efficacy. To ensure stakeholder satisfaction, the game is monitored and evaluated over time. This may involve player feedback, game performance data analysis, and adjustments. Specifically, this work references the application of an ADM to serious game development and highlights how it can assist organizations in creating the desired strategic resource game. Doing so emphasizes that the ADM not only assists in the development of the serious game but also identifies organizational capabilities, methods, and processes that can be leveraged in future projects, thereby enhancing the team's effectiveness.

Why? Stakeholder Identification, Analysis, and Management

Serious game design requires a stakeholder-centered conceptual framework for the following reasons:

- A stakeholder-centered approach considers various stakeholders' needs and expectations during design. This may lead to more effective, engaging, and audience-relevant games (Bopp, J, A, unpublished data, December 2020).
- A stakeholder-centered approach ensures that the game is designed for the end user, improving usability and effectiveness. This improves player engagement, learning, and game performance [26].
- A stakeholder-centered approach can involve stakeholders in the design process, facilitating participation and acceptance. By increasing stakeholder confidence and ownership, serious game adoption and implementation can succeed [27].
- To improve serious game sustainability and scalability, a stakeholder-centered approach can be used to design games that meet the evolving needs of stakeholders. This can help the serious game stay relevant and effective as stakeholders' needs change [28].

Serious game development relies on stakeholder identification, analysis, and management. This process begins with stakeholder identification. Stakeholder analysis prioritizes their needs and interests, while surveys, interviews, and focus groups help understand them. Stakeholder management involves planning how stakeholders will be engaged, their needs met, and their feedback incorporated into the serious game. Serious game development can use stakeholder management techniques such as regular meetings, an engagement plan, a registry, the prioritization of needs, feedback, and data analytics. Developers can create more effective, engaging, and audience-relevant games by managing stakeholder needs and expectations. A stakeholder-centered framework is needed for serious game design to ensure that stakeholders' needs are met and to improve game effectiveness, usability, and sustainability.

How? Stakeholder Identification, Analysis, and Management

Stakeholder identification, analysis, and management are crucial to project success, including serious game development. Stakeholders are people or groups who care about the project's outcomes and can influence them. Successful stakeholder identification, analysis, and management follow these four steps:

1. Identify internal, external, primary, and secondary stakeholders. Stakeholder analysis maps stakeholders and identifies key players [29].
2. Analyze stakeholders' interests, needs, expectations, and influence on project outcomes. A matrix that maps stakeholders by power and interest can do this [30].
3. The project team can develop strategies to manage stakeholder relationships based on stakeholder analysis. This involves prioritizing stakeholders by influence and interest and creating stakeholder-specific engagement strategies [31].
4. Implement stakeholder management strategies through ongoing communication and engagement, such as project updates, meetings, and consultations. Stakeholder interests must be monitored and the stakeholder management plan adjusted [32].

These steps for identifying, analyzing, and managing stakeholders can help serious game developers maximize project success and build long-term relationships. When a new serious game project begins, the organization or team will already know the relevant stakeholders from stakeholder management and EA. Thus, each project improves the organization or team.

Methods

Framework Development

Overview

This section discusses how the integrative literature review revealed relevant theories, determined its limits, found relevant sources, collected terminology, defined its theoretical pillars, and provided practical approaches to the stakeholder-centered framework. Moreover, this section assesses the framework's

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evolution over time; and it also theorizes future representations; reviews design processes; suggests improvements; and states the artifact design's aggregate, iterative, and consistent impacts.

Variant 1: Informed by Literature

The preliminary snapshot of the stakeholder-centered framework is a compilation of ideas for a flexible, general-purpose framework to aid in the design of serious games. Initial concepts included generating, developing, and visually communicating the system's fundamental elements, with a focus on user needs and empathy for the target demographic of serious game design stakeholders. Existing serious game literature, models, and approaches inform the framework variant, and an early exploration of these works provides a knowledge base for further consideration. Understanding the methods used in previous research on the same or similar issues assists in determining which methods will be most beneficial to advancing the topic and can aid in the evaluation of prior studies.

Various sources are represented in this formation because serious games' content, definition, sources, liminal works, methods, and existing frameworks are investigated. As such, a substantial portion of this work is theoretical in nature and largely represents the efforts to seek and collect literature on the nature of serious games.

Textbox 1 shows how theoretical and experiential exploration shaped our initial project impression. First, because serious game projects require people and management, stakeholder theory was added to the framework. Second, early EA readings may help organizations achieve their goals. The framework's third pillar, serious game design theory, positions the research and establishes its context. From this early stage, the framework must be applied and evaluated to determine its value for practitioners in the given milieu. This variant was extensively developer (self) reviewed. These steps close the DSR cycle loop and indicate that each variation is evaluated, even if reflectively.

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Textbox 1. Sources that informed the first variant of the framework.

Sources and detail with explanation

- Deterding et al [21]
  - The authors define "gamefulness" and "gamification." This influential work examines the differences between full-fledged games, serious games, pervasive games, extending games, game elements, and playful interaction. Even if not adopted, their definitions of "gamification" and "gamefulness" in contrast to serious games and playful interaction refine discourse and enable researchers to better understand and analyze the phenomena.
- Annetta [33]
  - The author has presented a nested model of educational game design elements. Serious games have 6 elements, ranging from identity to instruction. This paradigm is hierarchical, with identity as the foundation for serious game design.
- Garris et al [23]
  - A model by the authors shows the learning approach used in educational game research and its results. First, the main goal of any instructional content is to create a game-like educational program. Second, these qualities trigger a loop of user perceptions or responses such as interest or delight, user behaviors such as perseverance or concentration, and system input. If designers can match educational content with game elements, this cycle creates repeatable and self-motivated play. Third and last, game participation achieves training goals and learning outcomes.
- Ferdig [34]
  - The authors define the "heart of serious game design" as theory, content, and game design. Serious game success requires emergent theory, content, and game design knowledge. Managing disciplinary conflicts and agreeing on serious game design is a major challenge for serious game teams.
- Marne et al [35]
  - The authors list 6 serious game design aspects. This serious game design methodology shows the importance and distinction of pedagogical and game design expertise and their role in serious game development. This model's main benefit is selecting the right experts for each design area.
- Rooney [36]
  - The author proposes a triadic serious game design framework that considers pedagogy, play, and fidelity to create media.
- Vanden Abeele et al [37]
  - The authors advocate the player-centered, iterative, interdisciplinary, and integrated (P-III) serious game design framework. This prominent framework provides a way for creating serious games that hinges on 4 conceptual pillars: player-centered design (from user testing during development to participatory design workshops during the design phase, projects start with inquiries that are influenced by ethnographic research), iterative development (the team establishes multiple milestones, and user testing culminates in a final prototype that can be evaluated), interdisciplinary teamwork (collaboration between instructional and game designers), and integration of play and learning (seamless blend between the game vision and core mechanics on the one hand and learning principles on the other hand).
- Yussof et al [38]
  - The authors propose a serious game conceptual framework. The suggested outline combines gaming requirements with learning and pedagogy theory to provide a conceptual framework for serious game designers and educators.
- Gee and Hayes [39]
  - The authors adapted the mechanics, dynamics, and aesthetics (MDA) framework into the design, play, and experience (DPE) framework. The extended DPE framework shows serious game layers for storytelling, learning, game play, and user experience. Every layer includes design, play, and experience.
- Roungas and Dalpiaz [40]
  - The authors created a conceptual model of serious games to reduce misconceptions in serious game design teams by specifying a standard terminology that stakeholders can accept. The conceptual model also guides serious game design to address Game Design Document and other record keeping and administrative process inconsistency. Combining educational and game elements is the main challenge. Completed conceptual models are displayed in unified modeling language (UML) class diagrams.
- Breuer and Bente [41]
  - The authors examine how serious games relate to e-learning and game-based learning. Serious games may use different learning strategies than edutainment and e-learning, according to them. According to the authors, many serious game definitions and typologies are limited.
- Ferdig [34], Rooney [36], and Deci and Ryan [42].

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- Our novel synthesis combines the DPE framework, the serious game design framework proposed by Rooney [36], and self-determination theory (SDT). The idea emphasizes the importance of theory (pedagogy), content (fidelity), and game design (play) in serious game design. Effective serious game development is said to be central to these elements. In the DPE framework, SDT principles such as relatedness (the desire to connect with others), autonomy (the desire to choose one's own paths), mastery (the desire to develop skills and master them), and purpose (the desire to connect actions with greater reason) are proposed to clarify or distinguish the connections between human psychological patterns and game features, mechanics, and dynamics to argue that gaming approaches and thinking can be successful. All 3 theories are combined to create a new serious game development strategy. The final stakeholder-centered framework partially incorporates these theories, but much of it leads the authors of this study to literature on game design.

Variant 2: Position, Activity, and Specialization

The next stakeholder-centered framework revisits unknowns and defines user problems to generate problem statements for subsequent design phases. Recordkeeping is stressed to avoid future issues. Stakeholder theory is emphasized, and how to identify and analyze serious game stakeholders is a key question. These stakeholders include experts, developers, and consumers, whose power and interest are analyzed using stakeholder analysis methods such as the power-interest grid. In the initial framework visualization, the EA pillar influences responsible, accountable, consulted, and informed matrices; Gantt charts; and business process model and notation swimlanes. In addition, variant 2 introduces 2 phases, idea validation and conceptualization, which continue in subsequent variants. We also discuss the 4 main serious game stakeholders from a previous stakeholder management approach: development team, publishers, context-related staff, and supplemental staff. Consumer stakeholders are consulted during development, but only the 3 (or 4) main categories are relevant to core game production.

As shown in Table 1, serious game production stakeholders often play multiple roles in smaller teams due to constraints. Variant 2 of the framework includes idea validation and conceptualization. The former evaluates the team's serious game development prospects, while the latter starts project ideation. The framework has 3 levels: *execution*, *inquiry*, and *practical*. Serious game design stages include idea validation, conceptualization, development, and iteration in the execution level. Academic research and inquiry on serious game manufacture, participatory design, and more occur at the inquiry level. Stage-specific requirements and outcomes are listed in the practical level checklist.

The 3 levels are necessary due to the complexity of serious game development. The variant 2 framework shown in Figure 1 [43] also includes TOGAF ADM, DSR design, and the agile software development life cycle. Collaboration, adaptability, and rapid prototyping are hallmarks of agile software development. Rapid prototyping, customer focus, flexibility, and serious game development improvement are promoted by this approach. Serious game development levels include TOGAF ADM, DSR design, and the agile software development life cycle.

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Table 1. Serious game stakeholder categories, positions, activities, and specializations.

Category	Positions	Activities	Specializations
Development team	Programmer, artist, designer, producer, tester, composer, sound designer, and writer	The different tasks that game designers may perform during game development include coding, developing AI[a] systems and camera systems, drawing characters and environments, designing UI[b] elements, populating levels, managing the development team, managing schedules and resources, testing the game for bugs, creating music and sound effects, writing character dialogue, and setting up game objective prompts. Designers may also distinguish good from bad games and explain why, as well as ensure that the game achieves its goals and maintains its vision.	Over time, professionals specialize in 2D or 3D graphics, physics, mathematics, particle systems, UI, AI, input devices, and computer networking. Storyboard artist, concept artist, 3D modeler, environmental artist, texture artist, visual effects artist, UI artist, animator, technical artist, art director, level designer, game designer, system designer, scripter, combat designer, creative director, executive producer, associate producers, and assistant producers can specialize. Some positions are hired later in the development process and may be considered freelance rather than full time.
Publishing team	Product manager, project manager, creative manager, art director, technical director, marketer, and players and users	Publishing team members set priorities, review project milestones, set and meet targets or deadlines, provide feedback on improvements, collaborate with marketing to develop packaging and other visual assets, and promote the game. They also mediate between the studio and the publisher's legal department, work with licensors and the ESRB[c] to secure a rating, and provide technical support. They may also cooperate with marketing and PR[d] on press materials, co-design the game, and improve its visual language.	These positions may or may not affect the game's content and aim to streamline development and maintain quality within budget and time constraints. Game designers or writers in publishing usually fill these positions, which may vary in involvement depending on the publisher. In addition to programming, they may handle management issues and work with media outlets and advertising firms with different needs and capabilities.
Context-related team	Subject matter expert, educational theorist, scholar, and research director	They consult with teams on game content and requirements, provide educational material, maintain educational aspects, investigate and test game features, and manage or supervise scholars and data collection. They also propose, choose methods, supervise, budget, and report.	In all serious game design projects, these stakeholders must provide sufficient materials to address serious issues and express them through gameplay. Although they may not be educators, they focus on game curriculum and syllabus development. They may be specialists in a research field or pursuing specialization.
Supplementary team	Business developer, lawyer, brand manager, PR manager, quality assurance manager, talent recruiter, human resource officer, game reviewer, licensor, and funding entity	They create business opportunities, secure funding, and invest in games. They also provide legal advice, review contracts, and handle licensor negotiations. In addition, they maintain brand representation in the game and work with marketing on packaging, create marketing strategies, contact gaming publications and blogs, and organize press events. Moreover, they manage the test department, send developers bug sheets, and ensure quality, as well as recruit, manage, and train new hires.	Their responsibilities include building relationships with teams, reviewing game demonstrations, negotiating contracts, generating marketing strategies, managing the employment process, playing and reviewing games, and securing funding for serious game projects. Game producers run the test department, organize press events, recruit talent, and invest in serious game projects. These people play games, write reviews, and suggest improvements. In addition, they license IP[e] and may work with licensors to get ratings. Moreover, they financially support serious game projects and crowdfund.

[a]AI: artificial intelligence.

[b]UI: user interface.

[c]ESRB: Entertainment Software Rating Board.

[d]PR: public relations.

[e]IP: intellectual property.

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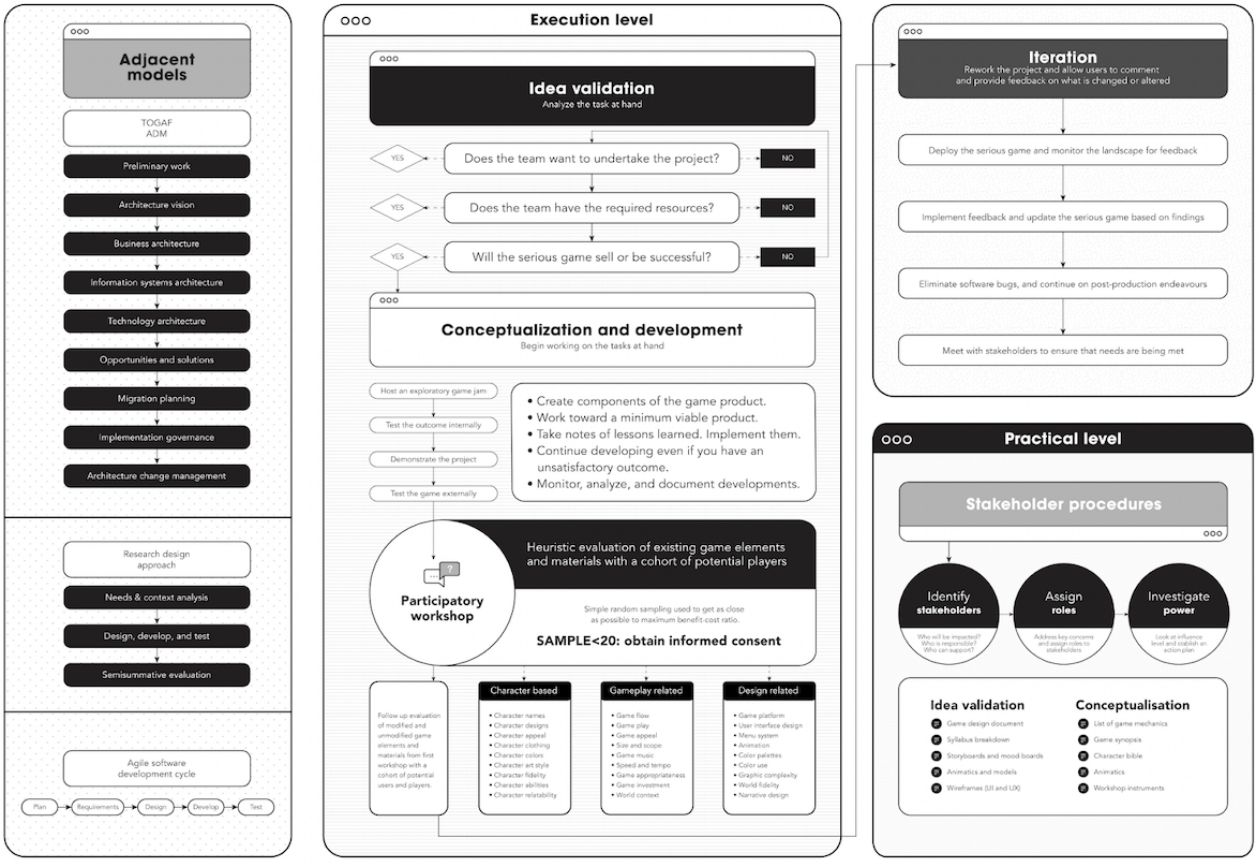
Figure 1. Simplified variant 2 of the stakeholder-centered framework. ADM: Architecture Development Method; TOGAF: The Open Group Architecture Framework; UI: user interface; UX: user experience. For a higher-resolution version of this figure, see Multimedia Appendix 1.



Variant 3: Refinement

Variant 3 of the framework emphasizes human-centeredness and separates idea validation and evaluation (Table 2). The 3 levels are *EA*, *execution*, and *practical*. Each level combines serious game and stakeholder theory literature, practices, and methods, but only the EA level fully represents 1 of the 3 TOGAF ADM research pillars. The levels help practitioners avoid not seeing the forest for the trees and understand the framework's many components, mechanisms, and prescriptions. The composite nature of serious game development makes the framework stratiform, and the levels isolate and aggregate all interaction-based components, connectors, and relations for every aspect of the system's functionality into a single structural model.

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Table 2. The third framework variant.

EA[a] level	Execution level	Practical level
This level establishes the strategic framework for serious game design, aligning game objectives with organizational goals and stakeholder needs through a comprehensive stakeholder analysis.	It transitions the process from strategic planning to the tangible design and development phases, detailing the game's mechanics, story, and technical requirements to ensure alignment with the defined objectives.	• This final level focuses on the deployment, testing, and evaluation of the game in real-world scenarios, emphasizing the adjustment of the game design based on user feedback and the effectiveness of achieving intended outcomes.
Core functions		

This level focuses on the strategic aspects of serious game design, aligning game objectives with broader organizational or project goals. It incorporates stakeholder analysis to ensure that the game's objectives meet the needs and expectations of all relevant parties.	At this level, the framework transitions from strategic planning to operational design and development. It involves the detailed design of the game, including gameplay mechanics, narrative elements, and technical specifications. This level ensures that the game's design is feasible and aligns with the strategic objectives outlined at the EA level.	• The practical level is where the game is deployed and assessed in real-world settings. This involves testing, gathering feedback from end users and stakeholders, and iterating on the design based on this feedback. The focus here is on practical application and the effectiveness of the game in achieving its intended outcomes. The level offers options for game developers:
		• Prediscovery stage
		  • Basic: stakeholder team selection, assembled team, and game design document
		  • Standard: basic outputs, selection of game mechanics, and storyboards
		  • Advanced: standard outputs and detailed curriculum itemization
		• Production
		  • Basic: stakeholder prioritization, game synopsis, and character bible
		  • Standard: basic outputs and mood boards
		  • Advanced: standard outputs, wireframes, and animatics
		• Periphery
		  • Basic: Ongoing stakeholder prioritization, game art development, and level design
		  • Standard: basic outputs and prototype development
		  • Advanced: standard outputs, deeper design practice, and quality assurance

[a]EA: enterprise architecture.

Ethical Considerations

This study was approved by the Institutional Review Board of North-West University, ensuring adherence to ethical standards in research involving human participants (approval number: NWU-01775-20-A9). Informed consent was obtained from all participants prior to their inclusion in the study (in the expert review questionnaire). Participants were informed of their right to opt out at any time without any consequences. Data collected during this study were anonymized to protect participant confidentiality. Identifiable information was removed, and data were stored securely in a password-protected database. Participants were not compensated for their time and effort in participating in the study. They were, however, promised a copy of the academic work once published.

Results

Expert Review Analysis

Overview

The expert review questionnaire regarding the stakeholder-centered framework was distributed to 220 serious game practitioners and experts internationally, of whom 29 (13.2%) completed it. On average, questionnaire completion took 57.2 (range 14.5-252) minutes. Considering the in-depth nature of the research, a completion time of approximately 24 minutes (excluding the outlier) is acceptable, despite the recommended 15-minute length for questionnaires. This study's niche focus on serious games results in a smaller expert pool; thus, the response rate and data volume are considered satisfactory. The questionnaire, designed for comprehensive data collection on the stakeholder-centered framework, uses both qualitative and inferential statistical analyses.

The research accounts for web-based survey challenges by ensuring content validity and question clarity, balancing open-ended and closed-ended questions, and maintaining

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reliability. Despite initial plans, level-specific explainer videos were excluded to prevent extending the questionnaire's length. An introductory explainer video was provided [44], and participants had full access to the framework for a thorough review. To ensure depth and accuracy, participants were granted access to all aspects of the framework to ensure that they could perform a multifaceted expert review.

Section A: General Information

The questionnaire respondents predominantly skewed younger, with 45% (13/29) aged 26 to 35 years and 38% (11/29) aged 36 to 45 years. Those aged 46 to 55 years constituted 10% (3/29) of the sample, while those aged 18 to 25 years and ≥66 years each represented 3% (1/29). White individuals made up 69% (20/29) of the respondents, followed by 14% (4/29) of individuals of other ethnic backgrounds including Hispanic individuals, Latinx individuals, people of color, and others. Asian respondents accounted for 7% (2/29) of the sample; and African, Indian, and undisclosed categories each accounted for 3% (1/29). Gender distribution among the respondents was fairly even, with 56% (16/29) identifying as man and 41% (12/29) as woman; of the 29 respondents, 1 (3%) preferred not to disclose their gender. In terms of geography, 45% (14/29) of the participants were from South Africa, reflecting the study's origin and local interest. Thailand and Australia each contributed 7% (2/29) of the respondents, while the remaining countries (11/13, 85%) each contributed 3% (1/29) of the respondents, broadening the international representation.

Section B: Game Development Experience

Overview

The survey section on game design experience collected data on qualifications, occupations, and development experience, including roles and satisfaction in game development. The respondents had high qualifications, with 55% (16/29) holding doctoral degrees, 24% (7/29) master's degrees, and 14% (4/29) honors degrees. The occupational profile was academic-centric, with 24% (7/29) being lecturers and 17% (5/29) senior lecturers. Others (17/29, 59%) included professors, researchers, and various roles in private industry. A significant proportion of the respondents (16/29, 56%) had >5 years of game development experience, showcasing their expertise in the field. Most (22/29, 76%) had also been involved in serious game development, although a few (3/29, 10%) had not, and some (2/29, 7%) were unsure or had projects in development. In terms of team experience, the majority (22/29, 76%) affirmed involvement, with a small percentage (3/29, 10%) either working independently or not at all in serious game development. Satisfaction across 11 development factors (DFs) was measured, with the highest scores (out of 4) being for collaboration (3.54), skills (3.56), vision (3.56), and educational aspects (3.7) and the lowest for management (2.85). The DFs and their resulting scores were as follows:

- DF1: collaboration, average score=3.54
- DF2: communication, average score=3.22
- DF3: resources, average score=3.19
- DF4: team composition, average score=3.3
- DF5: skills, average score=3.56
- DF6: management, average score=2.85 (this is the lowest average score among the 11 DFs studied)
- DF7: vision, average score=3.56
- DF8: procedures and processes, average score=2.96
- DF9: outcomes, average score=3.12
- DF10: conflict, average score=3.31
- DF11: educational and edifying aspects, average score=3.7 (this is the highest average score among the 11 DFs investigated)

Respondents expressed their views on various aspects of serious game development in this section:

- Collaboration (DF1): respondents were largely satisfied with their collaborative efforts in developing games.
- Communication (DF2): although rated slightly lower than collaboration, communication during serious game design was still positively regarded.
- Resources (DF3): the resources available for serious game development, including educational materials, software tools, and marketing aids, were deemed satisfactory.
- Team composition (DF4): the composition of serious game teams was viewed favorably, with the right mix of skills and expertise viewed as to the team's goals and performance.
- Skills (DF5): team members' skills were rated as fitting for serious game development tasks.
- Management (DF6): satisfaction with management was moderate, indicating that some areas may require improvement.
- Vision (DF7): respondents were content with the guiding visions for serious game projects, which help in goal setting and decision-making.
- Procedures and processes (DF8): there was some dissatisfaction with the processes involved in transforming ideas into final products.
- Outcomes (DF9): the outcomes of serious game projects were generally met with approval, suggesting satisfaction with the services or interventions provided.
- Conflict (DF10): opinions on conflict were mixed but leaned toward satisfaction with handling disagreements during serious game projects.
- Educational and edifying aspects (DF11): given the respondents' backgrounds in education and research, they highly rated the educational value of the games produced.

The section B responses indicated that the experts were well-versed in game development, with a specific focus on serious game development. Their moderate satisfaction across key production factors attested to their practical experience, reinforcing the study's credibility and reliability. Predominantly researchers, these individuals engage deeply with the field, often acting as SMEs in serious game projects. The most frequently reported challenges were resource-related: time, budget, and skills. Acknowledging these common hurdles faced by serious game professionals helps refine the framework to address and mitigate such issues more effectively.

Serious Game Development Roles

Researcher emerged as the most common role among serious game professionals, accounting for 14% (4/29) of the

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respondents, highlighting their involvement in data collection, analysis, and contribution to scholarly literature. The role of *educational theorist* followed at 10% (3/29), underscoring expertise in teaching methods. *Content expert*, *designer*, and *tester* each constituted 9% (3/29) of the respondents. Additional roles such as *project manager*, *CEO* (chief executive officer), and *UX* (user experience)/*UI* (user interface) designer were specified under *Other*. With education-related roles being predominant, this reflects the survey's findings on respondent occupations. A total of 176 roles were reported, averaging 6 roles per person, indicating the multifaceted nature of serious game stakeholder involvement. The diversity of roles suggests that stakeholders often wear multiple hats in their projects. Notably, *lawyer* and *licensor* were the only roles not represented among the respondents.

Serious Game Development Activities

Respondents reported a broad spectrum of activities within serious game development, categorized into *preactivity stage*, *development*, *postactivity stage*, *continuous*, and *unknown*:

- *Preactivities* are preparatory steps such as topic research, fundraising, context analysis, problem definition, game scope determination, learning content creation, and initial consultations.
- *Development* activities encompass the actual creation process, including game design, iteration, implementation, programming, artwork, and character design.
- *Postactivities* might consist of usability testing and game evaluations, depending on the project's goals.
- *Continuous* activities are ongoing tasks such as management, research, education, administration, and marketing that span the project's life cycle.
- *Unknown* captures any unclear or undefined responses.

The bulk of the feedback pertained to the hands-on development tasks—programming, art, writing, and design—aligning with the framework's emphasis on development processes. Game research and evaluation were equally represented, each with 9 mentions, while learning content development received 7 mentions, reflecting the educational aspect of serious game projects.

Serious Game Development Issues

Respondents were asked about common issues encountered during game development, with the question focused on *resources* and *game-specific* challenges.

Resource-related issues highlighted included the following:

- Time management, with 7 (24%) of the 29 respondents noting the extensive duration needed for serious game projects, often described as time consuming and unrealistic
- Budget constraints, also mentioned by 7 (24%) of the 29 respondents, indicating that limited funding, especially within educational environments, affects the scope of development
- Skills shortage, with responses pointing to a lack of necessary expertise and experience among serious game stakeholders
- Team-related factors, with, for example, size and composition, tools for development, intellectual property concerns, and marketing resources highlighted as challenges

Game-specific issues centered on the following aspects:

- The balance between educational content and entertainment value, with respondents expressing difficulty in finding the right mix
- Validation of serious game effectiveness, including measuring the impact of serious games on players, which was mentioned as a key concern

End-user considerations include player demographics, abilities, and gaming background, along with their engagement levels and ability to reach states of flow during gameplay.

Sections C, D, and E: Framework-Level Impressions

The 3 levels of the framework are *EA*, *execution* (process oriented), and *practical* (outcomes). The following aspects of the conceptual framework levels were examined in sections C, D, and E of the expert review questionnaire:

- Comprehensibility: the degree to which the framework, including its overall structure and key components, can be understood and comprehended by its intended audience
- Fluency: the ease with which the framework can be applied or implemented by its users, considering the clarity of instructions and the usability of any associated tools and resources
- Length: the appropriate duration or scope of the framework to ensure that it is neither too long nor too short and provides adequate guidance to achieve the desired results
- Accessibility: the extent to which the framework is accessible to all potential users, including those with physical or cognitive limitations, and the availability of the resources required to implement the framework
- Applicability: the relevance and utility of the framework in addressing the challenges or opportunities it is intended to address
- Utility: the effectiveness of the framework in achieving its intended outcomes, including its capacity to produce measurable and quantifiable outcomes
- Contextuality: the extent to which the framework is tailored to the context or situation in which it will be applied, including cultural and social considerations
- Outputs: the tangible and measurable results or outcomes produced by the application of the framework, such as changes in behavior and performance enhancements, as well as other demonstrable effects

The results from sections C, D, and E are presented in Table 3.

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Table 3. Questionnaire results for sections C, D, and E (n=29).

Framework aspect	5-point scale ratings					Overall comments
	Strongly agree, n (%)	Agree, n (%)	Neutral, n (%)	Disagree, n (%)	Strongly disagree, n (%)	
Comprehensibility (clarity of framework structure and components)						
EA[a] level	—[b]	9 (33)	11 (41)	—	7 (26)	Needs more clarity
Execution level	—	21 (75)	6 (21)	—	1 (4)	Clear to most respondents
Practical level	23 (81)	—	—	—	—	Rated highest for clarity
Fluency (ease of applying or implementing the framework)						
EA level	19 (68)	—	8 (29)	—	1 (4)	Logical progression noted
Execution level	22 (79)	—	4 (14)	—	2 (7)	Highly logical flow
Practical level	23 (81)	—	—	—	—	Streamlined progression
Length (adequacy of framework duration and scope)						
EA level	—	7 (27)	13 (46)	7 (27)	—	Divided opinions
Execution level	13 (46)	—	11 (39)	4 (14)	—	Some found it lengthy
Practical level	17 (62)	—	—	—	—	Most agreeable length
Accessibility (ease of access for all users, including those with limitations)						
EA level	—	5 (20)	12 (44)	10 (36)	—	Complex for laypersons
Execution level	—	13 (48)	11 (41)	3 (11)	—	Accessible to general users
Practical level	13 (48)	—	—	—	—	Most accessible level
Applicability (relevance and adaptability of the framework to different scenarios)						
EA level	—	11 (39)	13 (48)	3 (11)	—	Requires more relevance
Execution level	19 (68)	—	7 (25)	2 (7)	—	Pertinent to game design
Practical level	21 (74)	—	—	—	—	Highly relevant to practice
Utility (effectiveness in producing intended outcomes)						
EA level	—	10 (36)	15 (54)	3 (11)	—	Utility is acknowledged
Execution level	—	10 (36)	15 (54)	3 (11)	—	Comparable to EA level
Practical level	13 (46)	—	13 (46)	—	—	Divided on effectiveness
Contextuality (suitability of the framework for various cultural and social settings)						
EA level	—	10 (36)	15 (52)	3 (11)	—	Needs more adaptability
Execution level	15 (52)	—	7 (26)	3 (11)	—	Flexible across settings
Practical level	13 (48)	—	—	—	—	Well-tailored to contexts
Outputs (tangible results or benefits from using the framework)						
EA level	—	10 (37)	13 (48)	4 (15)	—	Essential outputs produced
Execution level	16 (57)	—	9 (32)	3 (11)	—	Effective in generating outcomes
Practical level	19 (67)	—	—	—	—	Highest positive review

[a]EA: enterprise architecture.

[b]Not applicable.

Section F: Overall Impressions

Expert feedback on the stakeholder-centered framework revealed several key themes. Most of the participants agreed that the framework is useful for facilitating serious game development, highlighting its organized approach and detailed guidance. However, worries about its intricacy indicate that it could be overwhelming for smaller teams or individuals inexperienced in serious game development. Some of the respondents proposed that the framework should be used primarily as a diagnostic tool rather than a prescriptive one, hinting at a possible adjustment in its application to better suit serious game developers' varying levels of expertise.

Feedback on the framework's features suggested the necessity for additional refinement to improve its structure and

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comprehensibility. Respondents requested a clearer definition of serious game design elements and a greater emphasis on the gameplay experience. The relationship between the different levels of the framework and how well they work together with other frameworks were recognized as areas that require focus. There was a clear desire for participatory processes, emphasizing a preference for a stakeholder-centered approach that maximizes production and team engagement.

The framework's implementation elicited varied responses, with a significant portion finding it easy to use, while a noteworthy percentage encountered challenges. These observations emphasize the significance of customized training and emphasize the intricate nature of the framework. Providing stakeholders with necessary tools and ensuring that the framework is easily accessible can help alleviate these challenges.

Opinions on the provision of necessary development instruments were mostly positive, although some of the respondents noted that the framework does not fully address all aspects of information systems development or early serious game design requirements. This indicates potential for growth and a more detailed incorporation of serious game design mechanisms. Many of the respondents viewed the motivation to excel while using the framework positively because it offers clarity on roles and progression through the serious game development stages. However, some of the respondents doubted its impact on motivation, citing the possibility of heightened demands because of the framework's procedural intricacy. Respondents had a positive outlook on how the framework would affect stakeholder efficiency and management, expecting enhancements in planning and stakeholder engagement. However, some of them believed that it might lead to increased resource demands and project delays, highlighting the importance of finding a balance between specific instructions and managing work efficiently.

Summary

Overall, the stakeholder-centered framework was acknowledged as a valuable tool for serious game development, but it requires simplification and more user-friendly adjustments. The feedback is crucial for future improvements, guaranteeing that the framework stays pertinent and efficient for various serious game development scenarios.

Discussion

Principal Findings

The study highlights that serious game practitioners, researchers, and specialists have varying knowledge needs and objectives; for instance, a serious game practitioner in private industry may seek financial information related to serious games for profitability, while a researcher may focus on evaluating the effectiveness of serious game media. Serious game specialists may require a combination of knowledge needs to fulfil their role. As indicated in Figure 2, it is crucial for managerial staff to be aware of these differences and understand their team members' knowledge needs and objectives to effectively manage operating costs and stakeholder needs in a serious game project.

The neglect of elements such as threat assessment in serious game practice can lead to increased risk, which can impact revenue and project success. It is important for administrative and managerial staff to consider different types of risks, such as integrated, behavioral, strategic, financial, compliance, legal, and operational risks before, during, and after serious game production. Risk assessment has significant implications for stakeholder management, uncertainty management, hazard evaluation, control measures, and workplace safety and should be considered in any framework aimed at supporting stakeholders in creating effective serious game media.

The stakeholder-centered framework is mostly prescriptive and lacks personalization, and stakeholder input is necessary for improvement. The framework also lacks emphasis on game design principles and evaluation. Future research can explore ways to facilitate stakeholder participation and integrate *serious* considerations such as learning analytics, knowledge management systems, evaluation frameworks, and more.

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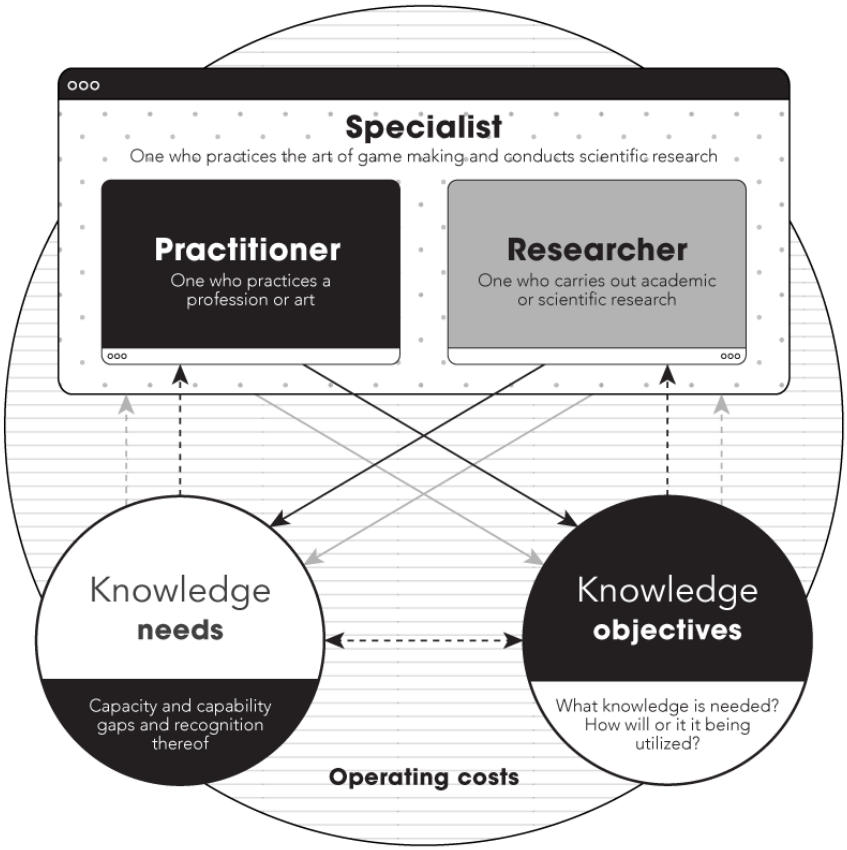
Figure 2. Overcoming variance in knowledge needs and objectives for serious game practitioners, researchers, and specialists.



Limitations

One limitation is the challenge of incorporating 3 different theoretical pillars, which increases the complexity and can make it difficult to achieve brevity in practical research. In addition, the qualitative nature of the investigation means that the focus is on a specific sample group with distinct demographic, psychological, social, and cultural traits, making it difficult to generalize the findings to all comparable groups or circumstances. As a result, transferability is more relevant for this qualitative research.

Time constraints are another limitation imposed on the study because it is cross-sectional in nature, giving us a limited time frame to deliver our work for examination. However, the DSR approach allows the framework to undergo imminent development and iteration.

The modest sample size of the study (n=29) could also be considered a limitation because serious games are a niche field that often require expertise in education, health, or public policy, which may limit their developers. However, we contacted 220 people to take part in the study after extensive market research, and additional data would have reduced random variation and increased statistical power, making the research more accurate and reliable.

Another limitation of the research is that the framework could only be evaluated on a particular level of response assessment. Future studies should be conducted with teams to see how the framework functions in practice, according to all 4 levels of artifact assessment: response (participant feelings), learning (knowledge transfer), behavior (work performance), and outcomes (effect over time).

Finally, the reliability of questionnaire data analysis is highly dependent on several factors, such as the quality and depth of the responses, the structure of the questionnaire, and the lack of observations regarding alterations in the respondents' states of mind, feelings, and behaviors. Therefore, these factors should be taken into consideration when interpreting the results of the study.

Recommendations

We offer the following recommendations for future work:

- Forthcoming work on this topic should isolate each theoretical domain, examine them discretely, and combine, compare, and synthesize the results.
- A positivistic study that gathers quantitative data would intensify the generalizability of the findings relating to the stakeholder-centered framework. Quantitative research, such as experimental studies, offers a good basis for developing wide generalizability, given that generalizability requires data from large populations.
- Longitudinal research over an extended period of time could better assess the affects and effects of the framework. The analysis could also be richer if the inquiry extends beyond a single moment in time. DSR is typically carried out in iterative cycles of design, implementation, and evaluation, which enables researchers to refine and improve their solutions over time, allowing for strong longitudinal studies. This iterative approach also allows for data collection at multiple points in time, which can provide insights into the

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effectiveness and long-term viability of the solutions being developed. The framework becomes a living artifact in this way.

- A larger sample population can feature in impending studies. The greater the sample size, the more precise the calculated mean values will be. Error margins are also reduced if a bigger sample is used.
- More participants enable the facts to speak for themselves, rather than depending on assumptions and the researcher's subjective relationships with the data. Additional data also lead to more accurate and precise units of analysis.
- The stakeholder-centered framework can be assessed according to all 4 levels of artifact assessment proposed by Petri and von Wangenheim [45]. A longitudinal study of this nature would be equipped to establish the effectiveness of the framework regarding its learning potential, behavioral impacts, and outcomes.
- The methods used to appraise the framework could be expanded in future work. This would improve the reliability of the data analysis carried out; for example, structured interviews, semistructured interviews, in-depth interviews, focus groups, field research, ethnography, and observation could be used to strengthen analysis efforts.

Features for the Framework Going Forward

Now that that main recommendations for future research have been presented, we need to consider the requisite features for the framework going forward (Table 4).

Variant 4 of the stakeholder-centered framework reflects the academic and investigative nature of serious games and their development (Figure 3). It includes instructions, demonstrations, descriptions, and definitions that facilitate game design and development and focuses on procedural information rather than technology, expertise, or resources. The length of the tool has been reduced, and the framework is less prescriptive, providing flexibility in project assumptions, goals, and processes. The progressive web application version of the framework enables users to take part in conversations with one another, categorizes procedural information into subdivisions, and includes built-in support mechanisms. The application affords the researcher added control over the transmission, presentation, structure, and extent of the intelligent system and can adapt to any changing needs or patterns of its user base.

Variant 4 also integrates the 3 theoretical domains in a more subtle manner than previous versions. It presents a terser technical diagram for serious game design that omits some information to improve accessibility and usability. The procedures still begin with stakeholder analysis, categorizing stakeholders by their impact and influence on value creation in the development endeavors. The resulting stakeholder categories are development, publishing, context-related, and supplementary teams, which consist of stakeholder roles with their own activities and specializations.

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Table 4. How desired framework traits correlate to improvement areas, as well as evidence for the intersection thereof in the progressive web artifact.

Desired framework trait	Improvement areas (from expert review)										Artifact execution (within the progressive web application)
	Abbreviation	Concentration	Configuration	Guidance	Idealism	Milestones	Prescription	Semantics	Simplification	Transmission	
Concerned with serious aspects		✓		✓			✓	✓			Serious game conventions built into the artifact: principles, designs, and evaluations
Concise	✓		✓					✓	✓	✓	Artifact uses chunking to boost content processing
Diagnostic		✓		✓		✓				✓	Artifact facilitates the achievement of development objectives through measurement
Flexible	✓		✓	✓			✓		✓	✓	Artifact is open to changes in assumptions, goals, and process
Informative		✓		✓	✓	✓		✓			Artifact includes instructions, demonstrations, descriptions, and definitions on serious game design
Invested in work, not technology		✓	✓	✓				✓		✓	Artifact makes provision for technology but focuses on procedural information
Participatory		✓	✓				✓			✓	Discussion is facilitated in the artifact by way of private and community chat functions
Procedural			✓	✓	✓	✓	✓			✓	Various activities are divided into practical sections and directed at various stakeholders

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Desired framework trait	Improvement areas (from expert review)										Artifact execution (within the progressive web application)
	Abbreviation	Concentration	Configuration	Guidance	Idealism	Milestones	Prescription	Semantics	Simplification	Transmission	
Relevant		✓		✓				✓			Extraneous information is removed using filters, and streams of material are categorized
Repeatable	✓			✓		✓			✓	✓	Sets of actions provided in the artifact are reusable and easily duplicated
Stakeholder centered		✓			✓		✓			✓	Sections of the artifact are targeted toward specific stakeholders
Supportive			✓	✓		✓	✓		✓		Frequently asked questions, data protection, and self or continual support
Sustainable	✓			✓		✓				✓	Scalable design is incorporated into the artifact
Usable	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	User control, consistency standards, minimalist design, and platform compatibility
Vehicle for good design		✓	✓			✓	✓			✓	Artifact encourages good design practice by encouraging users to assess their own practice

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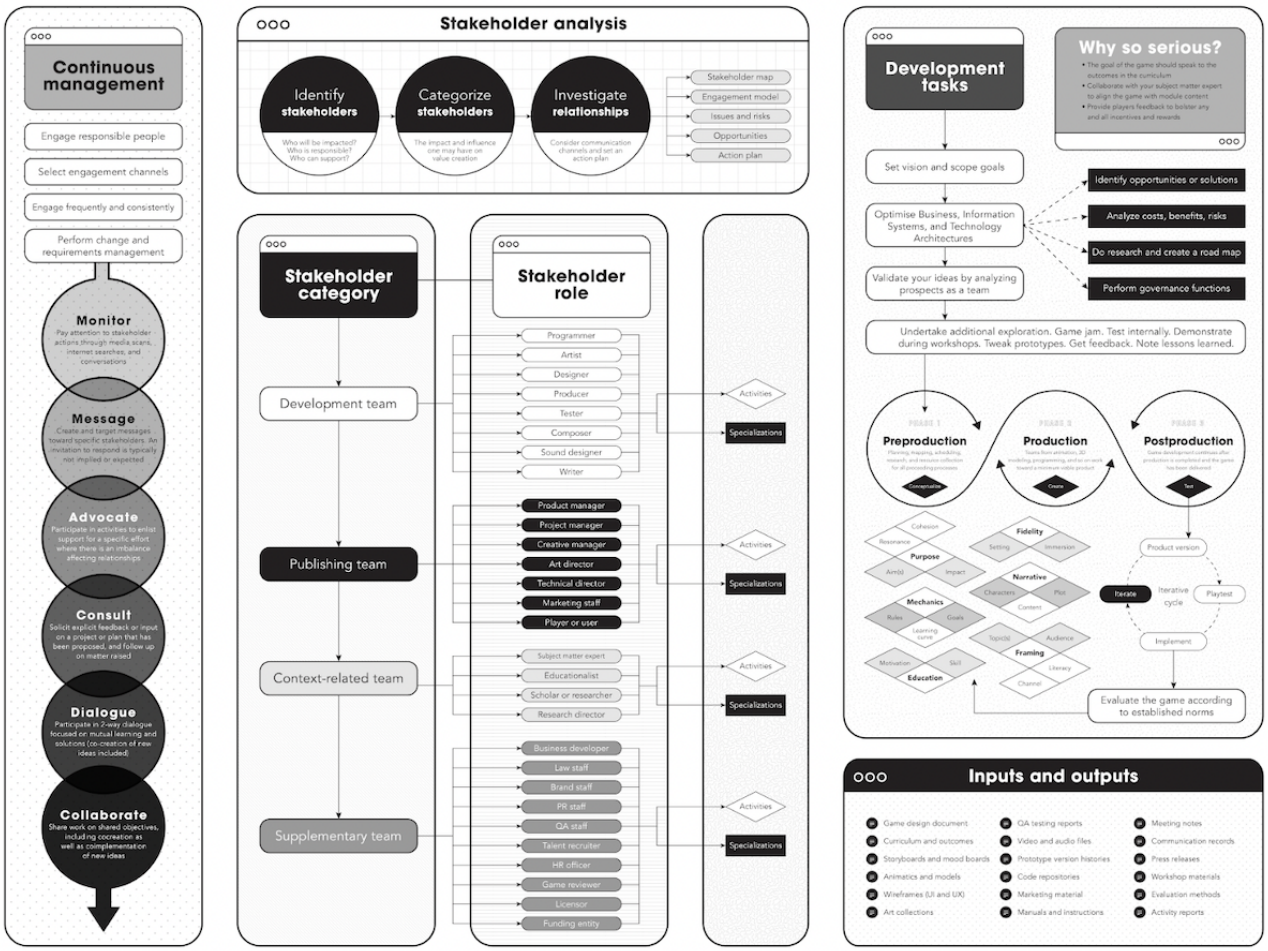
Figure 3. Variant 4 (version 2.0) of the stakeholder-centered framework. HR: human resources; MVP: minimum viable product; PR: public relations; QA: quality assurance; SME: subject matter expert; UI: user interface; UX: user experience. For a higher-resolution version of this figure, see Multimedia Appendix 2.



Conclusions

The proliferation of serious games and game-assisted learning in education and beyond requires keen awareness, careful contemplation, and steady advancement [46-48]. As serious games become more common in contexts aiming to edify in innovative ways, scholars should not only consider methods to improve the efficacy thereof but also think about how to realistically and efficiently fabricate them as well. Serious game project stakeholders need practical ways to align their interests with those of the enterprise. Stakeholder roles, activities, specializations, potential, competence, and capabilities all impact these experts' productive capacity and labor prospects. However, serious game initiatives vary significantly. To help future game makers, this research inspects serious game design stakeholders and techniques to produce a system capable of supporting these individuals in a range of environments. A stakeholder-centered framework, in this view, may help serious game developers manage their teams and drive practice in beneficial and sustainable ways. In the future, we hope that this investigation will aid in a decrease in serious game project failure, communication breakdown, and apathy regarding the genre of games intending to do more than purely entertain. However, additional research and innovation is needed in fields adjacent to, and embedded in, serious games to support the growing need for novel approaches to demonstrate, educate, simulate, and inform.

Acknowledgments

This work was undertaken as part of a doctoral study at the North-West University, Vanderbijlpark, South Africa. The authors are grateful to Professor Roelien Goede, Professor Japie Greeff, and Professor Estelle Taylor for their contribution and support. The financial support of the Unit for Data Science and Computing at North-West University is gratefully acknowledged. We used the generative AI tools QuillBot [49] to help refine text into manageable portions for the manuscript and ChatGPT [50] to condense the results presented in Table 3 into a more suitable format.

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Data Availability

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

Authors' Contributions

The study was conceptualized by LB along with JG and ET. All authors were involved in the interpretation of results, manuscript write-up, and revisions. LB was involved in the design of the framework, data collection, data analysis, and the writing of methods and results. Moreover, LB was involved in data collection and logistics. LB conducted statistical analysis under the supervision of JG and ET. JG and ET supervised LB on all tasks pertaining to this project.

Conflicts of Interest

LB is supported by the Unit for Data Science and Computing, North-West University. All other authors declare no other conflicts of interest.

Multimedia Appendix 1
Simplified variant 2 of the stakeholder-centered framework. ADM: Architecture Development Method; TOGAF: The Open Group Architecture Framework; UI: user interface; UX: user experience.
[PNG File , 2321 KB - games_v12i1e48099_app1.png]

Multimedia Appendix 2
Variant 4 (version 2.0) of the stakeholder-centered framework. HR: human resources; MVP: minimum viable product; PR: public relations; QA: quality assurance; SME: subject matter expert; UI: user interface; UX: user experience.
[PNG File , 4533 KB - games_v12i1e48099_app2.png]

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Abbreviations

ADM: Architecture Development Method
CEO: chief executive officer
DF: development factor
DSR: design science research
EA: enterprise architecture
SME: subject matter expert
TOGAF: The Open Group Architecture Framework
UI: user interface
UX: user experience

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Original Paper

Effects of Virtual Reality Therapy Combined With Conventional Rehabilitation on Pain, Kinematic Function, and Disability in Patients With Chronic Neck Pain: Randomized Controlled Trial

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Abstract

Background: Neck pain is a common condition that leads to neck motor dysfunction and subsequent disability, with a significant global health care burden. As a newly emerging tool, virtual reality (VR) technology has been employed to address pain and reduce disability among patients with neck pain. However, there is still a lack of high-quality studies evaluating the efficacy of VR therapy combined with conventional rehabilitation for patients with chronic neck pain, particularly in terms of kinematic function.

Objective: This study aims to investigate the effect of VR therapy combined with conventional rehabilitation on pain, kinematic function, and disability in patients with chronic neck pain.

Methods: We conducted an assessor-blinded, allocation-concealed randomized controlled trial. Sixty-four participants experiencing chronic neck pain were randomly allocated into the experimental group that underwent VR rehabilitation plus conventional rehabilitation or the control group receiving the same amount of conventional rehabilitation alone for 10 sessions over 4 weeks. Pain intensity, disability, kinematic function (cervical range of motion, proprioception, and mean and peak velocity), degree of satisfaction, and relief of symptoms were evaluated at 3 timepoints (baseline, postintervention, and at 3 months follow-up). A 2*3 mixed repeated measures analysis of variance was utilized for analyzing the difference across indicators, with a significant difference level of .05.

Results: Both groups demonstrated significant improvements in pain, disability, and kinematic functions ($P<.05$) at postintervention and at 3-month follow-up. The experimental group showed superior therapeutic outcomes compared to the control group in pain reduction (mean difference from the baseline: 5.50 vs 1.81 at posttreatment; 5.21 vs 1.91 at the 3-month follow-up, respectively; $P<.001$), disability improvement (mean difference from baseline: 3.04 vs 0.50 at posttreatment; 3.20 vs 0.85 at the 3-month follow-up, respectively; $P<.001$), and enhanced kinematic functions ($P<.05$). Moreover, participants in the experimental group reported better satisfaction and relief of symptoms than the control group ($P<.05$), with better initiative for exercising during the follow-up period. However, there was no between-group difference of improvement in proprioception. No adverse events were reported or observed in our research.

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Conclusions: The findings of our study support the efficacy of combining VR therapy with conventional rehabilitation in alleviating pain, enhancing kinematic function, and reducing disability of patients with chronic neck pain. Future research should focus on refining the therapeutic protocols and dosages for VR therapy as well as on optimizing its application in clinical settings for improved convenience and effectiveness.

Trial Registration: Chinese Clinical Trial Registry ChiCTR2000040132; http://www.chictr.org.cn/showproj.aspx?proj=64346

(JMIR Serious Games 2024;12:e42829) doi:10.2196/42829

KEYWORDS

virtual reality; neck pain; disability; kinematic function; rehabilitation; physiotherapy; neck; pain; chronic; therapy; kinematic; efficacy; patient; effect

Introduction

Chronic neck pain is a prevalent global health issue, with reported prevalence rates ranging from 10% to 24% [1,2]. This condition is closely associated with motor dysfunction in the cervical region, characterized by deficits in various kinematic functions of the neck [3-5]. Cervical kinematic functions can be operationally defined as the capacity of the neck muscles to generate and regulate movement of the head and neck, including range of motion (ROM), which is the degree of movement that can be achieved in various directions of the cervical spine, velocity, coordination, strength, and endurance. These parameters can be quantified through specific evaluations and measurements such as ROM assessments, manual muscle testing, and functional movement tests. Prior studies have proven that motor dysfunction occurs commonly in patients with neck pain [6-8], and these dysfunctions are highly correlated with the level of pain and disability. That is because weakness in neck muscle strength and coordination will provide more unstable support of the neck segments and additional stress on the neck structure, which restricts the patient's neck movement and results in pain [9]. These diminished motor dysfunctions as well as worse pain and disability undoubtedly impair a patient's work performance and quality of life, leading to large economic losses [10]. Given the abovementioned pivotal role of cervical kinematics in neck pain, interventions aimed at improving motor function hold promise in managing this condition.

To date, active exercise is recommended to be a valid therapy for patients with chronic neck pain based on the current clinical guidelines [11,12]. Virtual reality (VR) is a unique form of exercise established by Morton Heiling in 1962 and has been evolving over the past 60 years [13,14]. VR technology commonly generates virtual environments resembling the real world through devices such as computers or head-mounted displays and interacts with patients to enable them to accomplish the targeted therapeutic goals [15,16]. Regarding the economics of VR treatment, studies [17,18] have reported low costs in VR-based treatments. The hardware devices involved in VR therapy are readily available and inexpensive. Additionally, the one-time cost of patient-specific VR software allows for repeated use, making VR applications relatively less expensive in medical settings. VR serves as a valuable assessment and intervention tool in rehabilitation due to its clinical benefits supported by ongoing research [19], and orthopedic and neurological rehabilitation are the common areas where VR therapy is utilized in clinical practice [20,21]. The potential therapeutic mechanisms of VR include task-oriented repetition, positive feedback, and embodied simulation [22].

As a noninvasive method of pain reduction, VR therapy, both independently and in combination with other interventions, has been investigated in numerous studies. Prior research [23-25] has demonstrated the potential of VR therapy to alleviate pain and disability in patients with orthopedic conditions such as rheumatoid arthritis, shoulder impingement syndrome, and low back pain. However, to date, there is still less research exploring the effects of VR therapy or combined treatment on individuals with chronic neck pain, particularly in terms of improving the cervical motor function [26,27]. Mukherjee et al [28] investigated the efficacy of VR therapy in the treatment of cervical spondylosis. Their findings revealed that patients who underwent VR therapy along with conventional physiotherapy demonstrated notable improvements in pain intensity and active cervical ROM (CROM) compared to those who underwent conventional therapy alone in the short-term period ($P<.05$). However, another study [29] reported that after receiving 4 weeks of VR training, patients with neck pain exhibited significant improvement in mean and maximal velocity, with no observed improvement in CROM indicators compared with the control group. A recent meta-analysis [30] consisting of 2 randomized controlled trials (RCTs) suggested that VR therapy combined with kinematic training could enhance the global perceived effect, patient satisfaction, and general health of patients with neck pain compared to treatment with kinematic training alone. However, evidence supporting the efficacy of VR therapy in strengthening cervical kinematic function remains inconclusive. Given the current gaps in research and the conflicting findings, further high-quality studies are warranted to ascertain the therapeutic effectiveness of VR therapy or combined treatments for individuals with chronic neck pain. Therefore, this RCT aims to evaluate the effects of VR therapy combined with conventional rehabilitation on pain, kinematic functions, and disability in patients with chronic neck pain.

Methods

Study Design and Ethics Approval

This study was designed as an assessor-blinded, allocation-concealed RCT (Multimedia Appendix 1). Ethics approval for this study was obtained from the West China Hospital Clinical Trials and Biomedical Ethics Committee of Sichuan University (approval: HX-IRB-AF-18-2021-1102).

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This trial was registered in the Chinese Clinical Trial Registry (ChiCTR2000040132) on November 22, 2020. This study conformed to the Declaration of Helsinki, and all patients provided written consent after recruitment.

Participants

This study was conducted at the Department of Rehabilitation Medicine in West China Hospital. Patients were recruited through various channels such as social networks, posters, and brochures from October to December 2021. Inclusion criteria included age of 18 years and older, a diagnosis of chronic neck pain (>3 months) by a physician, reported pain intensity ≥3 on the numeric rating scale (NRS), and disability ≥6 on the neck disability index. Exclusion criteria included existing vestibular pathology, cervical fracture/dislocation, whiplash injuries, neurological/cardiovascular/respiratory disorders affecting patients' physical performance, inability to provide informed consent, and pregnancy.

Randomization

Randomization was performed using a computer-generated sequence from Randomization.com, with a researcher not involved in treatment overseeing the process. Patients were allocated to either the experimental group or control group based on the odd or even nature of the assigned number within sealed opaque envelopes to ensure blind allocation. Although a blinded researcher assessed the patients during the trial, blinding was not feasible for participants or therapists due to the layout of the VR therapy.

Intervention

VR Treatment

The VR equipment that we used included several hardware and software (Chengdu Feiming Technology Co, Ltd). Hardware included a Pico G2 4k head-mounted VR glass, monitor screen, and optical motion capture camera. Patients wearing VR glasses sat at a distance of 100 cm from the front of the monitor screen. The monitor will display the real-time virtual images that patients see during the experimental process. Therapists can assess the patient's real-time treatment stage by looking at the monitor screen and provide corresponding assistance. During treatment, the optical motion capture camera and customized software collected and analyzed the cervical movement trajectories. Meanwhile, considering the requirement of fully immersive VR therapy, a specific shoulder strap was designed for patient safety during treatment.

In VR therapy, 3 modules (ROM, proprioception, and velocity modules) were designed to enhance the specific kinematic functions of individuals experiencing chronic neck pain. These modules involved patients engaging in targeted cervical movements to attain therapeutic objectives through visual cues. Prior to the beginning of the treatment, each patient underwent a practice trial to mitigate any potential learning biases. Throughout the VR session, patients were fully immersed in a virtual setting resembling a living room, where they could manipulate virtual objects to interact with designated targets. The VR equipment incorporated visual and auditory feedback to augment the interactive and engaging nature of the therapy. The detailed descriptions of the 3 modules are provided below.

In the ROM module, a virtual flying bird is manipulated by the patients' cervical movement. Patients could move birds by neck flexion, extension, lateral flexion, and rotation movement to catch gold or avoid the fire rings appearing in the scene. The placement of the gold items and fire rings was based on baseline kinematic data, with the game's difficulty adjusted continuously to facilitate gradual improvements in CROM across all movement directions (Figure 1).

Figure 1. Range of motion module. The bird in the picture is manipulated by the patient's cervical movement (flexion, extension, lateral flexion, and rotation) to catch the gold and avoid obstacles appearing in all directions.

In the proprioception module, patients engage in tasks requiring them to control a virtual bow and arrow by using cervical movements to aim and shoot at a bull's-eye target with closed eyes. Initially, patients face the screen to align the arrow with the bull's-eye, memorizing this starting position. Subsequently, patients close their eyes and follow instructions from the VR

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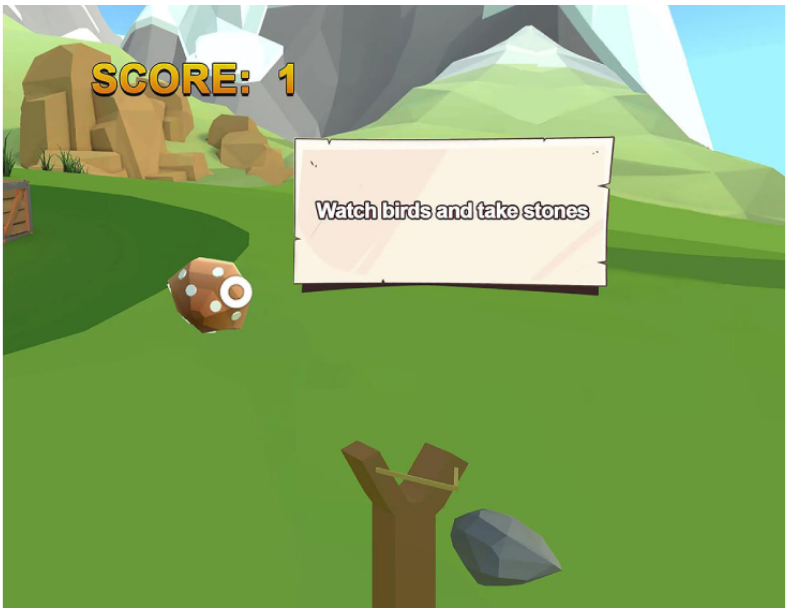
system to move their necks to a specific position. They then have to return their neck to the initial position (representing the bull's-eye location) and shoot the arrow. The relocation error, indicating the angular deviation between the shot point and the bull's-eye, serves as a measure of patients' proprioceptive abilities (Figure 2).

Figure 2. Proprioception module. The patient was asked to remember the initial bull's-eye position and then close the eyes. Thereafter, the computer would guide the neck of the patient with the eyes closed to a specific position. The patient needs to move the neck back to the original position based on memory and manipulate the bow and arrow to shoot the bull's-eye.

In the velocity module, participants were tasked with hitting randomly appearing mushrooms within the virtual scene by manipulating virtual stones with cervical movements. Upon mushroom appearance, patients adjusted the slingshot position by moving their neck and launched a stone to hit the mushroom before it disappeared after 5 seconds. Subsequent mushrooms would appear sequentially, prompting patients to swiftly target and strike them. Patient performance was scored based on the success rate of hitting the mushrooms, thereby fostering patient engagement and compliance with the virtual therapy protocol (Figure 3).

Figure 3. Velocity module. Patients were asked to manipulate stones at maximum neck movement speed to hit randomly appearing virtual mushrooms and obtain the corresponding scores.



Conventional Rehabilitation

Patients in the experimental group received a 10-minute conventional rehabilitation session consisting of 5 minutes of active exercise (eg, muscle stretching exercise, strengthening exercise, sling exercise therapy), supported by established guidelines [11,31]. Additionally, patients underwent a 5-minute transcutaneous electrical nerve stimulation for analgesia, which was validated for efficacy in prior studies [2]. Patients in the control group were treated with 30 minutes of conventional rehabilitation, including 15 minutes of active exercise modalities

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same as the experimental group and an additional 15 minutes of transcutaneous electrical nerve stimulation therapy. The prescription of conventional rehabilitation was tailored based on each patient's motor dysfunction and the clinical expertise of the rehabilitation therapists.

Procedure

Sixty-four patients were randomly allocated into the experimental group or control group, and they underwent 10 treatment sessions over 4 weeks. In the experimental group, interventions included 20 minutes of VR therapy and 10 minutes of conventional rehabilitation per session, while the control group received 30 minutes of only conventional rehabilitation per session. Throughout the treatment, patient safety was closely monitored, and sessions were halted if any adverse events (eg, motion sickness, headache, falls) occurred. Patients were allowed to resume training once the symptoms subsided; otherwise, they were advised to discontinue participation in the study. Following the intervention, both groups were encouraged to continue neck exercises at home for 3 months after treatment. On completion of the follow-up period, each patient was asked to rate their frequency of neck exercise within the 3-month interval to represent their adherence to continued neck exercise. The rating scale ranged from 0 to 4 (0 = no training; 1 = 0-1 hours of training per week; 2 = 1-2 hours of training per week; 3 = 2-3 hours of training per week, ≥4 = >3 hours of training per week). A comparison of the data sets from both groups was conducted to observe the patients' initiative in training at unsupervised situations.

Outcome Measures

All outcome measures were evaluated at 3 timepoints: preintervention, immediately postintervention, and 3-month follow-up. The primary outcomes focused on pain and disability (key concerns for individuals seeking medical help for neck pain). These outcomes were evaluated using offline scales. Secondary outcomes included kinematic indicators (eg, CROM, proprioception, mean and peak velocity), patient satisfaction, and relief of symptoms, which are all crucial aspects in the rehabilitation process for chronic neck pain. These secondary outcomes were assessed using a combination of web-based VR equipment and offline scales.

Primary Outcomes

NRS

The NRS was used to measure the current neck pain intensity. NRS graded the pain intensity from 0 (no pain) to 10 (worst pain imaginable), with higher scores indicating worse pain. Pain levels were categorized as mild (1-3), moderate (4-6), and severe (≥7) based on the score range [32-34]. The NRS has shown validity and reliability, with a minimum clinically important difference (MCID) of 2.7 established in previous studies [35,36].

Neck Disability Index

The neck disability index was employed as a self-reported questionnaire to measure neck pain–related disability. It consisted of 10 items about activities of daily living, with each item scored from 0 (absence of disability) to 5 (complete disability). The neck disability index is recognized for its validity and reliability, with an MCID of 3.5 points considered significant [37,38].

Secondary Outcomes

CROM

CROM was measured using a VR device in 6 directions: flexion, extension, left and right rotation, and left and right lateral flexion. The results were calculated by taking the average of 3 measuring values. This VR equipment evaluation approach demonstrates high repeatability and sensitivity on these cervical kinematics parameters (ie, CROM, proprioception, mean and peak velocity). The reliability and validity of VR devices to measure CROM have been validated. The minimal detectable change (MDC) of CROM in different directions has been previously reported, while the value changed across the 6 movements ranging from 3.6° to 6.5° [39,40].

Proprioception

Proprioception was defined as the perception of change in direction, position, or speed produced by motor organs (eg, muscles, tendons, joints) in 6 directions. It was calculated as the mean of the relocation difference in 3 tests. Prior studies have reported the psychometric properties of VR equipment evaluating proprioception [4,41] but not provided the MCID.

Mean and Peak Velocity

Mean and peak velocity are crucial indicators reflecting cervical kinematic functions. The mean and peak velocity in 4 directions (flexion, extension, left and right rotation) were obtained by calculating the average values of 3 assessed data on angular velocity during the trial. VR devices have shown good repeatability in measuring cervical motion velocity. Although the MDC for average speed is 14.31°/s, that for maximum speed is 34.95°/s [4,42].

Global Perceived Effect

Global perceived effect is a self-administered questionnaire applied to evaluate patient satisfaction and the relief of symptoms in this study [43]. The satisfaction level ranges from –5 (totally dissatisfied) to 5 (totally satisfied). Similarly, patients could report their relief of symptoms by using the Global Perceived Effect scale, with lower scores representing worse therapeutic effects. These 2 indicators were only measured immediately postintervention and at 3 months after intervention.

Sample Size Calculation

The NRS was chosen as the primary outcome measure in this study. With reference to a previous study [44], the effect size estimate for the NRS was medium (SE 0.25). The correlation between repeated measures was assumed to be 0.5. Three measurements were presumed to be performed (baseline, postintervention, and 3-month follow-up) with a sphericity correction of 0.5. Based on the statistical power of 0.85 and an α level of .05, a total sample size of 50 patients was initially estimated. To account for potential dropout rates that have been observed to exceed 15% in similar studies [27,29,45], a conservative dropout rate of 25% was chosen to ensure sufficient patients for statistical analysis, resulting in a final inclusion of

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64 patients. The sample size calculation was conducted using the G*Power software (version 3.1.7; University of Düsseldorf).

Statistical Analysis

Statistical analysis was conducted using the SPSS statistical software (version 25.0; IBM Corp) by a blinded researcher. Data analysis followed the intention-to-treat principle, while the Shapiro-Wilk test was applied to check the normality of various data. Descriptive statistics were used to reflect the different types of results such as mean and standard deviation for the parametric variables and median and quartiles for the nonparametric variables. Group equivalence was assessed via the 2-sided independent-sample *t* test or Pearson chi-squared test by comparing the baseline data between the groups. For most variables (all outcomes except the relief of symptoms), which showed normal distribution, a 2*3 mixed repeated measures analysis of variance (ANOVA) with 1 between-subject factor (treatment) and 1 within-subject factor (time) was performed to compare all variables. Post hoc comparisons were conducted using the Bonferroni test, with *P* values for multiple comparisons adjusted using SPSS software. To address violations of the sphericity assumption, the Greenhouse-Geisser correction was applied. With regard to the analysis of the relief of symptoms, nonparametric statistics were used due to the skewed distribution of data. To account for the dropouts, multiple imputations were used to fill the missing data. To show the effect sizes of observed between- or within-group change, partial eta squared and rank correlation were calculated for the parametric and nonparametric variables, respectively. Based on the previous study [46], effect sizes were classified into small (0.2-0.5), medium (0.5-0.8), and large effect sizes (≥0.8). *P* values less than .05 were indicated to be statistically significant.

Results

Baseline Measures

A total of 120 patients underwent the initial screening for eligibility, of which 56 participants were excluded. Following screening, 64 participants were randomly allocated to either the experimental group or the control group. In the 3-month follow-up period, 3 (5%) participants dropped out of the study due to time conflicts or personal reasons. The flow diagram of participant recruitment and research is shown in Figure 4. The baseline characteristics of the participants in both groups are detailed in Table 1. As shown, there was no between-group difference in age, gender, etiology, disability, pain, and other kinematic indicators. No adverse events were reported during treatment, except some discomfort (eg, complaints of heavy helmets, slightly aggravated pain). No differences existed between the 2 groups over the compliance of the patients continuing neck exercise during the 3-month follow-up period (experimental group 2.31, SD 1.25 vs control group 1.96, SD 1.19; *P*=.22). However, a higher proportion of experimental group participants (16 out of 31) engaged in neck exercises for an average of at least 2 hours per week during the follow-up period compared to control group participants, where only 30% (9/30) achieved this level of compliance, indicating the actual differences between the 2 groups.

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Figure 4. Flow diagram showing participants' flow and follow-up evaluation.

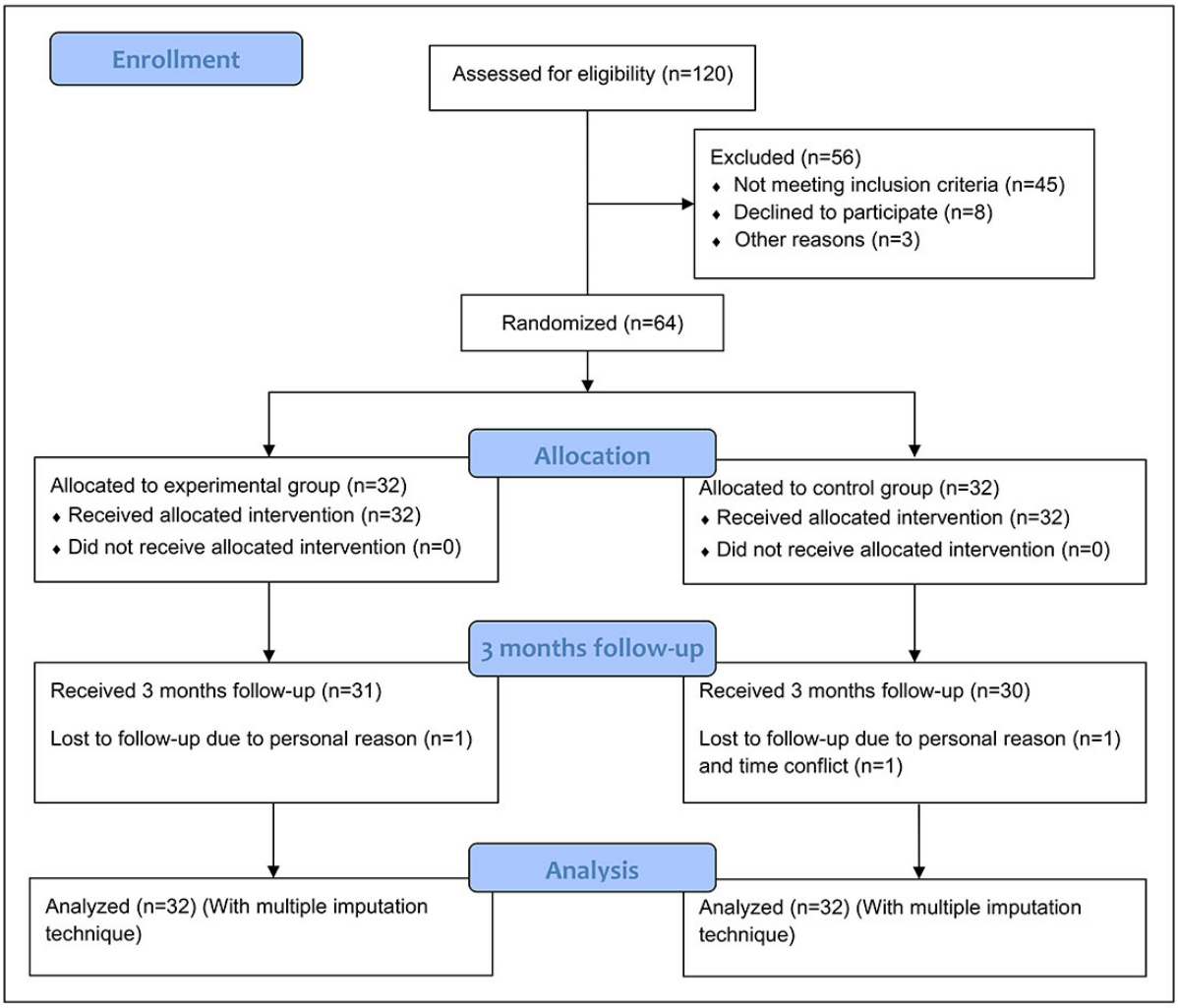

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Table 1. Baseline characteristics of the participants in the experimental and the control groups.

Variables	Experimental group (n=32)	Control group (n=32)	*P* value
Age (years), mean (SD)	35.94 (11.02)	40.09 (11.97)	.15[a]
Gender (female), n (%)	25 (78)	22 (69)	.40[b]
Etiology (idiopathic neck pain), n (%)	16 (50)	21 (66)	.43[b]
Disability (Neck Disability Index), mean (SD)	11.34 (2.74)	10.72 (2.32)	.33[a]
Pain intensity (Numeric Rating Scale), mean (SD)	5.38 (1.39)	5.16 (1.42)	.54[a]
Range of motion, mean (SD)			
Flexion	53.96 (10.69)	51.60 (9.99)	.37[a]
Extension	63.55 (8.88)	58.42 (12.85)	.07[a]
Left flexion	37.62 (7.78)	38.42 (8.90)	.71[a]
Right flexion	38.16 (8.67)	40.91 (8.47)	.20[a]
Left rotation	71.92 (9.8)	70.21 (8.96)	.47[a]
Right rotation	71.86 (8.16)	69.43 (9.55)	.28[a]
Proprioception, mean (SD)			
Flexion	2.96 (1.31)	3.33 (1.80)	.36[a]
Extension	3.03 (1.25)	3.16 (1.65)	.73[a]
Left flexion	2.85 (1.45)	3.00 (1.29)	.67[a]
Right flexion	2.73 (1.07)	2.86 (1.57)	.71[a]
Left rotation	1.96 (0.70)	2.53 (1.36)	.08[a]
Right rotation	2.85 (1.35)	2.98 (1.64)	.72[a]
Mean velocity, mean (SD)			
Flexion	12.54 (2.80)	11.02 (2.68)	.07[a]
Extension	14.24 (2.52)	14.90 (2.38)	.28[a]
Left rotation	15.64 (3.47)	15.15 (3.80)	.59[a]
Right rotation	17.27 (2.51)	16.59 (2.58)	.29[a]
Peak velocity, mean (SD)			
Flexion	68.63 (17.18)	76.77 (26.13)	.15[a]
Extension	77.62 (21.63)	77.71 (17.05)	.99[a]
Left rotation	88.71 (18.46)	88.97 (18.72)	.96[a]
Right rotation	94.15 (14.24)	100.66 (22.47)	.17[a]

[a]Independent sample *t* test.
[b]Pearson chi-squared test.

Primary Variables Measure

Neck Disability

As presented in Table 2 and Figure 5, a repeated measures ANOVA showed a main effect of group ($F_{1,3}$=12.738; P=.001; η_p^2=0.291), time ($F_{2,62}$=124.140; P<.001; η_p^2=0.800), and the group*time interaction ($F_{2,62}$=31.620; P<.001; η_p^2=0.505) on neck disability. Compared with those in the control group, participants in the experimental group showed a significant alleviation in neck disability at postintervention (P<.001; η_p^2=0.517) and 3-month follow-up (P<.001; η_p^2=0.438). Furthermore, therapies in both groups were shown to improve disability in patients with chronic neck pain after intervention or 3-month follow-up in comparison with the baseline (P<.01). Further, the extent of disability alleviation in the experimental

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group exceeded the MCID at both measurement timepoints (5.50 at posttreatment; 5.21 at the 3-month follow-up), while the controls showed a reduction in the disability score by 1.81 and 1.91 points compared to baseline. A higher percentage of experimental group participants experienced disability score reductions exceeding the MCID compared to the control group at both timepoints (experimental group: 29/32, 91% vs control group: 9/32, 28% at posttreatment; experimental group: 25/31, 81% vs control group 6/30, 20% at the 3-month follow-up).

Figure 5. Rehabilitation effect of virtual reality therapy on disability and pain intensity. NDI: neck disability index; NRS: numeric rating scale; *: a statistically significant difference ($P<0.05$) between the two groups at that timepoint (postintervention or 3-month follow-up).

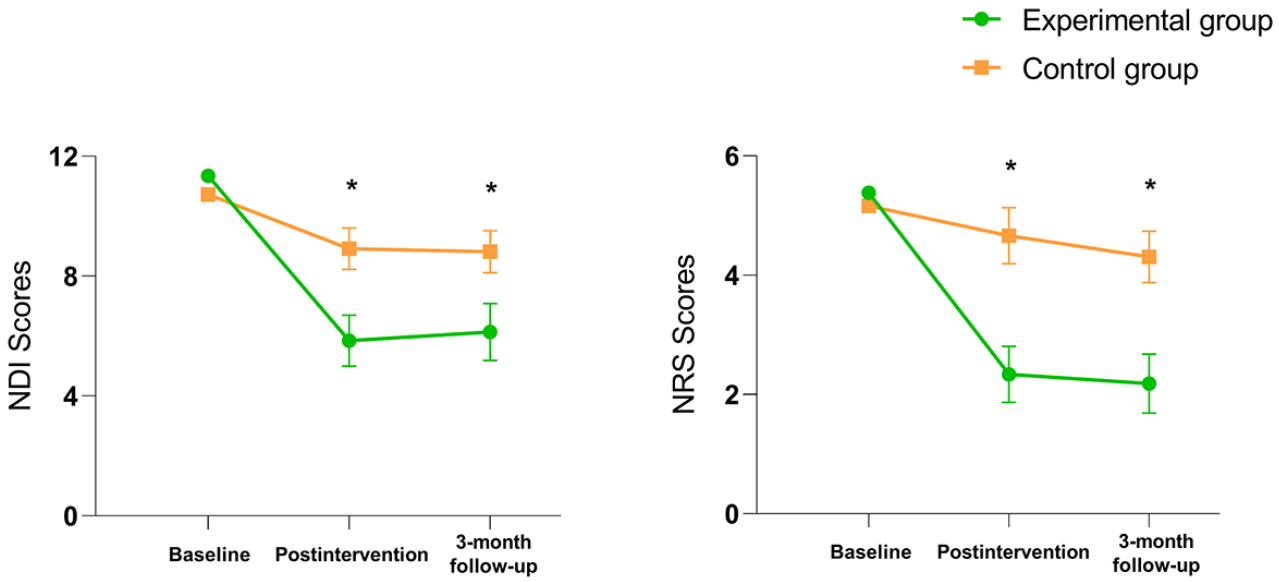

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Table 2. Within- and between-group differences in outcome measures.

Variables	Preintervention, mean (SD)		Postintervention, mean (SD)		Cohen *d*[a]	3-month follow-up, mean (SD)		Cohen *d*	Group*time, *F* test *(df)*
	Experimental group	Control group	Experimental group	Control group		Experimental group	Control group		
Disability	11.34 (2.74)	10.72 (2.32)	5.84 (2.38)[b,c]	8.91 (1.92)[c]	0.517	6.13 (2.66)[b,c]	8.81 (1.96)[b]	0.438	31.62 (2, 62)[d]
Pain intensity	5.38 (1.39)	5.16 (1.42)	2.34 (1.31)[b,c]	4.66 (1.31)	0.582	2.18 (1.38)[b,c]	4.31 (1.20)	0.587	27.28 (2, 62)[d]
Range of motion									
Flexion	53.96 (10.69)	51.60 (9.99)	64.78 (9.01)[b,c]	54.25 (8.25)	0.582	67.96 (6.03)[b,c]	53.76 (8.82)	0.680	11.31 (1.592, 49.363)[d]
Extension	63.55 (8.88)	58.42 (12.85)	70.89 (7.07)[b,c]	59.78 (9.93)	0.395	69.09 (8.97)[b,c]	54.29 (8.48)	0.603	8.74 (2, 62)[d]
Left flexion	37.62 (7.78)	38.42 (8.90)	44.23 (7.37)[b,c]	38.11 (8.22)	0.277	47.02 (4.02)[b,c]	35.83 (8.69)	0.578	22.40 (2, 62)[d]
Right flexion	38.16 (8.67)	40.91 (8.47)	45.78 (7.43)[b,c]	40.18 (7.55)	0.192	45.42 (5.73)[b,c]	35.17 (6.50)[b]	0.514	22.48 (2, 62)[d]
Left rotation	71.92 (9.8)	70.21 (8.96)	79.85 (6.47)[b,c]	70.85 (10.09)	0.305	84.92 (5.39)[b,c]	67.86 (11.13)	0.660	21.97 (2, 62)[b]
Right rotation	71.86 (8.16)	69.43 (9.55)	77.19 (7.34)[b,c]	70.62 (8.10)	0.239	82.23 (7.52)[b,c]	65.77 (6.83)	0.682	26.72 (2, 62)[d]
Proprioception									
Flexion	2.96 (1.31)	3.33 (1.80)	2.55 (1.28)	2.71 (1.38)	0.007	1.66 (1.02)	1.55 (0.81)	0.007	0.58 (2, 62)
Extension	3.03 (1.25)	3.16 (1.65)	2.43 (0.86)	2.67 (1.03)	0.035	2.53 (1.40)	2.24 (0.70)	0.026	0.96 (2, 62)
Left flexion	2.85 (1.45)	3.00 (1.29)	2.57 (1.13)	2.52 (1.38)	0.001	2.02 (1.28)	2.41 (1.02)	0.064	0.62 (2, 62)
Right flexion	2.73 (1.07)	2.86 (1.57)	2.28 (0.82)	2.98 (1.12)	0.182	2.56 (1.36)	2.66 (1.08)	0.003	1.33 (2, 62)
Left rotation	1.96 (0.70)	2.53 (1.36)	2.61 (1.38)	2.21 (0.92)	0.053	2.04 (1.31)	2.79 (0.97)	0.209	6.28 (1.687, 52.289)[d]
Right rotation	2.85 (1.35)	2.98 (1.64)	2.36 (1.19)	2.29 (1.43)	0.002	1.81 (0.95)	2.47 (1.45)	0.120	1.25 (2, 62)
Mean velocity									
Flexion	12.54 (2.80)	11.02 (2.68)	15.71 (2.74)	12.93 (3.12)	0.270	14.30 (2.59)	12.58 (2.27)	0.218	1.28 (2, 62)
Extension	14.24 (2.52)	14.90 (2.38)	14.85 (2.00)	13.68 (2.97)	0.085	15.22 (1.66)[b,c]	13.14 (2.39)	0.337	6.53 (2, 62)[d]
Left rotation	15.64 (3.47)	15.15 (3.80)	18.13 (3.76)[b]	16.44 (3.28)	0.105	20.27 (3.46)[b,c]	16.99 (2.13)[b]	0.452	3.80 (1.609, 19.872)[e]
Right rotation	17.27 (2.51)	16.59 (2.58)	18.75 (2.12)	17.56 (1.93)	0.156	17.50 (2.03)	16.63 (2.02)	0.079	0.24 (2, 62)
Peak velocity									
Flexion	68.63 (17.18)	76.77 (26.13)	81.74 (20.69)[b]	72.61 (21.01)	0.092	117.76 (31.10)[b,c]	91.55 (21.72)[b]	0.376	14.69 (2, 62)[d]
Extension	77.62 (21.63)	77.71 (17.05)	76.17 (16.90)	71.71 (18.45)	0.049	99.55 (25.10)[b,c]	70.74 (14.55)	0.530	13.31 (2, 62)[d]
Left rotation	88.71 (18.46)	88.97 (18.72)	93.97 (12.52)	98.71 (27.52)	0.022	173.00 (51.51)[b,c]	132.43 (29.69)[b]	0.365	13.75 (1.522, 47.174)[d]

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Variables	Preintervention, mean (SD)		Postintervention, mean (SD)		Cohen *d*[a]	3-month follow-up, mean (SD)		Cohen *d*	Group*time, *F* test *(df)*
	Experimental group	Control group	Experimental group	Control group		Experimental group	Control group		
Right rotation	94.15 (14.24)	100.66 (22.47)	102.32 (24.37)	89.02 (13.23)[b]	0.167	124.33 (29.63)[b,c]	93.26 (10.63)	0.534	13.29 (2, 62)[d]
Satisfaction	N/A[f]	N/A	3.03 (1.33)	1.66 (1.82)	0.860	2.97 (1.28)	1.81 (1.99)	0.693	N/A
Relief of symptoms	N/A	N/A	3.00 (2.00)	2.00 (3.00)	N/A	4.00 (1.00)	2.00 (2.00)	N/A	N/A

[a]Cohen *d* was calculated for the differences between postintervention or 3-month follow-up and preintervention in the experimental group compared to the control group.

[b]Indicates $P<.02$ (0.05/3) for within-group comparisons by Bonferroni correction compared to the baseline.

[c]$P<.05$ statistically significant differences were found compared to the control group at the same measuring timepoint.

[d]$P<0.01$ significant main effects were revealed on the group*time interaction.

[e]$P<.05$ significant main effects were revealed on the group*time interaction.

[f]N/A: not applicable.

Neck Pain Intensity

For pain, ANOVA results revealed significant differences over time ($F_{1.744,54.077}=87.369$; $P<.001$; $\eta_p^2=0.738$), group ($F_{1,31}=28.138$; $P<.001$; $\eta_p^2=0.476$), and the group*time interaction ($F_{2,62}=27.277$; $P<.001$; $\eta_p^2=0.468$). The post hoc analysis indicated a significant between-group difference at postintervention ($P<.001$; $\eta_p^2=0.582$) and 3 months postintervention ($P<.001$; $\eta_p^2=0.587$), with the experimental group representing better enhancement. Compared with baseline, patients in the experimental group experienced pain relief immediately postintervention and at 3-month follow-up, while control group participants did not exhibit significant pain reduction throughout the study. Besides, pain intensity scores decreased in both groups compared to baseline (experimental group 3.04 vs control group 0.50 at posttreatment; experimental group 3.20 vs control group 0.85 at the 3-month follow-up), with patients in the experimental group exceeding the MCID at 2 timepoints. The percentage of data exceeding the MCID significantly differed between the 2 groups (experimental group: 21/32, 66% vs control group: 3/32, 9% at posttreatment; experimental group: 20/31, 65% vs control group 4/30, 13% at the 3-month follow-up).

Secondary Variables Measure

CROM

The results of ANOVA on CROM revealed a significant effect of the group, time, and group*time interaction ($P<.05$). Participants in the experimental group obtained greater ROM improvement in 6 directions at postintervention and at 3-month follow-up ($P<.05$) compared to the control group participants. Notably, significant changes were observed after intervention and follow-up in the experimental group from those at baseline ($P<.05$), while no differences were observed in the control group. The experimental group participants achieved ROM improvements exceeding the MDC in all directions at both timepoints, except for extension ROM at the 3-month follow-up, highlighting the clinical effectiveness of the intervention in the experimental group compared to the control group. Specific data on this indicator can be found in Multimedia Appendix 2.

Proprioception

Regarding proprioception, the ANOVA results revealed no significant difference in the group*time interaction for 6 directions, except for left rotation. For the proprioception of left rotation, significant effects occurred in the group*time interaction. The post hoc analysis showed that patients receiving VR intervention attained lesser improvement after the 3-month follow-up than the control group. However, no within-group differences were reported. Upon further analysis of other directions, proprioception in flexion, extension, and right rotation directions was found to achieve improvement in both groups after treatment and follow-up versus the baseline, and proprioception of left flexion showed a noticeable improvement after the follow-up in comparison with the baseline. However, the between-group analysis showed no marked difference in all directions. The detailed data regarding this parameter are presented in Multimedia Appendix 2.

Mean and Peak Velocity

There were significant main effects for the interaction between time and group ($P<.05$) for the mean velocity of extension and left rotation. The post hoc analysis revealed significant gains after the 3-month follow-up in the experimental group compared to that in the control group or baseline for these 2 directions. No significant effects for the interaction between time and group were found in the mean velocity of flexion and right rotation. For intergroup comparisons, patients receiving VR training showed better improvement in the mean velocity of flexion than the control group, which was not found in the right rotation direction. As for the within-group comparison, both groups showed superiority over baseline in the mean velocity of flexion at posttreatment and the 3-month follow-up, and the mean velocity of right rotation remained negative. However, the magnitude of improvement in the mean velocity in both the groups did not surpass the corresponding MDC in any direction.

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A repeated measures ANOVA showed a main effect for the group*time interaction for the peak velocity in all 4 directions. Compared with the baseline, the experimental group participants gained significant enhancement ($P<.05$) at the 3-month follow-up. Furthermore, the between-group comparisons supported better therapeutic effects with VR devices than the control after intervention and 3-month follow-up period (Table 2). Increased maximal velocity of flexion and left rotation directions was significantly higher in the experimental group over MDC after the follow-up, which did not occur in the other directions or the control group. For specific data on the mean and peak velocity, please refer to Multimedia Appendix 2.

Global Perceived Effect

Considering patient satisfaction, the results revealed a significant between-group difference at postintervention and 3-month follow-up (experimental group 3.03, SD 1.33 vs control group 1.66, SD 1.82) with an advantage to the experimental group. The within-group analysis showed no significant effects among different timepoints for the 2 groups. In the Mann-Whitney *U* test, obvious between-group differences were found in the relief of symptoms at postintervention (experimental group 3.00, SD 2.00 vs control group 2.00, SD 3.00) and 3-month follow-up (experimental group 4.00, SD 1.00 vs control group 2.00, SD 2.00). Furthermore, significant improvements were observed in the experimental group after the 3-month follow-up compared to those at postintervention, while no differences were observed in the control group (Table 2). The specific data related to these indicators can be obtained in Multimedia Appendix 2.

Discussion

Overview

This RCT was intended to compare the benefits of combining VR therapy and conventional rehabilitation with those of conventional rehabilitation alone for treating chronic neck pain. Overall, our results show that patients in both groups reported reduced pain and disability and demonstrated improved kinematic functions. Direct comparisons between the 2 groups revealed that VR treatment in addition to conventional rehabilitation was superior to conventional rehabilitation alone for improvement in the pain, disability, and kinematic indicators, and the effects of combined therapy could be maintained over the 3-month follow-up period. Additionally, participants in the VR therapy group reported higher satisfaction levels, better symptom improvement, and greater willingness to engage in exercises during the follow-up period.

Effects of VR Therapy Combined With Conventional Rehabilitation on Pain and Disability

Although reduced pain and disability were found in both treatment groups at 2 timepoints, these indicators were decreased nearly 3 times more in the experimental group than in the control group. Furthermore, the improvement of pain and disability observed at 2 measuring timepoints in the experimental group was higher than the MCID, which has been previously reported as 2.7 and 3.5 points, respectively [37,38]. This finding indicates the significant and clinical effectiveness of VR therapy in addition to conventional rehabilitation in alleviating pain and disability. The corresponding size effects were medium, highlighting the notable differences between the 2 groups.

Multiple studies have shown that patients with neck pain experienced significant improvements in pain intensity with VR treatment compared to baseline [45,47] and markedly superior to control groups receiving laser training [27] or conventional rehabilitation [28]. Further, a recent meta-analysis [48] incorporating 8 RCTs revealed that better analgesic effects were found in the multimodal intervention (VR technique in combination with other therapies) than in the other interventions and in the patients treated in the clinic or research unit than the controls. This also provides a new perspective on VR analgesia research. However, some studies have reported conflicting results. For instance, a study [44] investigating the efficacy of a 120-minute VR therapy session for patients with chronic neck pain indicated remarkable improvement in pain intensity at rest or during motion compared to baseline as well as alleviation in the disability level. However, no significant between-group differences were observed in these metrics in the VR intervention group as compared to the 2 control groups undergoing conventional rehabilitation alone or general sensorimotor training plus conventional rehabilitation. This discrepancy may be attributed to the smaller sample size in that study (17 individuals per group) [44], which lowered the statistical power representation of between-group differences. Similarly, the VR gaming scenario utilized in that study [44] lacked sufficient visual and auditory feedback compared to the VR design in our research, and this might have limited the analgesic effect of VR treatment.

The potential efficacy of VR therapy in reducing neck pain and disability may be attributed to its ability to enhance coordination between the deep and superficial cervical muscles [49]. Poor sensorimotor control by cervical muscles in patients with neck pain has been indicated in previous research [5,9] and is considered to trigger associated disability and kinematic disorders. Although muscle activation was not evaluated in this study, VR therapy appears to promote the function and coordination of cervical muscles, thereby reducing the stress on cervical segments and alleviating neck pain and disability. Another possible reason could be the deep engagement required by the virtual environment, blocking the transmission of sensory information related to pain and achieving analgesic effects.

Effects of VR Therapy Combined With Conventional Rehabilitation on Cervical Kinematic Function

The secondary outcomes yielded interesting findings that VR therapy could increase the ROM, mean velocity, and peak velocity at 2 timepoints compared to those in the baseline or control group. This conclusion was consistent with that reported in previous research [28,44,50]. Tejera et al [50] in 2021 reported the positive results of VR therapy on increasing CROM in patients with chronic neck pain, which can be attributed to the sufficient feedback provided by VR devices. The visualization of images was widely perceived as useful in activating the corticospinal system and enhancing the intensity of muscle recruitment, thereby improving the overall neck kinematic functions. Fowler et al [51] showed that VR might encourage patients to turn their heads farther and faster by its

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effect on reducing fear of movement, which has been reported in other studies [52-54]. Besides these, continuous progressive VR treatment dosage based on real-time assessment data on motor function assisted patients in restoring their motor function.

As can be observed from the mean and maximum velocity data in various directions, the experimental group always showed no between-group differences after training but showed between-group differences after the 3 months follow-up compared to the control group, suggesting that this may be attributed to the insufficient training time during the intervention. Upon analyzing the training length after the intervention, we could see that the training frequency of patients in the experimental group was higher than that of the control group during the follow-up period, reaching an average of 1-2 hours of training per week, and more training time outside of the experiment would probably promote further improvement of motor function. These findings indicate that researchers as well as clinical specialists should pay more attention to the supervision and education of home-based active exercise in the future.

Regarding proprioception, both groups showed significant improvement in several directions after treatment or 3-month follow-up; however, no between-group differences were found. Prior studies [49,55] have confirmed that multiple exercise programs, including head relocation practice, gaze stability, eye-follow, and eye/head coordination, are effective in improving proprioception. In this study, however, only head relocation practice was used (the participant was instructed to memorize the head-neck position and try to find the initial position with eyes closed after moving), and satisfactory results were obtained. Moreover, other studies [27,44] have utilized alternative proprioceptive training with similarly favorable outcomes. Some investigators noticed that eye-follow and eye/head coordination training greatly enhanced patients' accuracy, which was likely attributed to improved motor control and coordination of the neck [47]. This suggests that more consideration should be given to focus on all forms of proprioceptive training in the clinical management of patients with chronic neck pain.

Effects of VR Therapy Combined With Conventional Rehabilitation on Satisfaction and Relief of Symptoms

Besides the indicators mentioned above, the marked between-group difference was observed in patient satisfaction and relief of symptoms at both timepoints, with some advantages in the combined treatment. These 2 self-rating indicators are considered important for recovering from chronic neck pain. The enjoyment derived from VR equipment, multiple visual and auditory feedback, personalized tasks, and adjustable difficulty levels likely contributed to the higher satisfaction levels and greater therapeutic efficacy in the experimental group. Notably, no adverse events such as motion sickness were reported during the research period.

Limitations

Several limitations of this study warrant consideration. The absence of a placebo group receiving sham VR therapy raises concerns about the potential overestimation of VR therapy's therapeutic effects. However, the substantial improvements in pain, disability, and CROM surpassing the MCID suggest that the effect may be due to the treatment itself other than the placebo effect. Moreover, the impact of varying durations of conventional rehabilitation (30 minutes vs 10 minutes) on therapeutic outcomes remains uncertain, potentially influencing the perceived efficacy of VR treatment. Additionally, the inability to blind patients due to the experimental nature of this study introduces a risk of bias. The lack of long-term follow-up data further limits the generalizability of the findings. Lastly, the absence of assessment indicators for mental function and quality of life hinders the comprehensive evaluation of VR therapy's overall therapeutic efficacy.

Implications

This study provides support for the effectiveness of a combined approach involving VR therapy and conventional rehabilitation in managing chronic neck pain. However, uncertainties persist regarding the optimal dosage, underlying mechanisms of VR therapy, and the comparative effectiveness of different VR equipment types (eg, semi-immersive, nonimmersive). Future investigations should design specific trials to address these knowledge gaps. Furthermore, exploring the synergistic benefits of integrating VR training with other evidence-based interventions such as manipulation and sensorimotor training is warranted.

Conclusions

In conclusion, the integration of VR intervention with conventional rehabilitation demonstrates significant improvements in pain, disability, and kinematic function among patients with chronic neck pain at both postintervention and 3-month follow-up assessments. Although patients can benefit from conventional rehabilitation alone, the combination of VR therapy and conventional rehabilitation is more effective for improvement in the abovementioned indicators. Considering the higher satisfaction as well as greater training initiative in the experimental group and the absence of adverse events, this feasible and effective intervention could be integrated into the standard rehabilitation treatment plan for patients with chronic neck pain. Future research endeavors should focus on refining therapeutic regimens, determining optimal dosages for VR therapy, and streamlining the implementation of this intervention in clinical settings to enhance convenience and efficacy.

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Authors' Contributions

Q Guo, LZ, LLH, CG, and Q Gao contributed to the conception and design, acquisition of data, drafting of the paper, and critical revision of important intellectual content. GC, CL, and WW were responsible for the analysis and interpretation of the data. All authors discussed the results, commented on the manuscript, and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online TeleHealth) checklist (v 1.6.1).
[PDF File (Adobe PDF File), 453 KB - games_v12i1e42829_app1.pdf]

Multimedia Appendix 2
The main and simple effect data sets.
[DOCX File , 18 KB - games_v12i1e42829_app2.docx]

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Abbreviations

ANOVA: analysis of variance
CROM: cervical range of motion
MCID: minimum clinically important difference
MDC: minimal detectable change

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NRS: numeric rating scale
RCT: randomized controlled trial
ROM: range of motion
VR: virtual reality

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Original Paper

Gamification of Behavior Change: Mathematical Principle and Proof-of-Concept Study

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Abstract

Background: Many people want to build good habits to become healthier, live longer, or become happier but struggle to change their behavior. Gamification can make behavior change easier by awarding points for the desired behavior and deducting points for its omission.

Objective: In this study, we introduced a principled mathematical method for determining how many points should be awarded or deducted for the enactment or omission of the desired behavior, depending on when and how often the person has succeeded versus failed to enact it in the past. We called this approach *optimized gamification of behavior change*.

Methods: As a proof of concept, we designed a chatbot that applies our optimized gamification method to help people build healthy water-drinking habits. We evaluated the effectiveness of this gamified intervention in a 40-day field experiment with 1 experimental group (n=43) that used the chatbot with optimized gamification and 2 active control groups for which the chatbot's optimized gamification feature was disabled. For the first control group (n=48), all other features were available, including verbal feedback. The second control group (n=51) received no feedback or reminders. We measured the strength of all participants' water-drinking habits before, during, and after the intervention using the Self-Report Habit Index and by asking participants on how many days of the previous week they enacted the desired habit. In addition, all participants provided daily reports on whether they enacted their water-drinking intention that day.

Results: A Poisson regression analysis revealed that, during the intervention, users who received feedback based on optimized gamification enacted the desired behavior more often (mean 14.71, SD 6.57 times) than the active (mean 11.64, SD 6.38 times; $P<.001$; incidence rate ratio=0.80, 95% CI 0.71-0.91) or passive (mean 11.64, SD 5.43 times; $P=.001$; incidence rate ratio=0.78, 95% CI 0.69-0.89) control groups. The Self-Report Habit Index score significantly increased in all conditions ($P<.001$ in all cases) but did not differ between the experimental and control conditions ($P>.11$ in all cases). After the intervention, the experimental group performed the desired behavior as often as the 2 control groups ($P\geq.17$ in all cases).

Conclusions: Our findings suggest that optimized gamification can be used to make digital behavior change interventions more effective.

Trial Registration: Open Science Framework (OSF) H7JN8; https://osf.io/h7jn8

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KEYWORDS

gamification; points; feedback; behavior change; habit formation; chatbot; digital interventions; mobile phone; artificial intelligence

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Introduction

Background

Overview

People often struggle to change their behavior in ways that would benefit them in the long run. For instance, many people could improve their health and life expectancy by building healthy habits such as exercising [1], healthy eating [2], or drinking a glass of water before every meal [3,4]. People who want to adopt healthy habits because they know about their benefits nevertheless struggle to change their behavior accordingly.

Building a good habit is especially difficult when the benefits of the desired behavior cannot be felt immediately. One approach to alleviate this challenge is to create apps that encourage the desired behavior using incentives or immediate positive feedback [5-7] or discourage unwanted behavior using immediate negative feedback [8]. Doing so in a gameful way can be a promising approach to improving people's health behaviors [5-7,9-12]. Using game elements to improve people's behavior in the real world is known as gamification [13]. One of the most commonly used gamification methods is awarding people points for specific behaviors [14,15]. The awarded points are often used to provide feedback to the user, define levels, award badges, or create leaderboards.

Despite the widespread use of points, levels, badges, and leaderboards, there is currently no principled way to choose precisely how many points a person should be awarded and when. This is a problem as making those decisions based on intuition can lead to point systems that inadvertently incentivize counterproductive behaviors or undermine the users' motivation [16-18]. For instance, a recent study found that the point system of the popular gamified habit formation app Habitica is actively harmful [17].

To help practitioners master the challenge of designing effective point systems that reliably foster positive behavior change, we introduced a mathematical principle for computing the number of points a person should receive for engaging in the desired behavior depending on their history of either engaging or not engaging in this behavior and how many points they should lose when they fail to do so. We called this principle *optimized gamification of behavior change*. As a proof of concept, we applied optimized gamification to design a chatbot that helps people develop the healthy habit of drinking water before every meal [3,4]. Our chatbot awards points for the desired behavior and deducts points for its omission. Critically, the number of points that the user gains or loses is computed using optimized gamification. Our chatbot combines optimized gamification with three established principles of behavior change: it (1) guides the user to set an implementation intention, (2) reminds them of their good intentions, and (3) supports self-monitoring.

We evaluated our chatbot in a longitudinal field experiment and found that optimized gamification can make digital behavior change interventions more effective. Our findings provide a proof of concept for a very general and principled approach to improving human behavior in the real world. In addition to this theoretical contribution, we introduced a chatbot for helping people develop a specific healthy habit (water drinking): the Good Habit Bot. This chatbot can easily be adapted to other health behaviors, including more critical health behaviors such as exercising, healthy eating, and other good habits that people want to establish.

The plan for this paper is as follows. We first introduce relevant background information about behavior change and gamification. We then present our theory of optimized gamification for behavior change. Next, we present the chatbot we designed as a proof of principle. After that, we present the methods and results of our field experiment and discuss its findings and implications.

Behavior Change Goals Versus Automatic Behavior

Human behavior is controlled by a combination of goal-directed decision-making (eg, *I will buy a gym membership because I want to lose weight*) and more automatic reactions to certain stimuli (eg, always stopping by the gym on the way home from work) [19]. Goal-directed decision-making derives choices from the outcomes that people value (eg, health or money) or want to avoid (eg, pain) according to their mental models of how those outcomes can be obtained. In contrast, automatic reactions do not consider the behavior's likely consequences in the current situation.

Obstacles to Behavior Change: Automaticity and Temporal Discounting

Most of our behavior is not primarily controlled by goal-directed decision-making but determined by people's automatic reactions. Therefore, automatic behavioral responses can interfere with people's ability to act in accordance with their behavior change goals. This is the proverbial conflict between bad habits and good intentions. People can inhibit and override their automatic behavioral responses (*bad habits*), but their capacity to do so is limited [20]. Therefore, the automaticity of human behavior is a crucial obstacle to intentional behavior change.

A second obstacle to successful behavior change is that the mechanisms of goal-directed decision-making are demonstrably biased in favor of immediate outcomes [21]. People give too much weight to their decision's immediate consequences and too little weight to its long-term consequences. This phenomenon is known as present bias [22]. It has been proposed that present bias occurs because the brain discounts delayed benefits as if they become less valuable the later they occur [23]. This phenomenon, which is known as temporal discounting, is well established in research on economic decisions and animal behavior.

Moreover, according to temporal motivation theory [24], temporal discounting is one of the main reasons why people fail to enact good intentions. Such failures of self-regulation are a critical obstacle to health behavior change [25,26]. Consistent with this explanation, people who discount delayed outcomes more strongly are likelier to engage in unhealthy behaviors and experience poor health [26].

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Reinforcement Learning as a Mechanism of Behavior Change

As automatic responses are powerful drivers of human behavior, successful behavior change typically involves translating behavior change goals into automatic behavioral responses [27].

Automatic behavioral responses, including exercise habits, can be acquired through learning from experience. Model-free reinforcement learning is a well-established mechanism of learning automatic behavioral responses from experience [19]. This mechanism increases or decreases a person's propensity to engage in a specific behavior in a particular situation (eg, going to the gym after work) according to whether they experience the behavior's overall consequences as positive or negative. The vast literature on operant conditioning in animals and humans underscores that learning from reward and punishment is a powerful mechanism of behavior change [28,29]. Another complementary learning mechanism involves strengthening habits through mere repetition [30].

Supporting Behavior Change Through Incentives and Reinforcement

The literature surveyed previously demonstrates that goal-directed decision-making and automatic behavioral responses are responsive to rewards and punishments. Goal-directed decision-making is sensitive to anticipated future rewards, and automatic behavioral responses are shaped by the rewards or punishments that those behaviors have generated in the past. These effects can be leveraged to support behavior change. To foster behavior change via goal-directed decision-making, behavior change interventions can create and announce incentives for engaging in the desired behavior. To foster behavior change via reinforcement learning, behavior change interventions can reinforce the desired behavior with rewards or positive feedback.

A highly effective behavior change intervention that leverages both effects is contingency management [31]. Contingency management incentivizes a desired behavior change and rewards people when they enact it. Voucher-based reinforcement therapy for treating addiction is a highly successful example of contingency management [32]. This behavior change intervention awards the patient a voucher every time they submit a negative drug test. More recently, it has also been applied to foster other types of behavior change, including physical exercise [7,33] and treatment attendance [34]. Contingency management appears to be more effective when the desired behavior is reinforced more promptly, more frequently, and with rewards that are larger or increase throughout the intervention [35-37].

Digital Behavior Change Interventions

Developing digital behavior change interventions is a young and booming field [38]. Mobile apps have shown potential for fostering positive behavior change in domains such as physical exercise and healthy eating [38,39]. However, the average effect size of such interventions is still relatively small [40,41]. Most behavior change interventions are not derived from any theory, model, or framework [38]. Therefore, we suspect that there is still room for improvement and that at least some of this potential can be realized by adopting a more theory-driven approach.

Goal setting and self-monitoring are the most commonly used behavior change techniques [38]. A meta-analysis of studies on digital interventions for promoting physical exercise found that these 2 techniques are also the most effective ingredients of current digital behavior change interventions [41]. Goal setting entails guiding people to articulate their intent to perform certain behaviors in certain situations (eg, drinking a glass of water before every meal). Supporting self-monitoring often takes the form of helping people check or record whether they have enacted those intentions or track related outcomes (eg, their weight). Goal setting is especially effective when people formulate simple plans that specify the intended behavior and the situation in which they want to perform it as concretely as possible [42,43]. This approach is known as *implementation intentions*. Moreover, reminding people of their intentions via SMS text messages [44] and presenting them with positive reinforcement when they enact their intentions [5,7,33] have been found to be highly effective in promoting physical exercise.

Gamification

A recent meta-analysis found that approximately 1 in 5 digital behavior change interventions are designed within the gamification framework [38]. Gamification entails applying principles from game design and game elements, such as storytelling and rules for earning points and winning the game, to address real-world problems [13]. The basic idea is to motivate people to do things that benefit them or others, such as exercising and studying, in a gameful way. Previous research has found that gamification can improve people's behavior, achieve desired outcomes, and improve people's subjective experiences [45].

Gamification is already widely used in designing digital behavior change interventions [5], and previous studies have suggested that it can improve people's health behaviors [7,9-12,33]. One gamification strategy that is effective in digital behavior change interventions is awarding the user points as positive feedback for the desired behavior [5,7,33]. Such extrinsic incentives can increase the frequency of the targeted behaviors without affecting people's intrinsic motivation [46,47].

However, when gamification is not correctly designed, it can backfire and have adverse effects [16,17,48]. This has also been observed in the behavior change literature [12,49] and in gamified habit formation apps [17]. Getting the incentives exactly right can be crucial as points, levels, badges, and leaderboards do not foster the user's intrinsic motivation [46,47] and might sometimes even undermine it when they are not embedded in a compelling narrative [18]. Motivated by these problems, many authors have called for a more theory-driven approach to gamification in general [50] and gamifying digital behavior change interventions in particular [12].

Optimized Gamification

Previous work has investigated how many points should be awarded for which behavior to maximally benefit the user in the context of to-do list apps that help the user achieve their

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own goals [51,52]. Building on temporal motivation theory [24], this work assumed that people's motivation is insufficiently sensitive to long-term benefits such as good health in old age and overly sensitive to immediate costs (eg, the effort of exercising) and short-term pleasure (eg, from receiving immediate positive feedback). To help people overcome the resulting motivational problems (eg, procrastination) [53], Lieder et al [51] developed a mathematical theory for designing point systems that provide immediate positive feedback for activities that are beneficial in the long run and immediate negative feedback for activities that are not. The basic idea is to align each action's immediate and long-term consequences. The action that is best in the long run should be made most appealing in the short run, and actions with undesirable long-term consequences should be made unappealing in the short run.

Therefore, optimized gamification strives to incentivize each of the available actions through a number of points proportional to how much that action increases or decreases the sum total of future happiness. This idea is implemented by modeling the activities to be incentivized as steps that lead toward a valuable goal or away from it. Actions that lead toward the goal increase the time the person will spend in the more valuable state in which the goal has been achieved. In contrast, actions that lead away from the goal decrease the time the person will spend in the more valuable state in which the goal has been achieved and increase the effort required to achieve it afterward. On the basis of this mathematical model, dynamic programming and reinforcement learning methods can estimate how much a given action improves or worsens the person's situation. These estimates are then translated into incentives that encourage good choices and discourage bad ones. The resulting point values are optimal in that they would enable even a purely myopic decision maker who only cares about immediate outcomes to choose the actions that are best for them in the long run [51].

Although optimized gamification construes points as incentives and uses mathematical and computational methods from the field of reinforcement learning, using it does not constitute a commitment to behaviorism and is fully compatible with cognitive theories of motivation [54].

Optimized gamification has been used to encourage users to tackle the tasks on their to-do lists [32] and encourage students to select the most valuable learning activities [55,56]. Optimized gamification has also been applied to give people feedback on how they think about what to do [57] and on whether they succeeded in staying focused on a chosen task or got distracted [58]. However, to date, this approach has never been applied to support habit formation.

Objectives

The first goal of this study was to introduce a principled method for computing feedback on the enactment or omission of the desired behavior and experimentally test whether it can be used to enhance digital behavior change interventions. The second goal of this study was to introduce a chatbot that uses this method to help people develop healthy water-drinking habits and evaluate it in a longitudinal field experiment.

Methods

Optimized Gamification of Behavior Change

Overview

We conceptualized behavior change as a special case of repeatedly choosing and learning when to do what. As reviewed in the *Background* section, optimized gamification can encourage desired behaviors and accelerate learning [57]. To apply this method to promote the desired behavior and accelerate the formation of healthy habits, we first have to model habit formation as a Markov decision process (MDP) [59].

Modeling Habit Formation

An MDP is a scenario in which an agent faces a series of choices. Each choice (a) has 2 effects. First, it yields an immediate reward (r) that may be positive, negative, or zero. Second, it may change the state (s) the agent finds itself in. In an MDP, the agent's goal is to maximize the sum of the rewards it accumulates from its first decision to its last one.

We model behavior change problems as a straightforward MDP, in which a person repeatedly chooses between 2 possible actions when they find themselves in a particular situation: enacting the desired behavior (a=1) or not enacting it (a=0). Our model assumes that a given behavior change intervention aims to turn the desired behavior into a habit. Therefore, we define the state as the strength of the person's healthy habit, measured using a single number, s_{habit}, which can range from 0 to 1. Following standard habit formation models [30], we assume that enacting the habit increases its strength from

$$s_{habit} \text{ to } s_{habit} + \alpha \times (1 - s_{habit}),$$

where α is a free parameter that describes how quickly habits form. Conversely, our model assumes that failure to enact the desired behavior decreases the strength of the habit to $s_{habit} \times (1 - \alpha)$. We assume that the habit has been cultivated when its strength exceeds some threshold θ (eg, θ=0.9) and model the health benefits conferred by achieving this goal as a reward (r_{goal}) that is attained when the habit strength crosses this threshold. Enacting the desired behavior is assumed to incur a cost that decreases with the strength of the habit ($r[s_{habit}, 1]=-[1 - s_{habit}]$), whereas not performing the behavior is assumed to be effortless ($r[s_{habit}, 0]=0$).

Computing Optimal Feedback

The basic idea of optimized gamification is to reward each action using a number of points that are proportional to its long-term benefits. These long-term benefits are measured via the decrease in future costs and the increase in future rewards brought about by transitioning to a state in which the habit is stronger. In situations in which the benefits of developing the good habit outweigh its costs, the value of having a habit of strength s_{habit} and then following through with the process of building the habit is as follows:

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where the number $n(s_{habit}; \theta)$ specifies how often the behavior must be enacted until the habit strength reaches its target value θ. Therefore, for someone who will follow through with building the habit, the long-term benefits of enacting the habit one more time when its current strength is s_{habit} are

$$f(s_{habit}, 1) = V^*(s_{habit} + \alpha \times [1 - s_{habit}]) - V^*(s_{habit}) = 1 - s_{habit}.$$

Conversely, the long-term costs of failing to enact the desired behavior in the situation in which it is supposed to become a habit are

$$f(s_{habit}, 0) = V^*(s_{habit} \times [1 - \alpha]) - V^*(s_{habit}).$$

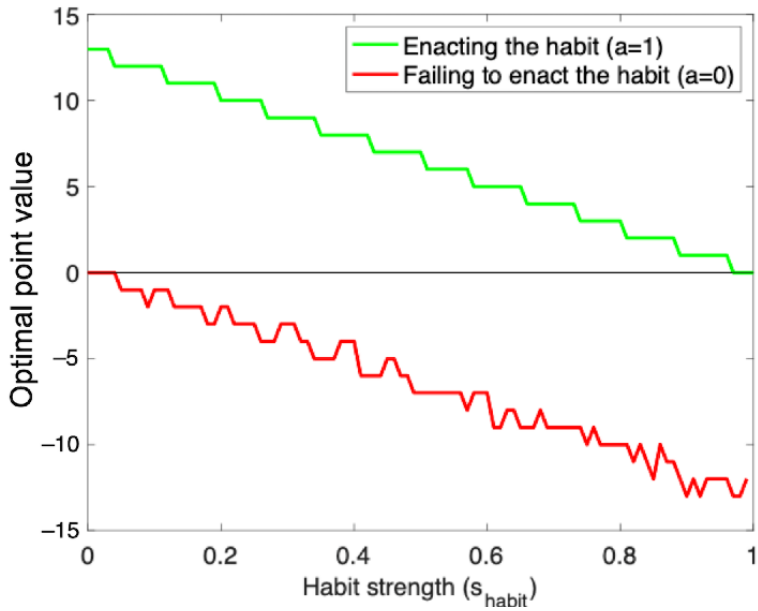
Please note that, even though we are talking about a situation in which it is rational for people to build the habit, this does not mean that we assume people to be rational. For our method, it does not matter why people follow through with building the habit. In fact, we assume that some people will follow through with building the habit only because they are (irrationally strongly) motivated by the immediate rewards conferred by feedback.

The lowest possible negative value of f is $f(\theta, 0)$, and the largest possible positive value is $f(0, 1)$. Although the exact values depend on the model parameters, they are typically approximately –1 and 1, respectively. Therefore, to transform those values into points, it is desirable to scale them by the desired maximum point value (M) that the application should award to the user and then round the scaled values to the nearest integer. This yields the following equation for the number of points that the application should award when a user reports that they have enacted their intention (a=1) or have not enacted their intention (a=0):

$$\text{points}(s_{habit}, a) = \text{round}(M \times f(s_{habit}, a)) \text{ (Equation 1).}$$

Figure 1 illustrates the point values as a function of the user's habit strength in an example application with a learning rate of α=0.1, a target habit strength of θ=0.9, and a maximal point value of M=13. Multimedia Appendix 1 provides more details on our mathematical model and the resulting optimal point system.

Figure 1. Point values for enacting versus failing to enact the habit at different habit strengths for a learning rate of α=0.1 and a threshold of θ=0.9.



As illustrated in Figure 1, the number of points for enacting the desired behavior is largest when the habit is weakest and gradually decreases toward 0 as the habit strengthens. This is intuitive as performing the desired behavior becomes easier the more often one has already performed it. Conversely, the number of points that should be deducted when the user fails to enact the habit is smallest when the strength of the habit is 0 and then increases as the habit becomes stronger. This is an intuitive consequence of our model's assumption that failing to enact the desired behavior in the specified situation weakens the habit strength by approximately 10%. The stronger the habit, the more is lost when its strength is reduced by 10%. The number of points awarded for enacting the desired behavior is a monotonically decreasing function of the habit strength. In contrast, the point value for failing to enact the desired behavior changes more erratically. This is because the number of steps required to reach the desired habit strength changes abruptly with the current habit strength. For instance, failing to enact the behavior at a habit strength of 0.09 increases the number of times the behavior needs to be enacted to achieve the desired habit strength from 21 to 22 times. However, if the habit strength is 0.08 or 0.10, the number of times the desired behavior has to be enacted remains 22 and 21 times, respectively. Individual users rarely experience such irregular changes as the change in their habit strength typically skips across those small areas in which the point value changes nonmonotonically. Moreover, our simulations suggest that the penalty for failing to enact the desired behavior can be approximated using a linear function with the same slope as the number of points for performing the desired behavior.

Application to Supporting Positive Behavior Change

The optimized gamification method described previously can be applied to help people form good habits. The equations for

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computing the number of points are easy to implement within digital behavior change interventions such as chatbots and habit trackers. All that is needed is to ask the user which habit they want to develop and estimate its initial strength, set the learning rate parameter and the habit's target strength to reasonable values (eg, α=0.1 and θ=0.9), and record when the user did versus did not act in accordance with the desired habit. To define the desired habit, the user has to specify the desired behavior and the situation in which they want to perform it. The user's initial habit strength can be estimated through the desired behavior's relative frequency in that situation in the previous weeks (eg, at 2 of the previous 7 lunches). The habit strength can then be initialized using that proportion. Alternatively, when it makes sense to assume that the user wants to build an entirely new habit, the strength can be initialized as 0. Then, whenever the user reports having or not having enacted their intention, the optimized gamification equation can be applied to compute how many points the user should gain or lose. Whenever the user reports having performed the desired behavior, the estimate of the habit strength should be increased to

$$s_{habit} + \alpha \times (1 - s_{habit}),$$

and whenever the user reports having missed an opportunity to enact their intention, the estimate of their habit strength decreases to $s_{habit} \times (1 - \alpha)$. Then, the same procedure repeats when the user reports on their next opportunity to enact the behavior.

This approach can be used to support many different types of positive behavior change. It can help people build good habits in areas such as exercise, sleep, taking medication, nutrition, work, chores, and leisure activities. It can be used in interventions focusing on specific habits and, in general, in habit formation tools that let users choose any habit they want to develop. Another possible application is helping people overcome bad habits (eg, smoking cessation) [60]. It can support applications that run on practically any device, from smartwatches and wristbands to mobile phones, desktop applications, web applications, and smart glasses.

Proof of Concept: A Chatbot for Building a Healthy Water-Drinking Habit

As a proof of concept for the application of optimized gamification to support behavior change, we implemented this idea as a Telegram (Telegram FZ LLC) chatbot called the *Good Habit Bot*. This chatbot helps the user develop a healthy water-drinking habit by combining 4 behavior change techniques: goal setting, reminders, support for self-monitoring, and feedback. Concretely, the Good Habit Bot guides the user to formulate an implementation intention that links a specific desired behavior to a concrete daily event, reminds the user of their intention on a daily basis, checks in with them on whether they followed through on their intention every day, and then gives them positive or negative feedback depending on whether they did or did not follow through on their intention.

When the user starts their first conversation with the Good Habit Bot, the chatbot introduces itself and says that its purpose is to help the user form a healthy water-drinking habit. The Good Habit Bot then asks the user to choose which of 8 concrete, recurring moments in their day they want to use as the trigger for their water-drinking habit (eg, *when my wake-up alarm rings* or *when I have the first bite of my lunch*; for the complete list, see Multimedia Appendix 2). Next, the Good Habit Bot asks the user how much water they want to drink in that situation (eg, 1 glass or 0.5 glasses) and how often they did so in the previous 7 days. The chatbot then uses the number of days *n* of the previous week in which the user acted in accordance with the habit (eg, n=2) to initialize their habit strength by n/7 (eg, s_{habit} = 2/7). Then, in the evening of the first day (ie, at 9 PM), the chatbot reminds the user of their intention to drink a specific amount of water at a particular moment of the following day (eg, *Remember your intention*: *When I have the first bite of my lunch, I will drink 1.5 glasses of water*). Then, sometime after the moment in which the user wanted to enact their intention, the chatbot asks them whether they did so (ie, *Did you accomplish your goal today to drink 1.5 glasses of water*). If the user affirms that they followed through on their intention, the chatbot gives them positive feedback (Figure 2). This feedback comprises a congratulatory message (eg, *That's wonderful!)* whose text alternates among 5 possible phrases (Multimedia Appendix 2) and a second message that awards the user the number of points computed by our optimized gamification method (eg, *I am glad to grant you 5 points for keeping a good habit! Your total score is 49 points*). In contrast, if the user responds that they missed their chance to enact their water-drinking intention, the Good Habit Bot tells them *Okay. Keep going tomorrow!* and informs them how many points they lost and how many they have left (Multimedia Appendix 2). Afterward, the chatbot updates the user's habit strength. Later that day, the Good Habit Bot reminds the user of their intention for the next day, and then the cycle repeats.

Critically, the chatbot computes how many points to award or take away from the user according to the optimized gamification method described previously (equation 1). One can read the number of points the chatbot we used in our experiment awarded in different situations in Figure 1 as it used the same set of parameters (ie, α=0.1; θ=0.9; M=13). For instance, if a user who reported having performed the desired behavior twice in the previous week enacted their intention on the first day, they earned 9 points, and their habit strength increased from

Conversely, if they failed to enact their intention, they would lose 4 points, and their habit strength would decrease to

The Good Habit Bot is freely available on the Telegram messenger app, where it can be found by searching for its alias, @learn_good_habits_bot.

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Figure 2. Screenshot of the feedback method with point values computed by our optimized gamification method.

Study Design

To evaluate the effectiveness of our intervention and assess the relative contributions of reminders versus optimized gamification, we ran a longitudinal between-subject experiment with 1 experimental condition with optimized gamification (*optimized gamification condition*), 1 *baseline condition*, and 1 *control condition with reminders and feedback* (Table 1). In the *optimized gamification condition*, the chatbot delivered all 4 techniques described previously, including feedback messages based on optimized gamification (Figure 1). Participants in the other 2 conditions could not gain or lose any points (no optimized gamification). They differed in whether they received feedback messages for enacting versus failing to enact the intended behavior. In the *control condition with reminders and feedback*, participants received a positive feedback message when they reported having enacted their intention (eg, *That's wonderful!)* and a more neutral message when they reported not having done so (eg, *Okay. Keep going tomorrow!)*. To create the *baseline condition*, we replaced the first control group's positive and negative feedback message with a neutral message (*OK*) and removed the daily reminders. Participants completed the self-report measures of habit strength described in the following sections before the intervention (pretest time point), immediately after the intervention (posttest time point), and approximately 3 weeks later (follow-up). Moreover, participants reported how often they engaged in the desired behavior the week before the intervention (pretest time point) and the week after the intervention (posttest time point). Finally, participants also completed daily reports of whether they enacted their intention on each day of the intervention.

Table 1. Experimental conditions.

Experimental condition	Implementation intentions	Support for self-monitoring	Reminders	Feedback
Optimized gamification condition	Yes	Yes	Yes	Optimized gamification and positive vs negative text
Control condition with reminders and feedback	Yes	Yes	Yes	Positive vs negative text
Baseline condition	Yes	Yes	No	None

Ethical Consideration

This experiment was conducted according to study protocol 401/2020BO2 approved by the Independent Ethics Commission at the Faculty of Medicine of the University of Tübingen. All data was collected and handled according to the General Data Protection Regulation of the European Union. All data has been de-identified.

Recruitment and Reimbursement

We recruited 132 participants (n=41, 31.1% for the baseline condition; n=43, 32.6% for the optimized gamification condition; n=48, 36.4% for the control condition; n=93, 70.5% female) on the web-based research platform Prolific. Based on considerations about the cost of the study, the sample size was determined a priori so that we would retain 3x40=120 participants after an anticipated 10% of participants dropped out of the study. The requirements for participation were being a native English speaker, not having interacted with our chatbot before, and having previously completed at least 10 prolific assignments with an approval rate of at least 95%. Moreover, participants had to be aged ≥18 years. The average age of the participants was 31.5 (SD 9.9; range 19-79) years.

The study description informed participants about the study's duration, activities, time commitment, and pay. Participants were paid £1.95 (US $2.45) for completing the onboarding survey. We informed them that the base pay for completing the remainder of the 40-day study would be £7.80 (US $9.81) and that they could earn an additional bonus of £8 (US $10.06). The

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description strongly recommended that only people who were already using Telegram on their smartphones should participate. Moreover, the study description informed potential participants about the potential health benefits of regular water drinking. Participants were then shown the consent form. Upon providing informed consent, participants who already had the Telegram app clicked on a link that started a conversation with the Telegram chatbot for their corresponding experimental condition. Participants who had not installed the Telegram app yet were directed to download it first.

At the end of the 40-day study, the chatbot directed participants to a second Prolific HIT where they received the announced payments contingent on their sustained active participation. All participants who completed the pretest, posttest, and follow-up measures and continued to report their daily intention enactment after the 10th day received a second payment of £15.80 (US $19.86). Participants who did not meet these criteria did not receive the second payment.

Outcome Measures and Procedure

Outcome Measures

We measured the outcome variables described in the following sections.

Dropout

We measured whether a participant dropped out of our study using a binary variable indicating whether the participant stopped responding to all daily reports at least 3 days before the end of the study.

Engagement

We measured each participant's *engagement* with our digital intervention based on the number of days on which they interacted with the Good Habit Bot.

Self-Report Habit Index

The Self-Report Habit Index (SRHI) [61] is a 12-item self-report measure of habit strength on a 7-point Likert scale. It comprises 3 subscales measuring the behavior's *history of repetition*, its *automaticity*, and the extent to which it is part of the person's *identity*. In this study, we administered the first 2 subscales. The SRHI has been found to be a 1D construct. Therefore, we averaged the scores of all items. The SRHI has been found to have high validity and very high reliability (Cronbach α of approximately 0.90; test-retest reliability: r=0.91).

Daily Intention Enactment

To measure how often each participant enacted their water-drinking intention during the intervention, we asked them the following question—*Did you accomplish your goal to drink 1 glass of water?*—on each day of the intervention. The question was asked between 30 minutes and 2.5 hours after the time at which the participant intended to drink water. Participants responded by selecting between the responses *Yes, I did!* and *No, I didn't*. After the study, we calculated each participant's *daily intention enactment* score by counting on how many of the 21 days of the intervention period they enacted their intention. Therefore, the daily intention enactment score could range from 0 to 21.

Retrospective Intention Enactment

To measure how regularly participants engaged in the intended behavior (eg, drinking a glass of water before lunch) in the weeks before and after the intervention, we asked them to answer the following question—*On how many days of the previous week did you keep the habit of drinking water?*—by selecting one of the answer choices (0, 1, 2, 3, 4, 5, or 6 days). We referred to the resulting number of days as the *retroactive intention enactment* score.

Procedure

We created 3 separate Prolific HITs for each of the 3 conditions of the experiment (Table 1), and each person was allowed to participate in at most one of these HITs. The experiment ran from November 11, 2021 to December 19, 2021. As illustrated in Table 2, the experiment was divided into 3 phases: the preintervention period (day 0), intervention period (days 1-21), and postintervention period (days 22-40). In the preintervention period, participants provided informed consent, completed the onboarding process, and completed the pretest. We blinded participants to the experimental manipulation by giving all participants the same information about the chatbot they were interacting with and the anticipated benefits of interacting with it. During onboarding, participants were directed to start the first conversation with the Good Habit Bot in the Telegram app on their mobile phones. In this initial conversation, the chatbot asked the participants to select a concrete daily situation in which they wanted to drink water and how much water they wanted to drink, as described previously. The pretest comprised 2 self-report measures: the *SRHI* and the *retrospective intention enactment* measure for the week before the study.

During the intervention period, each participant interacted with 1 of the 3 versions of our chatbot according to the condition they were in (Table 1). On each day of the intervention period, all 3 groups reported whether they successfully enacted their intention to drink water in the specific situation they had selected (*daily intention enactment*). At the end of the intervention period, all 3 groups completed the *SRHI* for the second time (posttest time point).

The postintervention period started with a 1-week break during which the chatbot did not communicate with the participants. Then, on day 28 (follow-up 1) and day 35 (follow-up 2), the chatbot asked participants from all 3 groups to report on how many days of the previous week (ie, the first and second week of the postintervention period, respectively) they had acted in accordance with the desired habit (*retroactive intention enactment*). Finally, on day 40, the chatbot asked all participants to complete the *SRHI* questionnaire for the third time (follow-up). Participants received 3 email reminders to resume interacting with the chatbot on the day of the first follow-up survey (day 28), the day of the second follow-up survey (day 35), and the day of the final follow-up survey (day 40).

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Table 2. Experimental procedure.

Experimental phase and day	Optimized gamification condition	Control condition with reminders and feedback	Baseline condition
Before the intervention			
Day 0	• Onboarding • Retrospective intention enactment • SRHI[a]	• Onboarding • Retrospective intention enactment • SRHI	• Onboarding • Retrospective intention enactment • SRHI
Intervention			
Days 1-21	• Reminder, report, and feedback (optimal points+text) • Daily intention enactment	• Reminder, report, and feedback (text only) • Daily intention enactment	• Daily intention enactment
Day 21	• SRHI	• SRHI	• SRHI
After the intervention			
Days 22-27	• No reports	• No reports	• No reports
Day 28	• Retrospective intention enactment	• Retrospective intention enactment	• Retrospective intention enactment
Days 29-34	• No reports	• No reports	• No reports
Day 35	• Retrospective intention enactment	• Retrospective intention enactment	• Retrospective intention enactment
Days 36-39	• No reports	• No reports	• No reports
Day 40	• SRHI	• SRHI	• SRHI

[a]SRHI: Self-Report Habit Index.

Data Analysis

The hypotheses and statistical analysis plan were preregistered on the internet [62]. Participants who completed 0 daily water consumption reports were excluded from all analyses apart from the dropout analysis. Other than that, all analyses were conducted on all available data from all participants who completed at least one daily water consumption report. We retained 37/41 participants from the baseline condition, 39/43 participants from the control condition with reminders and feedback, and 42/48 participants from the optimized gamification condition. All comparisons between conditions were based on the originally assigned groups. We used Poisson regression analyses for binary outcome variables. For continuous outcome variables, we used linear multilevel modeling.

Results

There was no indication of failure of random assignment for initial habit strength, automaticity, or history of repetition (pairwise $P>.14$ in all cases).

Dropout

As an initial step, we examined whether there was a differential dropout among the 3 conditions using a chi-square test of independence. There was no effect of condition on dropout ($\chi^2_2=0.7$; Cramer $V=0.07$; $P=.72$).

Engagement

The *engagement* variable was entered into a Poisson regression model with 2 dummy variables for the effects of optimized gamification and feedback and reminders. The *automaticity* and *history of repetition* scores from the SRHI before the intervention and the preintervention *retrospective intention enactment* score were entered as control variables. As shown in Table 3, optimized gamification did not increase engagement compared with the *baseline condition*. However, it appears that being in the control condition with reminders and feedback without optimal points reduced *engagement* compared with the *optimized gamification* condition (Table 3) and the *baseline* condition (incidence rate ratio=0.84, 95% CI 0.75-0.94; $P=.002$).

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Table 3. Predicting the number of days on which participants engaged with the app (engagement) from their condition and time-1 habit-related control variables (N=126)[a].

Predictor	Incidence rate ratio (95% CI)	*P* value
Intercept	18.88 (16.61-21.43)	<.001
Baseline vs optimized gamification	1.02 (0.91-1.14)	.72
Reminders and feedback vs optimized gamification	0.86 (0.76-0.96)	.008
Preintervention habit strength	1.03 (1.00-1.07)	.07
History of repetition	0.85 (0.79-0.92)	<.001
Automaticity	1.08 (1.01-1.16)	.03

[a]Nagelkerke R^2=0.33. The treatment group with optimal points is the reference group.

Daily Intention Enactment

The outcome variable measuring participants' daily enactment of the desired behavior (ie, water drinking) was subjected to a Poisson regression model with the same set of predictors as for *engagement*. Critically, we found that participants in the optimized gamification condition enacted the daily intention to drink water more often (mean 14.71, SD 6.57 times) than either the participants in the baseline condition (mean 11.64, SD 5.43 times) or the participants in the control condition with reminders and feedback (mean 11.64, SD 6.38 times; Table 4). Furthermore, reminders and feedback without points did not result in more water drinking than the *baseline condition* (incidence rate ratio=1.03, 95% CI 0.90-1.17; *P*=.70).

Table 4. Predicting the number of days on which participants drank water (daily intention enactment) from their condition and preintervention measurements of habit-related control variables (n=118)[a].

Predictor	Incidence rate ratio (95% CI)	*P* value
Intercept	16.02 (13.93-18.41)	<.001
Baseline vs optimized gamification	0.78 (0.69-0.89)	.001
Reminders and feedback vs optimized gamification	0.80 (0.71-0.91)	<.001
Preintervention retrospective intention enactment	1.01 (0.97-1.05)	.64
History of repetition	0.91 (0.84-0.99)	.02
Automaticity	1.07 (0.99-1.15)	.10

[a]Nagelkerke R^2=0.21. The treatment group with optimal points is the reference group.

Self-Reported Habit Strength

To test whether optimized gamification promoted habit formation, we compared the change in the SRHI self-report measures of *automaticity* and *history of repetition* from pretest to posttest to follow-up time points among the 3 experimental conditions (Figure S1 in Multimedia Appendix 3) using a multilevel model with fixed-effects predictors for time point, 2 dummy codes for the experimental condition with the *optimized gamification condition* as the reference, and all pairwise *time×condition* interactions (Tables S1 and S2 in Multimedia Appendix 3). We found that, compared with the pretest time point, both measures of habit strength were significantly higher immediately after the intervention (*P*<.001 in all cases) and at follow-up (*P*<.001 in all cases). However, these effects were no larger in the *optimized gamification condition* than in the baseline condition (*P*≥.20 in all cases) or the control condition with reminders and feedback (*P*≥.12 in all cases).

Behavior After the Intervention

As a further test of whether the behavior change we observed during the intervention was maintained, we analyzed the number of times participants reported having enacted their intention in the week before the intervention versus the first week after the intervention and the second week after the intervention (*retrospective intention enactment*; Figure S2 in Multimedia Appendix 3) using a multilevel model with fixed-effects predictors for time point, 2 dummy codes for the experimental condition with *the optimized gamification condition* as the reference, and all pairwise *time×condition* interactions (Table S3 in Multimedia Appendix 3). We found that, compared with the week before the intervention (mean 1.8, SD 2.1 times), participants enacted the desired behavior significantly more often after the intervention (1-week follow-up: mean 5.2, SD 1.9 times, t_{299}=15.21, and *P*<.001; 2-week follow-up: mean 5.1, SD 2.1 times, t_{299}=14.86, and *P*<.001). However, these effects were no larger in the optimized gamification condition than they were in the baseline condition (*P*≥.18 in all cases) or the control condition with reminders and feedback (*P*≥.32 in all cases).

Discussion

Principal Findings

In this study, we derived a mathematical principle for designing the point systems of gamified behavior change interventions. Our proof-of-concept study suggests that this principled

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approach to gamifying behavior change can be beneficial. We found that our gamified behavior change chatbot fostered positive behavior change during the intervention. This is consistent with previous findings that goal setting, reinforcement, reminders, and self-monitoring are effective techniques for promoting behavior change [7,33,39,41,44].

Moreover, we found that the behavior change that occurred during the intervention was maintained in all 3 conditions. The elements that the behavior change interventions in all 3 groups shared were goal setting and self-monitoring. Therefore, goal setting and self-monitoring may be sufficient for sustained behavior change. Adding reinforcement to goal setting and self-monitoring was beneficial during the intervention, but the additional benefits of reinforcement ceased to be statistically significant ($P \geq .17$ in all cases) in the week following the intervention. However, as our study had a small sample size, this apparent discrepancy could be an artifact of us having used different methods to measure behavior change during versus after the intervention. During the intervention, we measured behavior change through daily self-reports. After the intervention, we asked participants to retrospectively report on their behavior in the previous week, which is less accurate because of participants' fallible memory, and complete self-report questionnaires about their perceived habit strength, which are less objective than reports on behavior. Consistent with the interpretation that our study had insufficient statistical power for detecting retention effects, the measures we used to assess the maintenance of behavior change consistently showed a nonsignificant trend in favor of optimized gamification (Figures S1 and S2 in Multimedia Appendix 3). Moreover, previous studies have found that gamification-induced behavior change can persist over extended periods [63].

Limitations

From a theoretical perspective, the main limitation of our study is that it did not compare the effectiveness of the points computed by our optimized gamification method with alternative point schemes. Previous work has found optimized gamification to be more effective than several heuristic methods for designing point systems in contexts in which people choose among several activities [51]. However, the decisions that people face in behavior change applications appear to be simpler. Therefore, it remains unclear how much of the beneficial effects of optimized gamification on behavior change are specific to optimized gamification. Relatedly, it remains unclear which property of the points generated through optimized gamification is responsible for their effects on behavior change. Future work could address these questions by comparing optimized gamification of behavior change with simpler, alternative feedback mechanisms such as always awarding the same number of points or a streak-based point system.

However, we did evaluate optimized gamification against rewarding each enactment of the desired behavior using the same positive feedback message and punishing each failure to enact the desired behavior using the same negative feedback message (control condition with reminders and feedback). From a reinforcement learning perspective, this condition is equivalent to always awarding the same number of points when the behavior is enacted and always deducting the same number of points when the user fails to enact the behavior. We found that optimized gamification is more effective than this alternative feedback mechanism. This suggests that optimized gamification might be more effective than awarding the same number of points for each instance of the desired behavior. However, whether this interpretation is correct remains to be tested.

We illustrated the application of the general framework of optimized gamification to behavior change using a simple model of habit formation, which assumes that the user will indefinitely maintain the good habit once it has been established. This assumption is highly simplistic. In reality, maintenance is far from automatic. On the contrary, people may experience backsliding, and the strength of the habit may continue to wax and wane [64]. This could be captured by letting the process of deciding whether to perform the behavior continue indefinitely until the user dies. In this way, lapses could occur at any time and weaken the habit no matter how strong it is. In such a model, the health benefits of the behavior could be modeled explicitly in terms of its effects on a state variable that models the user's health status. Refining our method's model in this way would reduce the reinforcement for engaging in the behavior when the habit is weak and increase it when the habit is strong. This may make our method even more effective.

From an empirical perspective, the main limitation of the work presented in this paper is the relatively small sample size of our field experiment. Given that we collected <30 complete data sets per condition, the power of some of the statistical tests is relatively low. Therefore, the absence of significant differences in self-reported habit strength and retroactive intention enactment after the intervention does not provide strong evidence against the maintenance of the benefits of optimized gamification. Moreover, given that habit formation can take a very long time, our intervention may have been too short to fully capture the effects of the 3 different interventions on habit formation.

One flaw in our experiment was that some of the chatbot's messages were not worded in perfect, idiomatic English (Multimedia Appendix 2). We think that it is unlikely that our participants misunderstood any of the messages. However, it is possible that participants would have taken the messages more seriously if all of them had been written in perfect, idiomatic English. Another minor limitation of our chatbot is that its users started with a score of 0. Thus, if they failed to enact the desired behavior, their score fell to negative values, which might be demotivating. Therefore, future versions of our chatbot will award users a number of points (eg, 20) for setting the intention to build a good habit.

Finally, another weakness of our study design is that our intervention sought to strengthen water drinking in healthy people. Therefore, we cannot draw conclusions about the potential utility of our chatbot for clinical populations for which developing a healthy water-drinking habit might be crucial [3,4]. Moreover, it remains unclear whether our findings can be generalized to other habits that are more vital to people's health. In addition, our study was not specifically about water drinking as a weight loss strategy as only some participants tied water

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drinking to their meals. However, we introduced a general method that can be used to improve digital interventions for many critical behavior change applications.

Comparison With Prior Work

This study builds on previous work on optimized gamification [51]. Optimized gamification has been previously applied to help people decide what to work on [51] and which goals to set [52,55,56,65]. Moreover, optimized gamification has also been applied to help people stay focused on their work [58]. However, the work presented in this paper is the first application of optimized gamification to support habit formation. Moreover, it is one of the first real-world applications of optimized gamification as most previous work was confined to controlled laboratory experiments.

As our chatbot combined 4 established behavior change techniques (ie, goal setting, reminders, support for self-monitoring, and reinforcement), its design and effectiveness are therefore consistent with several extant theories of behavior change [66]. In particular, our optimized gamification method is consistent with behavior change methods that acknowledge the importance of providing positive feedback on improvements in behavior [28,66-69].

The most similar gamified digital intervention for behavior change that we are aware of is the SMS text messaging–based WalkIT intervention for promoting physical exercise [7,33,70]. Participants of the WalkIT trial received SMS text messages with daily physical exercise goals. Physical exercise (walking) was measured using the accelerometers of their smartphones and reported to a server. Participants received feedback on whether they met the exercise goal via an SMS text message that included points that were converted into money. Depending on the stage of the experiment, the number of points for achieving a goal was either constant or determined at random. The number of points awarded for failing to achieve a goal was 0. In contrast, our optimized gamification method provides a principled way to choose the exact number of points that a person should be awarded for meeting their daily goal or lose for failing to meet that goal. Therefore, our method could be used to enhance the WalkIT intervention with a more principled way of choosing the number of points depending on the user's history of successful and unsuccessful goal achievement. Conversely, WalkIT has many sophisticated features that go beyond the chatbot we introduced here. This includes an algorithm for adaptive goal setting, automatically delivered financial incentives, and an evidence-based sequence of different reward schedules that differ in the probability that goal achievement will be rewarded and whether the magnitude of the reward will be fixed or random. Consistent with our finding that the more performance-contingent feedback of the optimized gamification condition was more effective than less informative feedback or no feedback, the WalkIT studies found that immediate, behavior-contingent reinforcement was more effective in promoting behavior change than delayed, behavior-independent reinforcement.

Another gamified digital intervention for supporting behavior change is Habitica. Habitica embeds working through one's to-do list into a role-playing game in which the user's character can earn points by completing their daily to-dos. The points serve as an in-game currency that the player can use to buy weapons and armor for their avatar. Conversely, when the user does not complete a daily to-do, they lose points. As far as we can tell, the developers of Habitica chose the number of points the user gains for completing a to-do and the number of points they lose for failing to complete a daily to-do somewhat arbitrarily based on their intuitions. A recent study found that only 49% of Habitica's users rate its rewards as (rather) appropriate and that most experience counterproductive effects of Habitica's approach to gamification [17]. Given that optimized gamification was effective in our study and in previous studies, it is possible that redesigning Habitica's point system according to optimized gamification could alleviate some of the counterproductive effects of their users' experience.

The method introduced in this study mitigates the adverse effects of temporal discounting on people's health behavior [26]. Its approach is to add immediate rewards that are aligned with the behavior's long-term consequences for the user's health; that is, optimized gamification redesigns the decision environment so that people's shortsighted biases lead to decisions that are good for them in the long run [51]. Recent work on this topic introduced a computational model of intertemporal choice and applied it to compute personalized incentives for helping people more patiently work toward obtaining a larger reward later instead of abandoning the project in favor of a smaller immediate reward [71,72]. Similar to optimized gamification, their approach uses an MDP framework. However, their problem formulation and solution are different. The main difference lies in the application area. Sukumar et al [71] focused on canonical delay-of-gratification tasks, whereas we modeled habit formation. They tested their approach in online experiments in which participants played a *queue waiting game* and found that personalized incentives can increase people's patience while waiting in a simulated queue. In contrast, we conducted a field experiment on behavior change in which the incentives motivated people to act more farsightedly in the real world. Despite this critical difference, investigating whether modeling and measuring individual differences can be used to make optimized gamification more effective is an exciting direction for future work. Moreover, a computational model such as the one proposed by Sukumar et al [71] could be used to simulate the effects of alternative incentive schemes.

Previous work has found that drinking water before meals is an effective weight loss strategy for adults with obesity [3,4]. In the randomized controlled trial by Parretti et al [4], participants were instructed to use the water-drinking strategy in a face-to-face weight loss consultation. They did not receive any additional support in implementing this strategy. The chatbot we developed could be used to augment those weight loss consultations with a digital tool that helps people follow through on their resolutions. Alternatively, an appropriately adapted version of our chatbot could be used as a highly scalable, low-cost alternative to face-to-face weight loss consultations.

Conclusions

In conclusion, optimized gamification is a practically helpful theoretical principle for designing the point systems of (digital)

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behavior change tools and interventions. It can be implemented in just a few lines of code, and the point values can be computed instantaneously. It can be applied to improve or augment many existing (digital) behavior change interventions and can also be used to create new ones. Thus, optimized gamification can help tackle many challenging behavior change problems using scalable digital interventions. Testing whether, when, and how optimized gamification can make a positive difference in critical practical applications is an exciting direction for future research. A crucial next step will be to test our point system against simpler heuristic point systems for supporting behavior change. Moreover, our chatbot can be extended to support various health behaviors and other forms of positive behavior change.

Acknowledgments

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Data Availability

The data generated in this study, the R scripts used to analyze the data, and the MATLAB (MathWorks) implementation of the optimized gamification method are available on the project's Open Science Framework repository [73].

Authors' Contributions

FL conceived and designed the study, developed the optimized gamification method, and wrote the manuscript. PZC designed and implemented the Good Habit Bot and co-designed and conducted the field experiment. MP conducted the data analysis. VA supported PZC in designing and conducting the field experiment and in the design of the Good Habit Bot. MT contributed to the implementation of the Good Habit Bot.

Conflicts of Interest

None declared.

Multimedia Appendix 1
An optimal feedback method for accelerating positive behavior change.
[DOCX File , 16 KB - games_v12i1e43078_app1.docx]

Multimedia Appendix 2
Details about the Good Habit Bot.
[DOCX File , 17 KB - games_v12i1e43078_app2.docx]

Multimedia Appendix 3
Details about the statistical results and supplementary analyses.
[DOCX File , 122 KB - games_v12i1e43078_app3.docx]

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Abbreviations

MDP: Markov decision process
SRHI: Self-Report Habit Index

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Assessing the Importance of Content Versus Design for Successful Crowdfunding of Health Education Games: Online Survey Study

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Abstract

Background: Health education games make health-related tasks enjoyable and interactive, thereby encouraging user participation. Entrepreneurs and health educators can leverage online crowdfunding platforms, such as Kickstarter, to transform their innovative ideas into funded projects.

Objective: This research focuses on health education game initiatives on Kickstarter. Through an online user survey, it aims to understand user perceptions and evaluate the significance of 8 distinct components that may influence the success of such crowdfunding initiatives.

Methods: A total of 75 participants evaluated games using 8 dimensions: game rules, learning objectives, narrative, content organization, motivation, interactivity, skill building, and assessment and feedback. The survey data were analyzed using descriptive statistical analysis, exploratory factor analysis, the Wilcoxon-Mann-Whitney test, and multivariate analysis.

Results: Exploratory data analysis showed that, among the 8 dimensions, skill building, content organization, and interactivity were the top-ranking dimensions most closely associated with crowdfunding health education game. The 8 dimensions can be grouped into 3 categories from the exploratory factor analysis: game content–, instruction-, and game design–related components. Further statistical analysis confirmed the correlation between these dimensions with the successful crowdfunding of health education games.

Conclusions: This empirical analysis identified critical factors for game proposal design that can increase the likelihood of securing crowdfunding support.

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KEYWORDS

game-based learning; rubrics; Kickstarter; learning game campaign; collaboration; user perception; design; health; learning; gaming; game; evaluation; organization; user; engagement; skill; feedback; assessment; analysis; correlation; crowdfunding; support

Introduction

Background

Digital strategies, particularly gamification, have introduced a refreshing dynamic to health education [1,2]. Platforms, such as Kickstarter [3], champion these tech-infused health games, providing a unique avenue for their development. By leveraging the power of crowdfunding, Kickstarter and similar platforms facilitate the evolution of health education games. This allows entrepreneurs, educators, game developers, and supporters to access essential resources and connect with audiences eager for meaningful health support and intervention.

Gamification in Health

Gamification in health integrates game-design elements into nongame health scenarios, aiming to boost user engagement and immersion in health solutions. This transforms routine health tasks into enjoyable, competitive activities. This approach leads to positive behavioral changes, improving overall health, fitness, and adherence to medical treatments and programs [1,2,4,5]. Gamification has been applied to a wide range of medical fields, including health education, medical therapy, obesity, and mental health [1,2,4,5].

Health education games are interactive digital tools specifically designed to impart knowledge or skills related to health and wellness [1,2]. These games transform traditional health-related lessons into enjoyable and engaging tasks, aiming to enhance retention and application of health information in daily life [1,2,4]. Serious health games, created primarily for specific health objectives rather than solely for entertainment, use gaming components to create an educational environment [1,2]. They use gaming components to facilitate a teaching

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environment, enabling users to learn specific health skills or gain valuable health-related information [1,2]. Especially beneficial for long-term health and chronic-related applications, these games foster positive emotional or empathetic connections among users, leading to improved medical treatment plans and behavior changes [1,2,4].

The Role of Crowdfunding in Promoting Health Education Games

Given the modest initial investment required and the scale of crowdfunding, it is advocated that crowdfunding serves as a primary method to promote and support the development of health education games. With the recent success of platforms such as Kickstarter, researchers and health care advocates are turning to these tools to fund their projects [6,7]. Through crowdfunding, health educators, entrepreneurs, and other stakeholders can conduct their work to meet community needs while also achieving financial and community outreach goals. This method attracts a varied group of participants who contribute financially, participate in the development, and offer social support [8-12].

Health education games, similar to other game-based learning tools, motivate users by making health-related tasks more enjoyable [1,13]. Online crowdfunding can assist entrepreneurs and health educators with limited resources to translate their innovative ideas into solid and appealing content and formats [14,15]. Crowdfunding platforms help individuals transform ideas into fundable and actionable projects [16,17].

Crowdfunding for health education games benefits users' self-efficacy, well-being, chronic disease management, and physical activity [9-11]. Rewards, feedback, and socialization elements are frequently used to gamify eHealth in crowdfunding-based health education games. Furthermore, health education games can positively change their health behaviors, benefiting their overall health and wellness [2]. Successful health education crowdfunding projects elicit both intrinsic (altruistic) and extrinsic (rewards and feedback) motivation in order to attract a diverse range of crowdfunding donors, and they work by effortlessly facilitating online digital health engagement [18]. This study aims to explore 8 critical evaluation dimensions from the user's perspective that influence the success of crowdfunding campaigns for health education games. The findings will guide practitioners and entrepreneurs in strategizing and designing impactful crowdfunding campaigns for health education games.

Related Works

To understand the intricacies of successful crowdfunding for health education games, we performed a literature review to acquire insights on the various dimensions related to the subject. The literature review enabled us to systematically explore the dynamics of crowdfunding, the principles of game-based learning, and the factors that influence the success of health education games.

Dynamics and Success Factors of Crowdfunding Initiatives

To develop and promote content for successful crowdfunding campaigns, extensive planning, outreach, and marketing are required. Data suggest that the most popular crowdfunding projects are those that are creative, participatory, or consumable, such as games, technology, film and video, and art and design [19]. In general, crowdfunding projects have small funding sizes and offer various donor incentives, small gifts, or awards, which leads to a higher success rate for the projects [19]. Such success not only mirrors financial objectives but also nurtures the emergence of communities with shared interests [20]. Numerous game developers have used crowdfunding to fund the initial investment in educational applications [21]. This then encourages more entrepreneurs to participate in collaborative crowdfunding platforms and launch their projects.

Unlike a traditional purchase, crowdfunding involves a high level of social capital influence, particularly the status and reach on social network sites [17]. Social capital creates an online environment that combines collective knowledge, appeal, and emotional responses, enabling investors to make well-informed decisions [17]. This investment process shapes perception and investment behavior. The interaction mechanism has a broader and more pervasive contextual impact, and the crowdfunding campaign design and features also influence decisions [21].

Crowdfunding initiatives require both content richness and ownership diversity [22]. Several studies have explored strategies to optimize the success of such crowdfunding efforts [22,23]. Notably, during crowdfunding, potential investors often evaluate founders based on their personal communication skills and presentation, both of which influence investment decisions [24]. In addition, the use of specific language, the length of campaign text, the frequency of updates, and the inclusion of video in campaign texts have all been correlated with the success of crowdfunding campaigns [25,26]. Reducing the cognitive effort needed to understand campaign content has been shown to result in increased funding [15].

Researchers have also linked crowdfunding success to the trustworthiness and reputation of developers, as well as their experiences on social crowdfunding networks [27,28]. However, the quality of the presented information also plays an important role in determining crowdfunding success [9,29,30]. Factors that contribute to successful crowdfunding factors include the content of the campaign, audience participation, and the timing of fundraising development [31].

Health Education Game Development and User Experience

Gamification has been proven to enhance medication and treatment adherence among patients with chronic disease [4,32]. Health serious games, on the other hand, have been praised for their ability to help people with chronic illnesses improve their behavior [2,33]. These games mirror real-life challenges, allowing players to develop coping strategies [17]. They educate players about their condition and the necessary lifestyle alterations, with compelling storylines that ensure better engagement [15,17]. Game interactivity allows players to make

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decisions, learn from outcomes, and receive feedback on health implications [2,17].

When evaluating the feasibility of a game proposal, it is important to consider both the organization and narrative of the content, as well as the effectiveness of interactive games as a learning tool [34]. A well-organized and clearly written proposal can help the investor understand the purpose, goals, and potential value of the project [31]. Interactive health games can educate users with content and skills [34]. Users can also actively engage with the material, explore and experiment with different concepts and strategies, and receive immediate feedback on their progress [35]. This can help them understand and retain the content and skills being taught.

Game rules and interactivity stand as important components in health game design. Game rules ensure alignment with educational objectives, and the inherent challenge-reward system in these games drives players to continue, thereby continuously learning and adopting healthier behaviors [5,13]. Defining game rules or challenges and delivering feedback can increase users' self-concept, efficacy, knowledge skills, communication, and social support, resulting in better health behaviors for self-care and adherence, lowering health costs, and establishing a stronger health system [18].

Health education game users are drawn to characters that resemble them, experiencing validation when such characters are featured in media [36]. Young role models, especially those in media genres such as cartoons and video games, are particularly valued by these users [37]. For example, the motivation and design of the interactive health game series can focus on using positive role models to inspire and motivate players [37,38]. These role models are described as being successful in their adventures while also managing their health, which could help users, including children with chronic illnesses such as asthma or diabetes, feel more positive about their own abilities to manage their health and self-care [37,38].

Interestingly, health game players without specific medical conditions are often less certain about in-game decisions compared to their peers with those conditions [37]. Health education games allow players to try new things, fail, learn, and eventually win. Such games also motivate users to adopt a healthier lifestyle, adhere to medical advice when unwell, navigate life crises, and foster close social connections for support [39].

Regarding assessments and feedback mechanisms, health learners who receive personalized feedback and engage deeply with medical content tend to experience great benefit. This approach is especially effective in reaching younger individuals who might not typically consult other media or seek expert health advice [40]. Interactive health games not only foster communication and social support but also empower users to discuss their health with friends, family, and health care professionals. They also motivate users to actively seek out advice and support [37]. For instance, in a series of interactive health games, players accessed factual details about the causes, treatments, social contexts, and self-care options related to specific health topics [37].

Game-Based Learning Principles

One of the game-based learning principles that allows users to benefit from the game is the development of problem-solving skills [41], and educational games can assist users in developing these skills [41,42]. The modalities of game content representation should be adjusted to boost motivation and performance [43]. If learners cannot understand the app's content, no matter how rich and useful it is or how beautiful the design is, the app's entire instructional value is lost [44]. Learners can learn problem-solving, strategic and analytical thinking, decision-making, and other 21st century skills in narrative-centered learning environments [45].

Based on the constructivist learning theory, individuals gain deeper insights about the world through direct experiences and interactions [46,47]. Games offer a dynamic and interactive environment that aligns with this theory, enabling learners to actively explore, experiment, and tackle challenges [46,47]. The appeal of a game's narrative indicates its potential to captivate users [48]. The game creators should focus more on the content, storyline, and interaction components of the game to attract individual users when determining whether it will be successful or not [48].

The quality of a learning game is significantly influenced by the effectiveness of user feedback [49,50]. Numerous studies have shown that feedback enhances learning outcomes [51]. It provides learners with clarity on their strengths and areas that need improvement; it also serves as a motivational tool, encouraging continuous learning even within the gaming context [51].

Educational games can customize learning experiences by gauging a student's readiness, providing constructive feedback, and modifying the level of challenge [52]. It is essential for an educational game to have well-defined learning objectives that detail the desired skills and knowledge [53]. Game rules facilitate learning by allowing players to interact with their environment [54]. Achieving these objectives depends on adhering to specific rules, which may involve certain challenges or conditions that the learner must satisfy [43].

A learner's level of motivation can greatly influence their enthusiasm or indifference toward a task [55,56]. Moreover, there is substantial evidence suggesting that motivation enhances cognitive functions, particularly influencing what learners focus on and how they assimilate information [57-59].

Literature suggests that multiple factors influence the success of crowdfunding campaigns, especially those related to health education games [51,54]. These range from the trustworthiness of the developers and the quality of information presented to the design and content of the game itself. Although previous studies have shed light on the general principles of game-based learning and the dynamics of crowdfunding, there remains a gap in understanding how these principles specifically apply to health education games on platforms such as Kickstarter. Moreover, the user's perspective, which is crucial in determining the success of such campaigns, has not been thoroughly explored. We aim to bridge this knowledge gap by focusing on the user's perception and evaluating the critical components

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that resonate most with potential users, thereby influencing the success of health education game initiatives on crowdfunding platforms.

Objectives

This study aims to provide a comprehensive overview of 17 health education game projects launched on the crowdfunding platform Kickstarter and to understand user perceptions concerning the important factors that determine the success of such health education game crowdfunding initiatives. To achieve this, we conducted a user survey using a health education assessment rubric specifically designed to evaluate the key components contributing to the success of these projects on Kickstarter.

Methods

Data Collection for Health Education Games

A comprehensive keyword search using "Health, Education, Learning, Game" was conducted in August 2019 on Kickstarter, which identified 17 online health education game projects (Table 1). On the Kickstarter site, the system marked a project as "Successful" if it met or exceeded its financial goal within the time set by the creators. Conversely, projects that failed to meet their financial target within the designated period were labeled as "Unsuccessful" (Table 1).

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Table . Descriptive data of health education game projects from the crowdfunding site Kickstarter. A project's success on Kickstarter was determined by its ability to achieve its financial goal within the set time frame.

Health education game	Pledge (US $)	Goal (US $)	Backer count, n	Country	Successful[a]
Playout: The Exercise Card Game [60]	11,011	10,000	224	United States	Yes
ACLS MegaCode Simulator for health care professionals [61]	328	1997	8	Canada	No
Blush by Renaissance [62]	5065	3500	80	Canada	Yes
Body Cycle Health Education App [63]	1778	20,000	41	United States	No
CHiLD - a psychological 2D RPG [64]	1199	554	92	Norway	Yes
Destiny's Sword for mental health [65]	30,930	30,000	209	Canada	Yes
Facing Dragons: a mixed-reality game to unlock your purpose [66]	3361	7104	34	Canada	No
Freestyle Jam Camp [67]	1145	500	18	United States	Yes
Mobile games to quantify symptoms of mental health disorders [68]	127	450,000	5	United States	No
PRESCRIPTION Playing Cards [69]	30,420	7500	178	Canada	Yes
Talk to Me visual novel: mental health [70]	4977	4460	146	United States	Yes
TEN: a card game designed to promote brain health [71]	1445	14,000	39	United States	No
The Chakra Collectable Coin [72]	1682	1300	41	United States	Yes
The Woosah Kit: a mental health first aid [73]	41	6236	3	United Kingdom	No
Tournesol Kids Game: activity cards to build resilience [74]	10,435	5000	140	United States	Yes
Youth Run The World 5K [75]	7370	7000	74	United States	Yes
Zombied: gamify health and fitness activities [76]	12	37,217	2	United Kingdom	No

[a]"Yes" refers to "Successful" projects that met or exceeded their financial goal, whereas "No" refers to "Unsuccessful" projects that did not.

Ethical Considerations

Before commencing this study, the researchers obtained approval from the Institutional Review Board of the University of South Florida (001588). The participants provided informed consent, with the option to withdraw at any time without penalty. The Institutional Review Board approval sufficiently covered the secondary use of data. The study guaranteed that all collected data were either anonymized or deidentified to protect personal information, with stringent protective measures in place for any data that could not be fully anonymized. The study was voluntary, without any compensation for participation.

Online Survey Design

We use the Qualtrics online survey platform (Qualtrics) to create an online survey based on health education game assessment rubrics derived from the literature. This survey allowed participants to evaluate and rank crowdfunding health education

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games on the Kickstarter website. The survey incorporated 8 dimensions—each essential for the evaluation of health education games. These dimensions, along with their definitions and cited literature, are presented in Table 2.

Table . Crowdfunding health education game evaluation dimensions and definitions.

Dimensions	Definition	Related literature
Skill building	The game's ability to progressively impart and reinforce health-related skills to players, ensuring that learning is continuous and effective throughout the game's duration.	[42,77]
Content organization	The clarity, structure, and logical flow of the game's health education content, ensuring that it is presented in a manner that is both comprehensible and engaging for players.	[35,53,78]
Narrative	The clarity and continuity of the game's storyline in relation to health education, ensuring that players experience a coherent sense of progression and purpose as they navigate through the game's content.	[25,48]
Interactivity	The game's ability to facilitate effective interactions, the completion of health-related tasks, and active participation through user-driven inputs and actions.	[35,77,79]
Assessment and feedback	The game's capability to immediately evaluate and communicate a player's progression and provide timely and relevant feedback.	[35,80-82]
Game rules	The game provides clear, concise, and easily comprehensible rules to the players.	[35,52,83,84]
Learning objectives	The game delineates specific, measurable outcomes that players are anticipated to achieve upon its completion.	[35,85-87]
Motivation	The game's elements are intriguing and appealing enough to prompt user participation and action.	[88-90]

Before the main survey was launched, a pilot test of the survey instrument was conducted with 7 undergraduate students majoring in health science. This pilot test aimed to assess the validity and understandability of the survey questions. The participants were asked to read through the survey and provide feedback on its clarity and relevance. Based on their comments, necessary revisions were made to the questions to enhance the overall quality of the survey.

In the final version of the survey, participants rated the dimensions on a 3-point Likert scale. The scoring system for these dimensions ranged from 0 to 2, with the following interpretations: 0="Does not meet expectations" or "Poor," 1="Meets expectations" or "Fair," and 2="Exceeds expectations" or "Good." Participants could also select "Unable to decide" or "Not applicable" if they felt unable to make a judgment on a particular dimension. Additionally, an open-ended question was incorporated: "Do you have any comments or concerns (accuracy of terms, comprehensiveness, clarity of questions, etc) for this question sets?" This allowed participants to provide further feedback on the survey questions.

In November 2019, undergraduate students majoring in health science were invited to participate in the online survey. Those who agreed to participate were provided with a standardized set of questions, accompanied by comprehensive instructions and definitions for the 8 evaluation dimensions, as detailed in Table 2. Each student was then randomly assigned 1 specific crowdfunding health education game from a pool of 17 games, referenced in Table 1. Their task was to evaluate their assigned game based on these 8 dimensions. Ultimately, 75 undergraduate students were recruited as participants.

Data Analysis

We used STATA 15 software (StataCorp) for statistical analyses. We used several data analysis approaches to understand the results.

Descriptive Statistical Analysis

This method provides a summary of the main aspects of the data, offering a simple overview of the data. By calculating the percentage of ranking types and the mean scores of the dimensions, we can gain insights into the general behavior and preferences of the survey participants.

Exploratory Factor Analysis

Exploratory factor analysis is used to reduce the data's dimensionality and identify the underlying relationships between the measured variables [91]. It was used to group the 8 dimensions into meaningful categories, helping to decipher any latent structures within the data set. This ensured that we could identify which sets of dimensions tended to co-occur or were rated similarly by participants.

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Wilcoxon-Mann-Whitney Test

The Wilcoxon-Mann-Whitney test [92] is a nonparametric statistical hypothesis test used to compare 2 unrelated samples. This test was used to determine if there were any significant differences in the rankings given by participants to different game dimensions.

Multivariate Analysis

The aim of this study extends beyond merely understanding the dimensions. It also seeks to predict the success of crowdfunding health education games based on these dimensions. We used logistic regression with a binary variable—success of the crowdfunding project—for prediction [91]. This model can determine the odds of a game being successful based on the rankings of its dimensions, offering insights into which dimensions are the most influential predictors of success.

By using these methods, the study ensured a comprehensive analysis of the data—from understanding the basic patterns and deciphering underlying component structures to finally being able to predict the success of crowdfunding health education games based on their dimensions.

Results

A list of health education games launched on Kickstarter is presented in Table 1. This table enumerates 17 distinct health education games originating from various countries, namely the United States, Canada, Norway, and the United Kingdom. Some projects have exceeded their goals by a large margin, whereas others have fallen substantially short. The diversity of the sample provides a comprehensive foundation for our study. This diversity enabled an exploration into users' perceptions regarding educational game assessment rubrics. Such an investigation can discern potential factors that could influence the success trajectory of health education games on crowdfunding platforms such as Kickstarter.

Table 2 focuses on the various dimensions relevant to the design and evaluation of games. These dimensions were based on established literature, highlighting their credibility and validity. When assessing potential predictors of crowdfunding success based on feedback from 75 survey participants, certain dimensions stood out as being more important (Table 3).

Table . Ranking of the 8 assessed dimensions for crowdfunding health education games (n=75).

Dimensions	Score, mean (SD)[a]
Skill building	1.77 (0.54)
Content organization	1.7 (0.52)
Narrative	1.51 (0.69)
Interactivity	1.51 (0.75)
Assessment and feedback	1.49 (0.69)
Game rules	1.47 (0.71)
Learning objectives	1.39 (0.64)
Motivation	1.29 (0.59)

[a]Scoring system: 0="Poor," 1="Fair," and 2="Good."

Skill building was ranked first, followed by content organization and then narrative. Skill building holds the top rank due to its emphasis on continuous learning and engagement, ensuring that players progressively acquire and refine their skills throughout the game (Table 3). The importance of content organization is highlighted by its role in enhancing user experience; a well-organized game offers clear navigation, allowing players to immerse themselves fully (Table 3). Narrative further enhances the gaming experience by introducing an engaging storyline that lends context and purpose, enriching the gameplay. Interactivity is important for keeping players engaged. It gives them a sense of belonging and influence within the game world. Yet, intriguingly, motivation ranks the lowest among these dimensions, even though its presence ensures that games are compelling enough to retain players' interest and drive continuous participation (Table 3). Although skill building and content organization seem to be the areas where these games excel, motivation appears to be a challenging area for many developers.

To identify the assessment structure for campaign initiatives' quality reflected by 75 survey respondents' rankings, the study conducted an exploratory factor analysis using principal-components analysis as the extraction method and varimax with Kaiser normalization as the rotation method (Table 4). The cutoff size for criterion loadings was set to 0.45 [59]. Both the Bartlett (χ^2=68.26, P<.001) and measure of sampling adequacy (0.57) tests for the sample pointed to a significant level of correlation among the dimensions.

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Table . Factor components for the 8 dimensions in crowdfunding health education games. Principal-components analysis served as the extraction method, and varimax with Kaiser normalization served as the rotation method.

Dimensions	Component		
	1	2	3
Game rules	−0.050	−0.057	0.843[a]
Learning objectives	0.253	0.727[a]	−0.025
Narrative	0.181	0.629[a]	−0.335
Motivation	0.665[a]	0.102	−0.021
Interactivity	0.489	0.185	0.506[a]
Skill building	−0.136	0.727[a]	0.266
Assessment and feedback	0.883[a]	−0.036	−0.019
Content organization	0.490[a]	0.370	0.033

[a]Values above the cutoff size for criterion loadings (0.45).

The exploratory factor analysis indicated that these 8 dimensions can be grouped into 3 components: game content (content organization, motivation, and assessment and feedback), instruction (learning objectives, narrative, and skill building), and game design (game rules and interactivity; Table 4). The game content–related components suggests that a well-organized game with clear feedback mechanisms can effectively motivate players. The instruction-related components reflect the instructional journey of the player, from understanding the objectives and engaging with narrative to building skills. The game design–related components are fundamental to the gameplay experience, ensuring that players are not just passive observers but active participants.

To review the perception gaps among these dimensions for successful or unsuccessful crowdfunding campaigns, group-based comparison was conducted between these dimensional means. Table 5 showed the gaps between successful and unsuccessful games in dimension ratings. Among them, motivation, interactivity, game rules, and learning objectives demonstrated larger difference gaps in decreasing order, and these were followed by assessment and feedback, skill building, narrative, and content organization.

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Table . Wilcoxon-Mann-Whitney test of the 8 assessments based on successful or unsuccessful crowdfunding of health education games.

Dimensions and categories		Answers, n	Score, mean (SD)	*U* statistic	*P* value
Content organization				0.28	.78
	Success	53	1.68 (0.55)		
	Unsuccessful	15	1.67 (0.49)		
Interactivity				2.05	.04[a]
	Success	53	1.57 (0.72)		
	Unsuccessful	15	1.13 (0.83)		
Skill building				0.94	.35
	Success	53	1.79 (0.49)		
	Unsuccessful	15	1.60 (0.74)		
Learning objectives				2.03	.04[a]
	Success	51	1.43 (0.64)		
	Unsuccessful	15	1.07 (0.59)		
Narrative				.09	.37
	Success	53	1.53 (0.70)		
	Unsuccessful	14	1.36 (0.74)		
Motivation				2.91	.004[a]
	Success	53	1.38 (0.56)		
	Unsuccessful	15	0.87 (0.52)		
Game rules				2.14	.03[a]
	Success	53	1.55 (0.70)		
	Unsuccessful	15	1.13 (0.74)		
Assessment and feedback				1	.32
	Success	53	1.49 (0.64)		
	Unsuccessful	14	1.29 (0.73)		

[a]Significant level $P<.05$.

The Wilcoxon-Mann-Whitney test comparing distributions of successful and unsuccessful games showed that motivation (P=.004), game rules (P=.03), learning objectives (P=.04), and interactivity (P=.04) showed statistically significant difference among these 2 groups (Table 5). These dimensions showed clear distinctions between successful and unsuccessful games, suggesting that these dimensions might be crucial for the success of such games. On the other hand, dimensions such as content organization and skill building, while important, did not show a significant difference between the 2 categories of games. This could mean that both successful and unsuccessful games have well implemented these dimensions, but they might not be the distinguishing factors for success. The multivariate analysis showed that learning objectives and motivation were 2 significant dimensions associated with successful health education game crowdfunding campaigns (Table 6). This suggests that these 2 dimensions might be especially important for the success of health-related games.

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Table . Multivariate logistic regression predicting the success of the health educational games.

Dimensions	Odds ratio (95% CI)	*P* value
Game rules	3.24 (0.68-18.40)	.13
Learning objectives	3.55 (1.42-14.38)	.02[a]
Narrative	1.57 (0.37-6.61)	.54
Content organization	0.07 (0.01-1.55)	.09
Motivation	3.05 (1.46-9.36)	.03[a]
Interactivity	1.70 (0.46-6.22)	.42
Skill building	1.31 (0.21-8.18)	.77
Assessment and feedback	1.38 (0.21-8.88)	.73

[a]Significant level $P<.05$.

Figure 1 presents an empirical framework that outlines the key components underpinning the success of health education game crowdfunding. The model highlights the balance between foundational structural components, such as game rules and content organization, and experiential elements that enhance the player's immersion and engagement, such as motivation and narrative. A successful educational game should seamlessly integrate all these facets. This not only ensures the delivery of educational content but also fosters an environment where players are intrinsically driven to remain engaged and continue their learning journey within the game.

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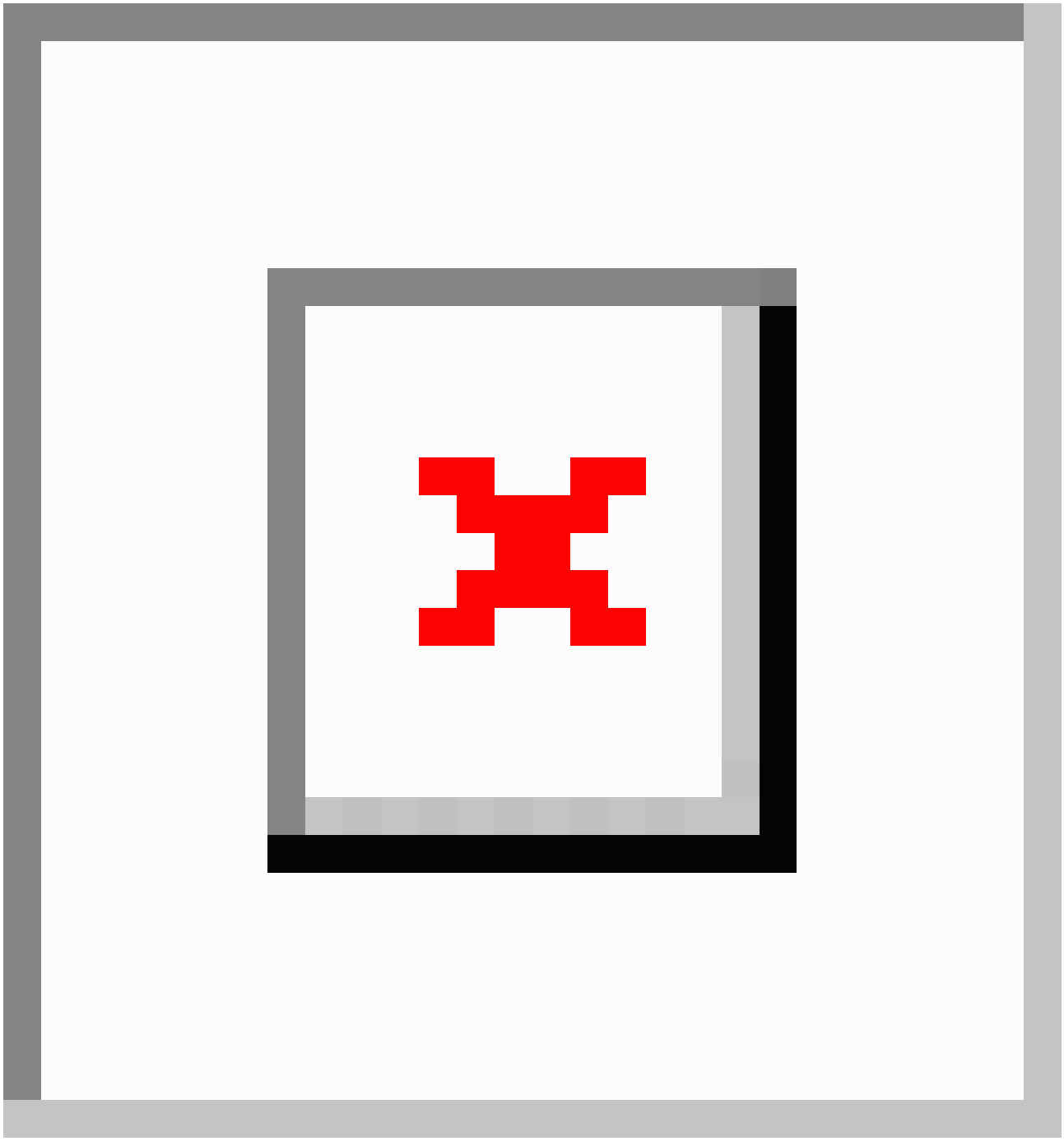
Figure 1. Framework for successful crowdfunding of health education games.



Discussion

Principal Findings

The crowdfunding landscape for health education games is diverse, with success determined by a myriad of factors beyond just a funding goal. Factors such as the clarity of the project's purpose, its presentation, and its marketing likely play a substantial role in attracting users [35,41]. It is also important to have a reasonable and attainable goal, as this might increase the likelihood of a project's success.

Crowdfunding backers, especially on platforms such as Kickstarter, often support projects that offer value beyond just entertainment. Skill building in games implies that players will acquire new abilities or knowledge, making them both fun and beneficial. This dual-purpose might appeal to game players who see an opportunity for a return on investment, not just in potential product rewards but also in personal or societal skill development.

The ranking of these dimensions sheds light on the preferences and priorities of both backers and players. It is possible that backers perceive tangible attributes such as skill building and content organization as immediate indicators of game quality and potential success. These elements can be readily demonstrated in promotional materials, making them more attractive to potential backers. On the other hand, motivation, being more abstract and subjective, might be harder to convey and measure, leading to its lower ranking. It is essential for

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game developers to recognize these perceptions and strike a balance in their design, ensuring a comprehensive and engaging game experience that appeals to a broad audience.

For skill building, it is essential for players to acquire and build skills as they progress in the game. This ensures continuous learning and engagement. Well-structured game content helps players navigate and understand the game better, thus enhancing their experience. An engaging storyline provides context and purpose, making gameplay more meaningful. Player interactivity is vital for player engagement. Players should feel that they are part of the game world and can influence it. Immediate feedback helps players understand their progression and areas of improvement. Clear rules ensure that players can easily understand how to play the games, leading to smoother game experiences. For health education games, it is important to have clear learning outcomes that guide the game design. The game must be engaging enough to keep players interested and motivated to continue.

The multivariate analysis identified learning objectives and motivation as the 2 significant predictors of a health education game's crowdfunding success, as detailed in Table 6. This indicates the emphasis users place on clear educational outcomes and the motivation to engage with the game. Users prioritize games that offer clear educational outcomes and that effectively motivate players to engage. The significance of learning objectives suggests that backers might prioritize games that have a clear educational goal, ensuring that players gain tangible knowledge or skills. Motivation, on the other hand, ensures that players remain engaged and committed to the game's objectives. When combined, these dimensions can lead to a game that not only educates but does so in a compelling manner, maximizing player retention and learning outcomes.

Limitations and Future Work

The study has some limitations due to the examination of user perception, which is based on a small number of user responses in a small number of crowdfunding campaigns. The study examined subjective opinions across 8 evaluation dimensions, but the reasons for crowdfunding's effectiveness in health education games require further investigation. In addition, we surveyed participants as potential backers. A more comprehensive approach would involve surveying actual backers, those who make real investments, to discern any differences in perceptions. This could provide a richer understanding of the dynamics at play. The impact of quality on the campaign content and media aspects, as well as user indicators of motivation and interactivity, was investigated in this study. Through crowdfunding, health education games improve engagements, learning components, and cultural adaptability for user engagement [8-10].

Conclusion

Crowdfunding for health education games presents a unique opportunity to bridge the gap between game developers and potential users. There has been little research that has provided empirical evidence for evaluating user perspectives on crowdfunding health education games. Further empirical evaluations are clearly beneficial to providing a rigorous validation of gamification's effectiveness in eHealth. This research conducted an exploratory study and identified 3 major components that matter for health game crowdfunding success. These components are related to game design, instruction, and game content. Interestingly, motivation and assessment and feedback were grouped into game content categories, not into game design categories. This indicates that the proposals for health-related crowdfunding education games are comprehensive, encompassing content that is engaging, interesting, and attractive, with solid assessment and feedback components. Among them, given the nature of health subjects, entrepreneurs and educators should pay more attention to game development factors such as motivation, interactivity, and game rules, so that the health or scientific subjects can be easily infused in the gaming process. Making health games look playful and attractive enables users to easily grasp basic health knowledge during the gaming process [93]. Interestingly, there is little difference in content organization between successful and unsuccessful games, which indicates that even if the game content is easy to follow, it is still not enough. Backers and potential funders or users mostly agree with the health content itself, but they care more about the game development components, using these dimensions to assess the crowdfunding game proposal and determine if these game designs are acceptable and make logical sense.

Our findings recognize the importance of aligning game design with user preferences. The success of health education games on crowdfunding platforms relies on a combination of clear educational objectives, effective player engagement mechanism, and well-structured game content. The study highlights the significance of learning objectives and motivation as key determinants of crowdfunding success for health education games. Game developers aiming for success in this domain should prioritize these dimensions, thus ensuring that their games offer a clear educational outcome.

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Conflicts of Interest

None declared.

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Original Paper

Psychometric Properties of the Metacognitions About Online Gaming Scale in the Chinese Population and Its Relationship With Internet Gaming Disorder: Cross-Sectional Study

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Abstract

Background: Metacognitions about online gaming have been shown to be correlated with Internet Gaming Disorder (IGD). Knowledge of metacognitions about online gaming can help to understand IGD. The Metacognitions about Online Gaming Scale (MOGS) is a reliable and valid tool to measure specific metacognitions about online gaming in both adults and adolescents, which is lacking in China.

Objective: This study was conducted to assess the psychometric properties of the Chinese version of the MOGS (C-MOGS) and its relationship with IGD in the Chinese population.

Methods: A total of 772 Chinese individuals (age: mean 21.70, SD 8.81 years; age range: 13-57 years; 458/772, 59.3% male) completed a web-based questionnaire survey, including the C-MOGS and a battery of validated scales measuring IGD, gaming motives, depression, and anxiety.

Results: Through exploratory and confirmatory factor analyses, the 3-factor structure was confirmed to have adequate model fit and internal consistency reliability (Cronbach $\alpha \geq .799$, Guttman split-half coefficients≥ 0.754). Concurrent validity of the C-MOGS was supported by its correlations with IGD ($P<.001$), gaming motives ($P<.001$), depression ($P<.001$), and anxiety ($P<.001$). Furthermore, the incremental validity analysis showed that the C-MOGS predicted 13% of the variance in IGD while controlling for gender, age, weekly gaming hours, gaming motives, depression, and anxiety.

Conclusions: This study provides evidence that the psychometric properties of the C-MOGS are appropriate and emphasizes its positive association with IGD. The C-MOGS is a reliable and valid instrument for mental health workers to assess metacognitions about online gaming in the Chinese population.

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KEYWORDS

metacognition; metacognitions about online gaming; Internet Gaming Disorder; psychometric properties; Chinese

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Introduction

Metacognition refers to the awareness of one's own thoughts and behaviors, as well as the ability to monitor and alter behavior. It encompasses any cognitive process that receives information from and exerts a controlling influence on another cognitive process [1-4]. More specifically, it comprises metacognitive knowledge and metacognitive regulation. Metacognitive knowledge refers to information and beliefs about one's cognitive processes, while metacognitive regulation pertains to skills to regulate thoughts, including planning, supervision, and regulation [5]. Metacognition contributes to effective decision-making across a variety of contexts [4]. For instance, it facilitates the smooth operation of ongoing thought and behavior by helping us recognize our errors [6], regulate the deployment of executive function [7], and detect lapses of attention [8]. Originating from cognitive psychology, metacognition has been linked to psychological disturbances [9,10].

In recent years, studies have highlighted the potential role of metacognitions in the development of addictive behaviors, such as problematic gaming behavior [11,12]. However, due to the lack of suitable research instruments, conducting further investigations in China has been challenging. To address this issue, this study aimed to evaluate the validity of the Metacognitions about Online Gaming Scale (MOGS) [13] among the Chinese population and its association with gaming behavior.

According to the self-regulatory executive function model, metacognitions play a critical role in the occurrence and development of psychological dysfunction [14]. In this model, psychological dysfunction is activated and perpetuated by a fixed thinking pattern called cognitive attentional syndrome (CAS), which comprises several maladaptive coping strategies (eg, rumination, threat-monitoring, and avoidance). The CAS is driven and maintained by maladaptive metacognitions [15]. Maladaptive metacognitions mistakenly regard the CAS as an effective coping style, resulting in a vicious cycle of ineffective self-regulation [16]. Over the last 40 years, metacognitions have been associated with several mental and psychological problems [17], such as obsessive-compulsive disorder, schizophrenia, addiction, anxiety, and depression [18-20].

In the domain of addictive behaviors, metacognitions are divided into 2 subtypes: positive and negative [21]. The former refers to the beliefs that engaging in specific addictive behaviors is a strategy of affective and cognitive self-regulation, such as "Drinking helps me think more clearly" and "Gambling can improve my mood" [22,23]. The latter refers to the concerns about the uncontrollability and danger of thoughts or engagement with addictive behaviors. For example, "Drinking will interfere with my thought" and "Once I start thinking about drinking, I cannot stop" [24]. Previous studies have shown that positive metacognitions can motivate addictive behaviors in the early stage, while negative metacognitions contribute to their perpetuation by activating negative emotional states as a reinforcement [11,21]. In recent years, metacognition has been correlated with many addictive behaviors, such as problematic alcohol use [25-27], nicotine dependence [28,29], gambling disorder [30-32], problematic Internet use [33-35], problematic social media use [36-38], and Internet Gaming Disorder (IGD; problematic online gaming) [39,40].

As an addictive behavior, IGD was first included in the research appendix section of the Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) in 2013 [41], then it was officially included in the addiction disease unit of the *Eleventh Revision of the International Classification of Diseases (ICD-11)* in 2018 [42]. Its core characteristics include losing control while gaming, prioritizing gaming over other interests, and causing functional damage in daily life. Excessive online gaming results in various problems, such as sacrificing real-life relationships, sleep, work, and education, leading to brain damage [43-46]. According to a recent review, the global prevalence of IGD was 3.05%, and it was higher among Asians (5.08%) than Europeans (2.72%) [47]. In China, the prevalence ranges from 3.5% to 17%, which is higher than the global average level [48-50].

In order to effectively prevent and treat this disorder, extensive research has been conducted to investigate its etiology. These studies have revealed a significant association between IGD and various psychological factors, including negative affect, gaming motives, and maladaptive cognition [51]. The Interaction of Person-Affect-Cognition-Execution (I-PACE) model proposed by Brand et al [52,53] suggests that the initiation of addictive behaviors arise from the integration of emotional and cognitive responses to internal or external stimuli along with specific motivations. Motives are sets of knowledge that represent the emotional preferences expressed in our thoughts and concepts. Gaming motives could be considered as stimulating factors of gaming behavior, which may play an important role in the development of IGD [51]. Furthermore, Spada et al [21] posited that the development and persistence of addictive behaviors, including IGD, are strongly influenced by particular metacognitions about addictive behaviors.

According to previous studies, metacognitions have been associated with IGD [38,39]. However, these studies mainly focused on generic metacognitions (eg, beliefs about worry, cognitive monitoring, the need for thought suppression). To assess specific metacognitions about online gaming, Spada and Caselli [13] developed a self-rating instrument called the Metacognitions about Online Gaming Scale (MOGS). In the original validation of the MOGS, an exploratory factor analysis (EFA) was performed with 225 adults in Study 1 that suggested a 2-factor solution: Negative Metacognitions about Online Gaming (N-MOG; 6 items) and Positive Metacognitions about Online Gaming (P-MOG; 6 items) [13]. The N-MOG assesses negative metacognitions about the uncontrollability and danger of thoughts on gaming. The P-MOG measures positive metacognitions in which online gaming helps individuals regulate affect and thought. In Study 2, the confirmatory factor analysis (CFA) with another sample of 348 individuals further divided N-MOG into 2 factors and built a 3-factor structure: Negative Metacognitions about the Uncontrollability of Online Gaming (N-MOGU), Negative Metacognitions about the Dangers of Online Gaming (N-MOGD), and P-MOG [13]. All 3 factors reported adequate internal reliability (Cronbach $\alpha \geq .79$).

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While exploring predictive validity, the study showed that MOGS was positively related to gaming hours and Internet addiction [13]. Overall, these findings demonstrated the reliability and validity of the MOGS.

To extend the utility of the MOGS to adolescent populations from other countries, Akbari et al [54] translated it into Persian and evaluated its psychometric properties among 769 Iranian adolescents. The results showed that the 3-factor structure had appropriate construct validity and internal consistency (Cronbach α≥.79). Furthermore, metacognitions about online gaming were able to independently predict problematic gaming behavior while controlling for personality traits, gaming motives, gaming-related cognitions, and negative affect [54]. Another study investigating the association between IGD and social anxiety reported that metacognitions about online gaming were significantly correlated with IGD and mediated the latter's relationship with social anxiety [55].

These studies indicated an association between specific metacognitions about online gaming and IGD. Further exploration could be beneficial for the treatment and prevention of IGD, especially in countries with a higher prevalence, such as China. However, it is difficult to conduct relevant research in China because of the lack of instruments used to evaluate specific metacognitions. Therefore, the primary objective of this study was to translate the MOGS into Chinese and validate its psychometric properties among Chinese adolescent and adult gamers using online convenience sampling. Additionally, the study aimed to investigate the unique influence of metacognitions about online gaming on IGD while considering variables such as anxiety, depression, and motivation. The hypothesis was that, within the Chinese population, positive and negative metacognitions about online gaming would serve as independent risk factors for IGD, distinct from other contributing factors.

Methods

Participants

We recruited all individuals online through convenience sampling in June 2021. The inclusion criteria were as follows: (1) age ≥13 years, (2) Chinese speakers who could understand the questionnaires, (3) consent to participate (adolescents with parental consent), and (4) played games at least one hour every week (excluding online gambling) in the last 12 months.

In total, 996 individuals participated in this survey. We excluded 88 individuals whose answer was "No" to the item "Are your answers to this questionnaire true and reliable?", 37 who gave the same answers to more than 50% of the questions and whose time spent on the questionnaire was less than the mean minus 3 SD, and 99 who were younger than 13 years old. The final sample included 772 participants.

Ethical Considerations

Before starting the anonymous online investigation, participants were informed about the purpose and rights of the study and signed an online informed consent form. Those younger than 18 years needed to inform their guardians and obtain consent before filling out the questionnaire. The ethics committee of the Second Xiangya Hospital of Central South University approved this study (protocol code 2020004; dated March 1, 2020).

Measures

Basic Information

Basic information included sociodemographic information and Internet gaming characteristics. The former included gender, age, employment, years of education, and family structure (eg, single-child family). For the latter, participants reported their average time spent gaming (weekly gaming hours), gaming devices (a multiple-choice question), the number of long-term gaming partners, and self-evaluation of gaming addiction.

Metacognitions About Online Gaming

Metacognitions about online gaming were measured using the MOGS [13], which contains 12 items rated on a 4-point Likert scale (1=Do not agree to 4=Agree very much). The MOGS comprises the following 3 factors: (1) N-MOGU (3 items, such as "Once I start online gaming I cannot stop"), (2) N-MOGD (3 items, such as "Online gaming makes me lose control"), and (3) P-MOG (6 items, such as "Online gaming stops me from worrying"). A higher score indicates a higher degree of specific metacognition about online gaming.

IGD Symptoms

The severity of IGD symptoms was assessed using the Internet Gaming Disorder Scale-Short Form (IGDS9-SF) [56,57]. The IGDS9-SF is a 9-item scale developed from the core symptoms of IGD proposed by the DSM-5 and assesses gaming activities and their adverse effects in the past 12 months. All items are rated on a 5-point Likert scale (1=never to 5=very often). The scores range from 9 to 45. Higher scores represent more severe IGD symptoms. With adequate reliability (Cronbach α≥.9), the Chinese version of the IGDS9-SF was used in our research [58,59]. The Cronbach α was .90 in this study.

Gaming Motives

We assessed gaming motives using the Motives for Online Gaming Questionnaire (MOGQ) [60]. It includes 27 items comprising the following 7 motivational dimensions (all rated on a 4-point Likert scale): escape, skill development, recreation, competition, coping, fantasy, and social. The Chinese version of the MOGQ has excellent reliability (Cronbach α≥.83) and validity [61]. Higher scores reflect stronger motives for online gaming. In this study, the Cronbach α was .95 for the total scale and ranged from 0.84 to 0.89 for each subscale.

Depression and Anxiety

The Patient Health Questionnaire-9 (PHQ-9) [62] was used to measure depressive symptoms. It is a diagnostic screening tool that monitors the severity of depression over the last 2 weeks. All items are scored on a 4-point Likert scale (0=Not at all to 3=Nearly every day). The scores range from 0 to 27. Higher scores denote worse depressive symptoms. The Chinese version of the PHQ-9 [63] has suitable reliability (Cronbach α=.85). The Cronbach α was .89 for this study.

The Generalized Anxiety Disorder-7 (GAD-7) [64] was used to measure anxiety symptoms. It is a self-rated scale that

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assesses the severity of anxiety symptoms over the last 2 weeks. All items are scored on a 4-point Likert scale (0=Not at all to 3=Nearly every day). The scores range from 0 to 21. Higher scores represent worse anxiety symptoms. The Chinese version of the GAD-7 [65] was used, with appropriate internal consistency (Cronbach α=.90) and validity. The Cronbach α was .92 for this study.

Procedures

The MOGS was translated into Chinese by 2 professional translators using a standard translation and back-translation method [66]. For some controversial items (eg, "Online gaming makes me lose control," "Online gaming makes my worries more bearable"), we consulted the author of the original scale. Considering the original scale, 2 bilingual psychologists revised the translated version and checked its face validity. A pilot study was conducted with 5 adults and 5 adolescents to test the understandability. Based on their feedback, some descriptions of items were modified, and the final Chinese version of the MOGS (C-MOGS) was created.

We conducted this survey online using Questionnaire Star, a professional online survey platform. By reading recruitment advertisements posted on social networking sites (eg, WeChat, Weibo, and other webcast platforms), individuals could open the questionnaire link. On the first page, participants could read the objectives and content of this research and confirm their participation (minors, those younger than 18 years, had to obtain the consent of their guardian). Each IP address can only be used once to avoid repeated participation. After the questionnaire was submitted, all the data were sent to the researcher's account, and only the researcher could view the data.

Data Analyses

Data analyses were conducted using SPSS version 25.0 (IBM Corp) and AMOS version 24.0 (IBM Corp). First, basic statistical analyses (eg, descriptive analysis, independent samples *t* tests, chi-square tests) were performed on sociodemographic variables and Internet gaming characteristics. To analyze the construct of the C-MOGS, the total sample was randomly split into 2 subsamples. Sample-1 (n1=390; 229/390, 58.7% male; age: mean 22.25, SD 9.05 years) was used for EFA, and sample-2 (n2=382; 229/382, 59.9% male; age: mean 21.14, SD 8.52 years) was used for CFA. Except for EFA and CFA, all analyses were conducted on data from the entire sample. Independent samples *t* tests and chi-square tests showed that there were no significant differences between the 2 subsamples regarding age (t_{770}=–1.754, *P*=.08), gender (χ^2_1=0.121, *P*=.73), average weekly gaming time (t_{770}=0.775, *P*=.44), gaming devices (χ^2_1<1.012, *P*=.31), long-term gaming partner (χ^2_3=4.046, *P*=.26), and other demographic variables (*P*=.33-.88). An EFA with principal component analysis (PCA) and varimax-rotation method was conducted on the C-MOGS items. To validate the models derived from the EFA, a CFA was completed with AMOS 24.0 using the maximum likelihood method. The model fit was appraised using multiple fit indexes, including chi-squared:degree of freedom ratio (χ^2/df<5), goodness-of-fit index (GFI>0.90), Tucker-Lewis Index (TLI>0.90), comparative fit index (CFI>0.90), standardized root of the mean square residual (SRMR<0.08), root mean square error of approximation (<0.05=close fit; <0.08=acceptable fit; <0.1=mediocre fit) [67]. The reliability of the C-MOGS was examined by assessing the internal consistency of the scale and subscale. Acceptable values for the Cronbach α and Guttman split-half coefficients are >0.70, while values >0.80 are considered good [68]. Finally, to test the concurrent and incremental validity, correlation analyses and hierarchical multiple regression analyses were conducted between the C-MOGS and Internet gaming characteristics (gaming time, IGD, gaming motives) as well as anxiety and depression.

Results

Sample Characteristics

In this study, analysis was conducted on data from 772 participants (458 men, 59.3%) aged between 13 years and 57 years (age: mean 21.70, SD 8.81 years; participants aged 13-17 years: 281/772, 36.4%). The majority of them were students (555/772, 71.9%). Smartphones were the most popular device for gaming (705/772, 91.3%). Of the sample, 69.4% (536/772) had one or more long-term gaming partners. Participants spent an average of 13.43 (SD 10.88) hours every week playing games. More details on the sample characteristics are shown in Table 1.

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Table 1. Sociodemographic and Internet gaming characteristics of the sample (n=772).

Characteristic	Participants' results
Gender, n (%)	
Male	458 (59.3)
Female	314 (40.7)
Age (years), mean (SD)	21.70 (8.81)
Employment , n (%)	
Student	555 (71.9)
Full-time employee	186 (24.1)
Part-time employee	13 (1.7)
Unemployed	18 (2.3)
Length of education (years), n (%)	
≤12	339 (43.9)
>12	433 (56.1)
Single child, n (%)	
Yes	289 (37.4)
No	483 (62.6)
Gaming devices, n (%)	
Smartphone	705 (91.3)
Computer	278 (36.1)
Tablet	125 (16.2)
Game console	51 (6.6)
Long-term gaming partners, n (%)	
None	236 (30.6)
≥1 and <3	198 (25.6)
≥3 and <6	159 (20.6)
≥6	179 (23.2)
Self-evaluation of gaming addiction, n (%)	
Yes	129 (16.7)
No idea	203 (26.3)
No	440 (57.0)
Weekly gaming time (hours), mean (SD)	13.43 (10.88)

Factorial Structure of the C-MOGS

EFA

To identify the potential factorial structure of the C-MOGS, an EFA was performed on data from sample-1 (n=390). First, we used the Kaiser-Meyer-Olkin (KMO) and Bartlett tests of sphericity to ensure that the sample was suitable for EFA. The KMO value was 0.894, and the Bartlett test of sphericity was significant (χ^2_{66}=3159.742, P<.001), confirming the data were sufficient.

The initial analysis extracted 2 factors using the criteria of an eigenvalue>1 and factor loading>0.40. The 2-factor solution (eigenvalues of 5.573 and 2.597) accounted for 68.08% of the total variance, and the loading of all the items was >0.4 (0.646-0.918; Table 2). Factor 1 included items 1 through 6, referred to as the N-MOG; factor 2 included items 7 through 12, which described the P-MOG.

Additionally, according to the dimension of the original scale [13], we also conducted a PCA by setting 3 factors to be extracted. The 3-factor solution (eigenvalues of 5.573, 2.597, and 0.797) explained 74.73% of the total variance (37.44%, 19.31%, and 17.98%, respectively). Item-factor loadings are presented in Table 2. The factors were as follows: factor 1 (items 1, 2, and 3) referred to the N-MOGU; factor 2 (items 4, 5, and 6) was related to the N-MOGD; and factor 3 (items 7, 8, 9, 10, 11, and 12) was related to the P-MOG [54].

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Table 2. Item-factor loadings of the Chinese version of the Metacognitions about Online Gaming Scale (C-MOGS) based on exploratory factor analyses (sample-1, n=390).

Items	2-factor model			3-factor model			
	F1[a,b]	F2[b,c]	Communality	F1[b,d]	F2[b,e]	F3[b,c]	Communality
(1) I continue to play despite I think it would be better to stop	0.646	0.215	0.463	0.809	0.110	0.178	0.698
(2) I have no control over how much time I play	0.830	0.177	0.721	0.808	0.370	0.151	0.813
(3) Once I start online gaming, I cannot stop	0.808	0.178	0.684	0.743	0.403	0.157	0.739
(4) Online gaming makes me lose control	0.746	0.108	0.569	0.213	0.840	0.134	0.768
(5) Thoughts about online gaming interfere with my functioning	0.743	0.007	0.552	0.222	0.825	0.032	0.731
(6) Thoughts about online gaming are becoming an obsession	0.776	0.165	0.630	0.474	0.624	0.169	0.643
(7) Online gaming makes my worries more bearable	0.275	0.734	0.614	0.190	0.204	0.735	0.618
(8) Online gaming reduces my negative feelings	0.131	0.882	0.796	0.087	0.104	0.885	0.801
(9) Online gaming helps me to control my negative thoughts	0.093	0.918	0.852	0.125	0.014	0.915	0.852
(10) Online gaming stops me from worrying	0.116	0.849	0.734	0.083	0.087	0.850	0.737
(11) Online gaming reduces my anxious feelings	0.107	0.917	0.853	0.081	0.076	0.919	0.856
(12) Online gaming distracts my mind from problems	0.222	0.808	0.703	0.256	0.064	0.800	0.710

[a]Negative Metacognitions about Online Gaming (N-MOG).

[b]Factor loadings present the factor matrix values.

[c]Positive Metacognitions about Online Gaming (P-MOG).

[d]Negative Metacognitions about the Uncontrollability of Online Gaming (N-MOGU).

[e]Negative Metacognitions about the Dangers of Online Gaming (N-MOGD).

Confirmatory Factor Analysis

To further evaluate the structural validity of the C-MOGS, we conducted a CFA on sample-2 (n=382) using AMOS 25.0. We compared the goodness of model fit between the 2 aforementioned models. We first tested the 2-factor model, which had a substandard fit in some indexes: χ^2/df=3.962 and root mean squared error of approximation (RMSEA)=0.880. In comparison, the 3-factor model showed an adequate model fit: χ^2/df=3.477, GFI=0.929, CFI=0.958, TLI=0.945, SRMR=0.065, RMSEA=0.081 (Table 3). The correlations between P-MOG, N-MOGU, and N-MOGD were moderate (r=0.389 and 0.377, respectively) and were relatively strong between N-MOGU and N-MOGD (r=0.905).

Due to the high correlation between the 2 negative metacognitive factors, we also created a bifactor model (Figure 1), in which N-MOGU and N-MOGD loaded on a second-order factor (N-MOG) and P-MOG was a first-order factor. In this model, the goodness of model fit was the same as that of the 3-factor model (Table 3), and the correlation between N-MOG and P-MOG was moderate (r=0.396).

Table 3. Model fit indices of the confirmatory factor analyses for the Chinese version of the Metacognitions about Online Gaming Scale (C-MOGS; Sample 2, n=382).

Model	χ^2 (df)	χ^2/df	GFI[a]	CFI[b]	TLI[c]	SRMR[d]	RMSEA[e]
2-factor model	205.517 (52)	3.962	0.917	0.948	0.935	0.067	0.880
3-factor model	173.867 (50)	3.477	0.929	0.958	0.945	0.065	0.810
Bifactor model	173.867 (50)	3.477	0.929	0.958	0.945	0.065	0.810

[a]GFI: goodness-of-fit index.

[b]CFI: comparative fit index.

[c]TLI: Tucker-Lewis Index.

[d]SRMR: standardized root of the mean square residual.

[e]RMSEA: root mean square error of approximation.

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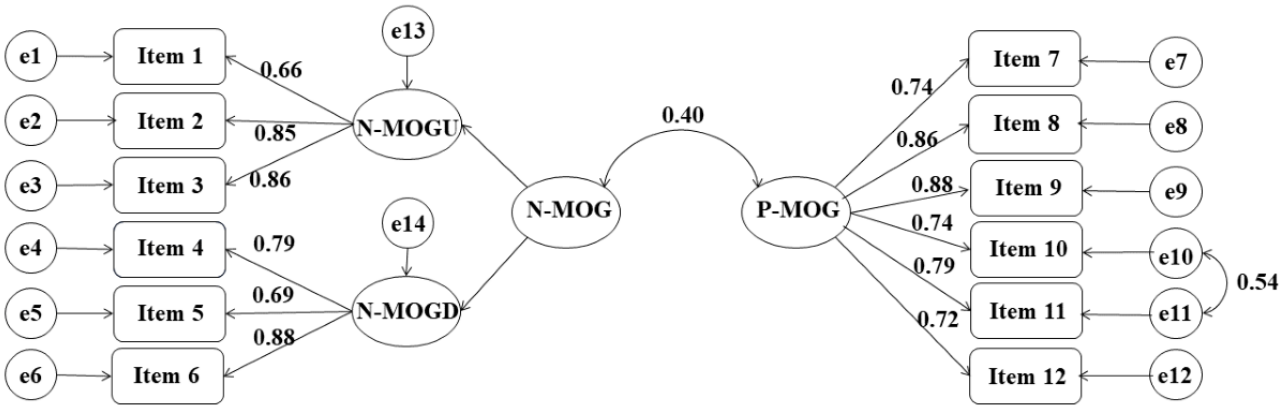
Figure 1. The bifactor model of the Chinese version of the Metacognitions about Online Gaming Scale (C-MOGS), showing the latent factors as ovals, the 12 items in the C-MOGS as rectangles, the error terms (e1-e14) as circles, and the standardized factor loading above the arrows. N-MOG: Negative Metacognitions about Online Gaming; N-MOGD: Negative Metacognitions about the Dangers of Online Gaming; N-MOGU: Negative Metacognitions about the Uncontrollability of Online Gaming; P-MOG: Positive Metacognitions about Online Gaming.



Reliability

The Cronbach α coefficient and split-half reliability were calculated for the scale and its subscales in the total sample (n=772). The α coefficient for the total scale was .894, and it was .823 for the N-MOGU, .799 for the N-MOGD, and .925 for the P-MOG. No item deletion improved the internal consistency. The Guttman split-half coefficient of the overall scale was 0.942, and for each dimension, the coefficients were 0.776, 0.754, and 0.841. These findings confirmed that the C-MOGS and its subscales exhibit adequate internal consistency.

Moreover, we calculated the correlation coefficient between each item and its relative factor scores. The results showed that the item-total correlations for all items were high (r≥0.551).

Concurrent Validity

We further analyzed the correlation between the 3 factors of the C-MOGS and IGD, gaming motives, anxiety, and depression to test the concurrent validity. Based on the Shapiro-Wilk test, these variables did not follow a normal distribution (all *Ps*<.05). Therefore, Spearman correlation analysis was chosen to explore the relationships between the variables. Table 4 shows the descriptive statistics (median and IQR), and Table 5 shows the correlations between the variables. Each factor of the C-MOGS showed positive correlations with the IGDS9-SF, weekly gaming hours, every dimension of the MOGQ, the PHQ-9, and the GAD-7 (r=0.153 to 0.759, all *Ps*<.01). Moreover, the correlation matrix showed positive correlations between the IGDS9-SF and the other variables (r=0.352 to 0.700, all *Ps*<.01).

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Table 4. Descriptive statistics for the variables (n=772).

Variables	Median (IQR)	Range
IGDS9-SF[a]	17 (10)	9-45
WGH[b]	9 (11)	1-69
Motives for Online Gaming Questionnaire (MOGQ)		
Social	7 (6)	4-20
Escape	7 (5)	4-20
Competition	7 (6)	4-20
Coping	9 (6)	4-20
Skill	7 (6)	4-20
Fantasy	6 (5)	4-20
Recreation	9 (6)	3-15
PHQ-9[c]	6 (7)	0-27
GAD-7[d]	4 (6)	0-21
N-MOGU[e]	4 (3)	3-12
N-MOGD[f]	4 (2)	3-12
P-MOG[g]	11 (7)	6-24

[a]IGDS9-SF: Internet Gaming Disorder Scale-Short Form.
[b]WGH: weekly gaming hours (average time).
[c]PHQ-9: Patient Health Questionnaire-9.
[d]GAD-7: Generalized Anxiety Disorder-7.
[e]N-MOGU: Metacognitions about the Uncontrollability of Online Gaming.
[f]N-MOGD: Negative Metacognitions about the Dangers of Online Gaming.
[g]P-MOG: Positive Metacognitions about Online Gaming.

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Table 5. Spearman correlation coefficients among the variables (n=772).

Variables	IGDS9-SF[a]	WGH[b]	MOGQ[c]							PHQ-9[d]	GAD-7[e]	N-MOGU[f]	N-MOGD[g]	P-MOG[h]
			Social	Escape	Competition	Coping	Skill	Fantasy	Recreation					
IGDS9-SF														
Correlation	1	0.501	0.352	0.589	0.494	0.542	0.380	0.488	0.416	0.466	0.420	0.700	0.587	0.511
P value	—[i]	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
WGH														
Correlation	0.501	1	0.196	0.326	0.288	0.353	0.190	0.290	0.386	0.253	0.193	0.364	0.280	0.312
P value	<.001	—	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
MOGQ: Social														
Correlation	0.352	0.196	1	0.473	0.521	0.544	0.606	0.523	0.378	0.108	0.118	0.246	0.174	0.398
P value	<.001	<.001	—	<.001	<.001	<.001	<.001	<.001	<.001	.003	.001	<.001	<.001	<.001
MOGQ: Escape														
Correlation	0.589	0.326	0.473	1	0.503	0.786	0.563	0.658	0.458	0.412	0.412	0.435	0.352	0.674
P value	<.001	<.001	<.001	—	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
MOGQ: Competition														
Correlation	0.494	0.288	0.521	0.503	1	0.544	0.615	0.552	0.467	0.188	0.196	0.372	0.316	0.412
P value	<.001	<.001	<.001	<.001	—	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
MOGQ: Coping														
Correlation	0.542	0.353	0.544	0.786	0.544	1	0.684	0.636	0.617	0.284	0.297	0.396	0.245	0.759
P value	<.001	<.001	<.001	<.001	<.001	—	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
MOGQ: Skill														
Correlation	0.380	0.190	0.606	0.563	0.615	0.684	1	0.589	0.403	0.121	0.151	0.249	0.153	0.531
P value	<.001	<.001	<.001	<.001	<.001	<.001	—	<.001	<.001	.001	<.001	<.001	<.001	<.001
MOGQ: Fantasy														
Correlation	0.488	0.290	0.523	0.658	0.552	0.636	0.589	1	0.442	0.289	0.295	0.370	0.322	0.476
P value	<.001	<.001	<.001	<.001	<.001	<.001	<.001	—	<.001	<.001	<.001	<.001	<.001	<.001
MOGQ: Recreation														
Correlation	0.416	0.386	0.378	0.458	0.467	0.617	0.403	0.442	1	0.234	0.226	0.348	0.157	0.430
P value	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	—	<.001	<.001	<.001	<.001	<.001
PHQ-9														
Correlation	0.466	0.253	0.108	0.412	0.188	0.284	0.121	0.289	0.234	1	0.789	0.411	0.411	0.270
P value	<.001	<.001	.003	<.001	<.001	<.001	.001	<.001	<.001	—	<.001	<.001	<.001	<.001
GAD-7														
Correlation	0.420	0.193	0.118	0.412	0.196	0.297	0.151	0.295	0.226	0.789	1	0.383	0.376	0.280

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Variables	IGDS9-SF[a]	WGH[b]	MOGQ[c]							PHQ-9[d]	GAD-7[e]	N-MOGU[f]	N-MOGD[g]	P-MOG[h]
			Social	Escape	Competition	Coping	Skill	Fantasy	Recreation					
P value	<.001	<.001	.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	—	<.001	<.001	<.001
N-MOGU														
Correlation	0.700	0.364	0.246	0.435	0.372	0.396	0.249	0.370	0.348	0.411	0.383	1	0.530	0.359
P value	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	—	<.001	<.001
N-MOGD														
Correlation	0.587	0.280	0.174	0.352	0.316	0.245	0.153	0.322	0.157	0.411	0.376	0.530	1	0.257
P value	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	—	<.001
P-MOG														
Correlation	0.511	0.312	0.398	0.674	0.412	0.759	0.531	0.476	0.430	0.270	0.280	0.359	0.257	1
P value	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	—

[a]IGDS9-SF: Internet Gaming Disorder Scale-Short Form.

[b]WGH: weekly gaming hours (average time).

[c]Motives for Online Gaming Questionnaire.

[d]PHQ-9: Patient Health Questionnaire-9.

[e]GAD-7: Generalized Anxiety Disorder-7.

[f]N-MOGU: Metacognitions about the Uncontrollability of Online Gaming.

[g]N-MOGD: Negative Metacognitions about the Dangers of Online Gaming.

[h]P-MOG: Positive Metacognitions about Online Gaming.

[i]Not applicable.

Incremental Validity

We conducted a hierarchical multiple linear regression analysis to identify the incremental effect of metacognitions about online gaming on IGD. The IGDS9-SF was the outcome variable, and the 3 factors of the C-MOGS were predictor variables, along with other variables related to the IGDS9-SF (gender, weekly gaming hours, the 7 factors of the MOGQ, and the total PHQ-9 and GAD-7 scores). Each variable was input in the following order: step 1: age and gender (0=female, 1=male); step 2: weekly gaming hours; step 3: the 7 factors of the MOGQ; step 4: GAD-7, PHQ-9; step 5: the 3 dimensions of the C-MOGS.

The Durbin-Watson statistic showed that the observed values were independent of each other (D-W=2.077). All tolerance values were above 0.1 (0.180-0.878), indicating no multicollinearity. The results are presented in Table 6. The 3 factors of the C-MOGS accounted for 13.0% of the variance in the IGDS9-SF (P<.001). In step 5, the final model indicated that gender, weekly gaming hours, the PHQ-9 score, the MOGQ-Escape score, the MOGQ-Competition score, and the factors of the C-MOGS were significant positive predictors of the IGDS9-SF (R^2=0.729, P<.001, adjusted R^2=0.724), and the most important predictor was the N-MOGU (β=0.326, P<.001).

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Table 6. Hierarchical multiple regression analyses with the Internet Gaming Disorder Scale-Short Form (IGDS9-SF) as the outcome variable and the Chinese version of the Metacognitions about Online Gaming Scale (C-MOGS) factors as predictor variables, together with gender, weekly gaming hours, motives related to online gaming, depression, and anxiety (n=772).

Variable	Step 1[a]			Step 2[b]			Step 3[c]			Step 4[d]			Step 5[e]		
	β	T	*P* value	β	T	*P* value	β	T	*P* value	β	T	*P* value	β	T	*P* value
Age	–0.056	–1.551	.12	–0.110	–3.633	<.001	–0.068	–2.640	.008	–0.050	–2.044	.04	0.004	0.206	.84
Gender	0.204	5.694	<.001	0.110	3.603	<.001	0.084	3.170	.002	0.114	4.588	<.001	0.076	3.712	<.001
WGH[f]	—[g]	—	—	0.540	17.971	<.001	0.315	11.137	<.001	0.277	10.309	<.001	0.155	6.705	<.001
Motives for Online Gaming Questionnaire															
Social	—	—	—	—	—	—	–0.019	–0.567	.57	0.008	0.241	.81	0.010	0.387	.70
Escape	—	—	—	—	—	—	0.381	8.805	<.001	0.265	6.328	<.001	0.132	3.743	<.001
Competition	—	—	—	—	—	—	0.163	4.740	<.001	0.149	4.632	<.001	0.066	2.458	.01
Coping	—	—	—	—	—	—	0.022	0.425	.67	0.016	0.333	.74	–0.022	–0.493	.62
Skill	—	—	—	—	—	—	–0.106	–2.607	.009	–0.058	–1.529	.13	0.024	0.761	.45
Fantasy	—	—	—	—	—	—	0.098	2.601	.009	0.068	1.916	.056	0.020	0.688	.49
Recreation	—	—	—	—	—	—	0.017	0.515	.61	0.009	0.299	.77	0.016	0.618	.54
PHQ-9[h]	—	—	—	—	—	—	—	—	—	0.224	5.553	<.001	0.104	3.091	.002
GAD-7[i]	—	—	—	—	—	—	—	—	—	0.073	1.847	.07	0.025	0.784	.43
N-MOGU[j]	—	—	—	—	—	—	—	—	—	—	—	—	0.326	11.286	<.001
N-MOGD[k]	—	—	—	—	—	—	—	—	—	—	—	—	0.206	7.248	<.001
P-MOG[l]	—	—	—	—	—	—	—	—	—	—	—	—	0.089	2.969	.003

[a]R^2=0.049; adjusted R^2=0.047; ΔR^2=0.049; *P*<.001.
[b]R^2=0.331; adjusted R^2=0.328; ΔR^2=0.281; *P*<.001.
[c]R^2=0.539; adjusted R^2=0.533; ΔR^2=0.208; *P*<.001.
[d]R^2=0.599; adjusted R^2=0.593; ΔR^2=0.061; *P*<.001.
[e]R^2=0.729; adjusted R^2=0.724; ΔR^2=0.130; *P*<.001.
[f]WGH: weekly gaming hours (average time).
[g]Not applicable.
[h]PHQ-9: Patient Health Questionnaire-9.
[i]GAD-7: Generalized Anxiety Disorder-7.
[j]N-MOGU: Metacognitions about the Uncontrollability of Online Gaming.
[k]N-MOGD: Negative Metacognitions about the Dangers of Online Gaming.
[l]P-MOG: Positive Metacognitions about Online Gaming.

Discussion

Principal Findings

To investigate the psychometric properties of the Chinese MOGS and its association with IGD, this study translated and tested it in China for the first time. In general, the results suggested that the C-MOGS could potentially serve as a valid and reliable tool to assess specific metacognitions about online gaming and it may have the capacity to predict IGD independently.

First, factor analyses were used to explore the structural validity of the scale. The EFA suggested a 2-factor solution (N-MOG and P-MOG), which was consistent with the first assumption of the original scale [13]. By setting 3 factors to be extracted, the EFA also obtained the same 3-factor solution as the final version of the original scale (N-MOGU, N-MOGD, and P-MOG) [13,54]. Through CFA, the 3-factor model was later proved to have the best data fit. Moreover, we attempted to build a bifactor model that included a first-order factor (P-MOG) and a second-order factor (N-MOG: N-MOGU and N-MOGD). This model had the same goodness of model fit as the 3-factor structure. To maintain consistency with the original scale, the 3-factor structure is recommended for measuring specific online gaming metacognitions in the Chinese population. For studies that compare N-MOG and P-MOG, the bifactor model can be considered.

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The 3-factor structure of the C-MOGS demonstrated adequate internal consistency, with Cronbach α coefficients ranging from .799 to .925 for each factor and the full scale, along with Guttman split-half coefficients ranging from 0.754 to 0.942. The current findings also provide evidence for the concurrent and incremental validity of the C-MOGS. Each subscale was significantly positively correlated with IGD, weekly gaming hours, gaming motives, depression, and anxiety. Moreover, the C-MOGS accounted for 13.0% of the variance in IGD while controlling for other variables. These findings highlight the utility of the C-MOGS as a reliable and valid tool to assess metacognitions about online gaming among the Chinese population.

Furthermore, this study explored the effects of metacognitions about online gaming, gaming motives, anxiety, and depression on IGD using hierarchical multiple linear regression analysis. After adding metacognitions about online gaming to the regression equations, the final model accounted for 72.9% of the variance in IGD. In addition to metacognitions, gender, weekly gaming hours, escapism motives, competition motives, and depression significantly predicted IGD, suggesting that these factors collectively contribute to the development and maintenance of IGD [69-71]. Importantly, the inclusion of metacognitions led to a reduction in the standardized regression coefficients of these variables, and the predictive effect of anxiety on IGD became nonsignificant. This indicates that metacognition may partially mediate or explain the impact of these factors on IGD. This finding is consistent with previous research, suggesting that metacognitions about online gaming may mediate the influence of other psychological factors, such as psychological dependence, anxiety, and depression, on IGD [55,72-75]. These results indicate that specific metacognitions about online gaming are important predictors of IGD, which is consistent with previous studies [13,54,55]. However, the mechanisms underlying the role of metacognitions in IGD seem to be interrelated with other psychological factors, which remains inconclusive.

In a hypothesized model, metacognitions about online gaming may promote problematic gaming engagement by increasing gaming time and disrupting normal emotion and cognition [76]. Consistent with this view, our study found that people with more metacognitions about online gaming would spend more time playing games and feel more anxious and depressed. P-MOG increases gaming time by promoting online gaming as a self-regulation method for emotion and cognition [13,21]. N-MOGU will maintain problematic gaming engagement by destroying one's confidence in self-control, while N-MOGD can induce negative reinforcement and compulsive gaming engagement by triggering negative emotions such as anxiety and depression [21,76]. Furthermore, gaming motives may be an intermediate factor, as our study found: Gaming motives were simultaneously significantly correlated with MOGS and IGD. Dysfunctional metacognition activates maladaptive coping strategies and motivation, which causes negative emotions to persist and eventually leads to IGD [77]. Moreover, other studies have different views. For example, metacognitions have a mediating effect on the association between emotional dysregulation and problematic Internet use [78], and online gaming thought suppression and impulsiveness mediate the relationship between metacognition and IGD [79]. Therefore, the association between metacognition and IGD cannot be summarized by simple causality. Other psychological variables, such as motives, coping style, impulsiveness, and emotional regulation, should be considered in future research.

Since maladaptive metacognitions are an important predictor of IGD, interventions specifically addressing maladaptive metacognitions, such as metacognition therapy (MCT), may be beneficial for the prevention and treatment of IGD. MCT, an intervention aimed at modifying dysfunctional metacognition, is effective for treating psychiatric and psychological diseases such as anxiety, depression, and schizophrenia [80-84]. Although MCT is not widely used in the treatment of addictive behaviors, researchers are attempting to prove its efficacy [11]. In some pilot studies, MCT was used to effectively treat alcohol abuse and gambling disorder [85,86]. However, the specific efficacy of MCT for treating IGD needs to be further verified in clinical research. This study provides evidence for the potential value of MCT in the clinical treatment of IGD and offers an effective tool for conducting MCT for IGD specifically in the Chinese population.

Limitations

Although this study has the advantages of a large sample size with people of different ages, it has several limitations that should be considered. First, this study adopted convenience sampling instead of random sampling, and only gamers were included. Therefore, it does not sufficiently represent all Chinese people. Second, collecting data using an online self-report questionnaire may increase the probability of participants giving false answers. However, this procedure is reported to be as reliable as pencil-and-paper surveys [87], which is likely to reduce social desirability and increase levels of honesty [88]. Third, this study lacked test-retest reliability of the C-MOGS; further research is required to test its stability. Finally, as a cross-sectional study, we could not infer the causality of the studied variables. Thus, longitudinal research is needed to further explore the relationship between metacognition and IGD.

Conclusion

In summary, this study offers some evidence that supports the satisfactory psychometric properties of the C-MOGS and highlights the possibility of metacognition as an independent risk factor in gaming behavior. It may be a useful and prospective tool for exploring psychological mechanisms of IGD and helping health professionals identify risky gamers (eg, individuals with more metacognitions about online gaming, specifically negative metacognitions about the uncontrollability of online gaming). Additionally, MCT may be beneficial for the prevention and treatment of IGD. This study may support more attention for metacognitive beliefs in addictive behaviors.

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Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

CAS: cognitive attentional syndrome
CFA: confirmatory factor analysis
CFI: comparative fit index
C-MOGS: Chinese version of the Metacognitions about Online Gaming Scale
EFA: exploratory factor analysis
GAD-7: Generalized Anxiety Disorder-7
GFI: goodness-of-fit index
***ICD-11*:** *Eleventh Revision of the International Classification of Diseases*
IGD: Internet Gaming Disorder
IGDS9-SF: Internet Gaming Disorder Scale-Short Form
I-PACE: Interaction of Person-Affect-Cognition-Execution
KMO: Kaiser-Meyer-Olkin
MCT: metacognition therapy
MOGQ: Motives for Online Gaming Questionnaire
MOGS: Metacognitions about Online Gaming Scale
N-MOG: Negative Metacognitions about Online Gaming
N-MOGD: Negative Metacognitions about the Dangers of Online Gaming
N-MOGU: Negative Metacognitions about the Uncontrollability of Online Gaming
PCA: principal component analysis
PHQ-9: Patient Health Questionnaire-9
P-MOG: Positive Metacognitions about Online Gaming
RMSEA: root mean squared error of approximation
SRMR: standardized root of the mean square residual
TLI: Tucker-Lewis Index

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Letter to the Editor

Therapeutic Uses of Gaming in Mental Health: An Untapped Potential

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KEYWORDS

digital mental health interventions; mental health; psychiatry; gaming; serious games; casual video games; commercial games; exergames; adolescent; anxiety; teenage; video game; youth

In their exploratory study, Pine et al [1] unveil promising results indicating the potential therapeutic benefits of using casual video games. While caution is necessary, particularly concerning the interpretation of student feedback, self-assessment effectiveness, recruitment, pandemic effects, and the absence of mental distress screening, the study demonstrates that video games integrating brief mental health messages provide a promising approach to merging digital intervention with the accessibility of commercial gaming. Although a randomized controlled trial is also required for precise clinical impact assessment, these preliminary findings bolster the notion that "gaming" (primarily commercial video games, serious games, and exergames) within mental health services is validated as a viable alternative or complement to conventional methods of prevention, assessment, and treatment.

Gaming, in a broad sense, is one of the most popular leisure activities globally, estimated to involve millions of gamers worldwide [2], making it ubiquitous and omnipresent, regardless of whether one has a mental illness or not. Considering the growing disparity between demand and supply for mental health assistance, combined with factors such as high disease burden, treatment costs, and long waiting lists, new alternative solutions must be explored. Coupled with accelerating technology-based game development and popularity, it may just be a matter of time before gaming truly disrupts several aspects of psychiatric work.

At present, gaming research has been conducted in the context of different psychiatric disorders such as anxiety, depression, eating disorders, attention-deficit/hyperactivity disorder (ADHD), stress symptoms, posttraumatic stress disorder (PTSD), autism, phobias, and schizophrenia, as well as in forensic psychiatry. The results vary, but reduced symptomatology, improved social, executive, and cognitive functions, as well as improved attention processes and problem-solving, have been reported. Gaming has also proven effective in offering temporary distraction from serious events, and it fosters social communities [3].

However, there are several challenges to research and practical application of gaming in mental health services. Moreover, there are critical concerns regarding the limited number of high-quality studies; weak research designs; methodological issues; and questions about generalizability, causality, mechanisms of action, control groups, effect sizes, definitions, terminology, comparability, theoretical strength, harmful effects, and transferability [2,3]. In addition, critics highlight concerns, such as gaming disorders as outlined in the *ICD-11 (International Classification of Diseases 11th Revision)*, prolonged sedentary screen time, exposure to violence, and instances of excessive or problematic gaming behavior [2,4]. Furthermore, critics argue that gaming encourages avoidance tactics, hindering physical interactions within communities. This challenge is compounded by distant communication, escapism, isolation, loneliness, emotional detachment, addiction, sleep disturbances, and physical inactivity, all posing risks of worsening the individual's condition. Critics argue gaming is not a treatment strategy but rather a tool for enhancing communication and presence among individuals.

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Research and applications of gaming in psychiatry are expanding and proving beneficial for specific patient demographics, yet there is a pressing need for a more robust knowledge base to fully grasp both the potentials and challenges involved [5]. Capitalizing on these opportunities for clinical use will demand innovative thinking within multidisciplinary research environments [2]. In conclusion, it is evident that gaming, which is deeply embedded in our culture, possesses promising yet unexplored avenues to emerge as a vital component in forthcoming treatments for mental disorders.

Conflicts of Interest

None declared.

Editorial Notice

The corresponding author of "A Novel Casual Video Game With Simple Mental Health and Well-Being Concepts (Match Emoji): Mixed Methods Feasibility Study" declined to respond to this letter.

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
***ICD-11*:** *International Classification of Diseases 11th Revision*
PTSD: posttraumatic stress disorder

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Review

The Role of AI in Serious Games and Gamification for Health: Scoping Review

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Abstract

Background: Artificial intelligence (AI) and game-based methods such as serious games or gamification are both emerging technologies and methodologies in health care. The merging of the two could provide greater advantages, particularly in the field of therapeutic interventions in medicine.

Objective: This scoping review sought to generate an overview of the currently existing literature on the connection of AI and game-based approaches in health care. The primary objectives were to cluster studies by disease and health topic addressed, level of care, and AI or games technology.

Methods: For this scoping review, the databases PubMed, Scopus, IEEE Xplore, Cochrane Library, and PubPsych were comprehensively searched on February 2, 2022. Two independent authors conducted the screening process using Rayyan software (Rayyan Systems Inc). Only original studies published in English since 1992 were eligible for inclusion. The studies had to involve aspects of therapy or education in medicine and the use of AI in combination with game-based approaches. Each publication was coded for basic characteristics, including the population, intervention, comparison, and outcomes (PICO) criteria; the level of evidence; the disease and health issue; the level of care; the game variant; the AI technology; and the function type. Inductive coding was used to identify the patterns, themes, and categories in the data. Individual codings were analyzed and summarized narratively.

Results: A total of 16 papers met all inclusion criteria. Most of the studies (10/16, 63%) were conducted in disease rehabilitation, tackling motion impairment (eg, after stroke or trauma). Another cluster of studies (3/16, 19%) was found in the detection and rehabilitation of cognitive impairment. Machine learning was the main AI technology applied and serious games the main game-based approach used. However, direct interaction between the technologies occurred only in 3 (19%) of the 16 studies. The included studies all show very limited quality evidence. From the patients' and healthy individuals' perspective, generally high usability, motivation, and satisfaction were found.

Conclusions: The review shows limited quality of evidence for the combination of AI and games in health care. Most of the included studies were nonrandomized pilot studies with few participants (14/16, 88%). This leads to a high risk for a range of biases and limits overall conclusions. However, the first results present a broad scope of possible applications, especially in motion and cognitive impairment, as well as positive perceptions by patients. In future, the development of adaptive game designs with direct interaction between AI and games seems promising and should be a topic for future reviews.

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KEYWORDS

artificial intelligence; AI; games; serious games; gamification; health care; review

Introduction

Background

Artificial intelligence (AI) and serious games are both relevant topics in the health sector, and the body of studies and literature is continuously growing. Interestingly, in terms of the research landscape, the 2 topics are not connected; rather, existing research views them independently.

The use of games for educational and serious purposes is nearly as old as the history of humankind and is an integral part of our culture [1]. In 1970, Abt [2] used the term "serious games" for the first time in his book with the same name. Sawyer and Smith [3] take a broad definition and consider serious games as "any computerized game whose chief mission is not entertainment and all entertainment games which can be reapplied to a different mission other than entertainment." What serious games have in common is that they pursue a concrete (pedagogical) intention and aim to provide information on a specific topic (eg, health) that is accessible in an entertaining and interactive way to deepen competencies or to achieve a change in behavior [4].

Serious games for health can be used in the fields of medical diagnostics, therapy, and prevention, as well as health promotion and medical or patient education [5]. From a didactic and learning psychology perspective, the effect of serious games is based on the integration of the motivating and multimedia aspects of computer and video games. Serious games can increase engagement, motivation, enthusiasm, and interest [6,7]. There are several existing use cases in health contexts [8-11]. One example is the game EndeavorRx. In 2020, the US Food and Drug Administration permitted its marketing as the first game-based digital therapeutic device to improve attention function in children with attention-deficit/hyperactivity disorder (ADHD) [12]. The game Re-Mission was developed for children with cancer and showed good results regarding compliance and the understanding of disease-related issues in the target group [13]. EMERGE is a simulation game that recreates an emergency department in real time to improve the clinical reasoning skills of physicians [14].

Next to serious games, gamification has emerged as a major trend in the health sector, which is reflected in a growing number of publications, including several meta-analyses [15-17]. The most used definition of this concept is "the use of game design elements in non-game contexts" [18]. The motivational effect of the game elements can be explained in different ways. Sailer et al [19] established the link between various gamification elements (eg, points, leaderboards, and badges) and the self-determination theory proposed by Ryan and Deci [20]. As a theory of motivation, this defines three universal psychological basic needs that determine human action: (1) competence, (2) autonomy, and (3) social inclusion. If ≥1 of these needs are addressed (eg, through gamification elements), this has positive effects on behavior and its determinants [19]. In the health sector, there are numerous studies that have demonstrated the effects of using gamification on motivation, performance, engagement, health, and well-being status [5,21,22].

According to Westera et al [23], computer games have been linked with AI since the first computer was programmed to play chess [24]. New AI methods have been used in computer games, for instance, to generate levels, scenarios, and storylines; to balance complexity; or to add intelligent behaviors to nonplayer characters (NPCs) [25]. However, over the years, various authors have pointed at the marginal penetration of academic game AI methods in industrial game production [26]. AI techniques will become indispensable to coordinate the ever-growing complexity and dynamics of games [23]. AI-driven adaptation and assessment systems are used to offer learner-centered environments [27]. As an example, NPCs controlled by AI can adapt to the behavior of the gamer and can enrich immersive and challenging experiences within the game play.

When transferring these principles to health care, the interaction between AI and games could provide a benefit, especially in the management of chronic diseases, which most game designs already target. The possibility to quickly adapt to new game-generated data or performance and provide live feedback could lead to more individual and thus more patient-centered game design in both illness detection and treatment. This could increase motivation and engagement for patients, leading to higher therapy adherence through more personal involvement. The vast body of evidence in the field of serious games and gamification, along with the growing body of evidence in the use of AI, may thus form a new field of research.

Scope

Therefore, this scoping review sought to generate an overview of the currently existing literature on the interaction of AI and game-based approaches in health care. At this point, to the best of our knowledge, this is the only review that targets this interaction.

The primary objective was to analyze the current body of evidence based on (1) the disease or health issue being evaluated, (2) the process of care in which these projects are located, and (3) the kind of AI and type of game-based approach used and the interaction of both techniques.

A secondary objective was to obtain an overview of publications on the interaction of AI and game-based approaches such as serious games, gamification, commercial games, and game periphery. Another secondary objective was to analyze the quality of the existing studies in this field regarding their grade of evidence and the conducted study types.

Methods

Overview

For this scoping review, we applied the PRISMA-P (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols; Figure 1) guidelines [28]. Furthermore, we used the

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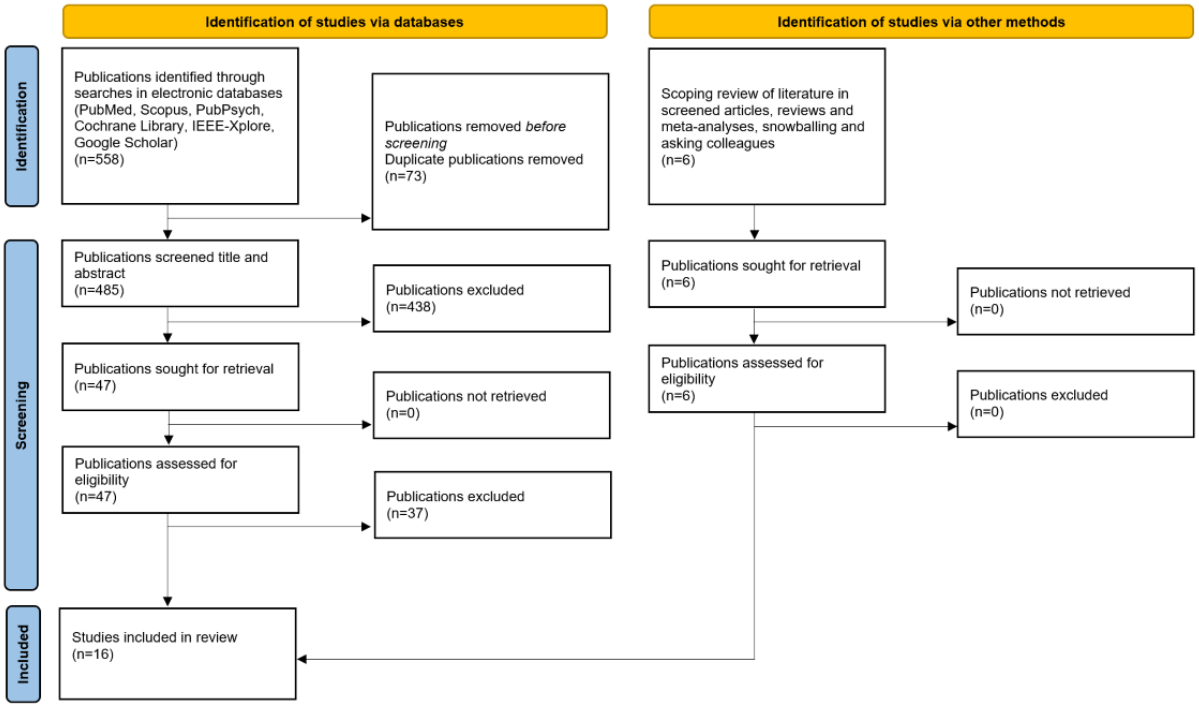
recommendations of the Cochrane Consortium for conducting systematic reviews and the RefHunter website as guidance [29].

Before starting the review process, we defined the inclusion and exclusion criteria (Textbox 1).

Figure 1. PRISMA-P (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols) flow diagram.



Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Article type: original study, journal article, or conference paper
- Article scope: articles report the use of artificial intelligence (AI), machine learning, and deep learning in combination with game-based approaches (serious games, gamification, and game-based-learning)
- Health profession: medicine
- Area of application: articles that conducted research in the field of education, therapy, and health
- Language: English
- Publication period: last 20 years

Exclusion criteria

- Article type: opinion, commentary, or letter to the editor
- Article scope: not related to AI and game-based approaches
- Health profession: other than medicine
- Area of application: not related to health and medicine
- Language: not in English
- Publication period: published >20 years ago

For this review, we conducted the following steps:

1. Literature search
2. Title and abstract screening
3. Content screening
4. Further in-depth screening (snowballing method and asking colleagues)

Step 1: Literature Search

We applied the search terms primarily in the database PubMed on February 2, 2022. We tested and honed different search terms and Boolean operators (Multimedia Appendix 1) until sufficiently fitting results seemed to have been obtained (n=305). The final search term was defined as follows:

[“game” OR “gamification”] AND “artificial intelligence”

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The search was extended to more open databases to assess studies that target AI and serious games in medicine-related research areas or interprofessional approaches that may include medical professions and in more technically oriented databases such as IEEE Xplore [30] to include papers from informatics and engineering with a focus on technical issues.

The same search term ([“game” OR “gamification”] AND “artificial intelligence”) AND “artificial intelligence”) was used for IEEE Xplore (n=98), Cochrane Library [31] (n=25), and PubPsych [32] (n=89). In Scopus, the search term used in the other databases showed fewer results and were modified to extend the range of hits (“serious” AND “game” AND “artificial intelligence”; n=41).

In addition, we conducted a search in Google Scholar [33]. However, the results from Google Scholar were not precise enough for inclusion in a review, which is consistent with the results of several studies [34-36].

After deduplication using Rayyan software (Rayyan Systems Inc), the combined search in these databases identified 545 (97.7%) publications out of the initial 558 identified. We then performed a manual deduplication, which resulted in 60 (11%) of the 545 publications being excluded; thus 485 (89%) publications remained (Multimedia Appendices 1 and 2; Multimedia Appendix 3 [37-51]).

Step 2: Title and Abstract Screening

For the second step of the scoping review (title and abstract screening), we used Rayyan software. The results from the literature search were transferred to the citation software Zotero (version 5.0.85; Rayyan) and to Rayyan software [52]. This software automatically identified duplicates. After iterative deduplication, the publications were subjected to manual screening. The first screening step was conducted using Rayyan and permitted publication inclusion based on their titles and abstracts. Given the volume of the publications to be screened, the title and abstract screening was distributed among 2 authors of this paper (JS and DT). To ensure the uniformity of the screening, the authors conducted several training sessions in Rayyan with the coreviewers. In addition, the authors randomly double-checked some of the excluded publications (25/485, 5.2%) to warrant the consistency of the screening by the other reviewer. This step was conducted independently by both researchers and was followed by a discussion of the results between the 2. As all analysis steps were conducted independently by the 2 researchers, a discussion of differently categorized literature (marked as “Conflict” in Rayyan) and subsequent adaptation were necessary in this step. Overall, only a few adjustments were necessary, and a good agreement between the 2 researchers could be reached. Possible conflicts and all included articles were discussed with a third team member (SK). The data generated by Rayyan can be found in Multimedia Appendix 2.

Step 3: Content Screening

After the primary screening, full-text publications were screened by the 2 lead authors. Toward this end, a table was prepared to compile relevant information (Textbox 2).

Textbox 2. Information compiled for full-text screening.

Relevant details obtained

- Authors, year, title, journal, and digital object identifier (DOI)
- Study type (according to Röhrig et al [53])
- Population, intervention, comparison, and outcomes (PICO) criteria
- Subject (topic of the study)
- Level of evidence (according to the Oxford Centre for Evidence-Based Medicine: Levels of Evidence [54])
- Disease or health issue
- Level of care (prevention, diagnostics, therapy, rehabilitation, nursing, organization or monitoring, and other [55])
- Game variants (serious games, gamification, games, and game controller or periphery)
- Artificial intelligence (AI) technology (machine learning, deep learning, and AI [not further specified])
- Function type (promoting health literacy, analysis and cognition, indirect intervention, direct intervention, documentation of health and medical history, organization and administration, and purchasing and supply) [56]

Some of the studies (4/16, 25%) showed an overlap among different categories (eg, in level of care). In these cases, double classifications were performed. All eligible studies were categorized and coded in detail (Multimedia Appendix 3 [37-51]).

Step 4: Further In-Depth Screening (Snowballing Method and Asking Colleagues)

After conducting the scoping review, we additionally used the “snowballing” approach described by Greenhalgh and Peacock [57], who have stated that in reviews of complex and heterogeneous evidence, formal protocol-driven search strategies may fail to identify important evidence. Informal approaches such as browsing and asking colleagues can substantially increase the efficiency of search efforts. Snowballing methods such as pursuing references of references and electronic citation tracking are very useful for identifying high-quality sources in obscure locations. Therefore, to validate the results of the review, the 2 reviewers searched the literature references used in meta-analyses, reviews, and papers that were closely related to the topic of the search. In addition to using the snowballing

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method, the method of asking colleagues, as recommended by Greenhalgh and Peacock [57], was applied as a last step.

Results

Overview

When applying the aforementioned search terms, we initially identified 335 studies on the topic of games and the use of AI in health care in the last 20 years. The subsequently performed step of title and abstract screening reduced the number of the initially identified studies from 335 to 47 (14%). In the next step, assessing the actual full-text literature, of the 47 papers, 3 (6%) were excluded because their full text was not in English, and the aforementioned inclusion and exclusion criteria were applied to the remaining 44 (94%). After the full-text screening, 10 (23%) of the 44 papers met all inclusion criteria. Using the snowballing method, 1 additional paper could be identified. Asking colleagues revealed 5 additional papers, which led to an overall total of 16 eligible papers (Figure 1). Not all criteria showed hits (eg, function type showed hits only in 2 categories, whereas level of care showed no hits in nursing).

Categories

Overview

The eligible papers showed a clear emphasis on certain categories (Table 1). Regarding the targeted diseases, the field of motion impairment was investigated the most (5/16, 31%). Cognitive impairment was targeted in 19% (3/16) of the studies, phantom limb pain or limb absence in 19% (3/16), rheumatoid arthritis in 13% (2/16), cancer in 6% (1/16), and ADHD in 6% (1/16). The primary focus on rehabilitation (10/16, 63%) was the most compelling. Of the 16 studies, 5 (31%) took place in the field of prevention, 4 (25%) in the field of diagnostics, and 1 (6%) in a nonrehabilitation therapeutic context (4 double assignments).

Most of the studies (12/16, 75%) applied machine learning as the AI technology, and 13% (2/16) used deep learning, whereas the remaining studies (2/16, 13%) did not specify the AI technology. Most of the studies (11/16, 69%) used a serious game, whereas 19% (3/16) used a commercial games approach. Despite the highly increased use of gamification in health and education, of the 16 studies, only 1 (6%) specifically used gamification to improve the motivation of patients, and 1 (6%) used game design–like interactions.

We further clustered and outlined the eligible papers according to the targeted disease (Table 2). A more detailed description of every included publication with a more specific outline of the use of AI and game variant can be found in Multimedia Appendix 4 [37-51].

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Table 1. Categories.

Category	Studies, n (%)
Disease or health topic (n=16)	
Motion impairment	5 (31)
Phantom limb pain or limb absence	3 (19)
Cognitive impairment	3 (19)
Rheumatoid arthritis	2 (13)
Cancer	1 (6)
Attention-deficit/hyperactivity disorder	1 (6)
Other	1 (6)
Function type (n=16)	
Direct intervention	9 (56)
Analysis and cognition	7 (44)
Level of care (n=20[a])	
Prevention	5 (25)
Diagnostics	4 (20)
Therapy	1 (5)
Rehabilitation	10 (50)
AI[b] technology (n=16)	
Machine learning	12 (75)
Deep learning	2 (13)
AI (not further specified)	2 (13)
Game variant (n=16)	
Serious games	11 (69)
Gamification	1 (6)
Games	3 (19)
Game periphery	1 (6)

[a]A total of 4 studies showed an overlap between prevention and diagnostics and were double classified, resulting in an overall total of 20 studies.
[b]AI: artificial intelligence.

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Table 2. Overview of included papers, structured by disease or health topic.

Authors; year	Target group (participants, n)	Subject	Study design	Level of evidence[a]	Level of care	Function type	AI[b] technology	Game variant
Disease or health topic: motion impairment								
Yeh et al [43]; 2014	Patients (48)	Noninvasive balance training	Case control study	3b	Therapy	Direct intervention	Machine learning	Games
Lyu et al [44]; 2019	Healthy individuals (8)	Electromyography-controlled knee exoskeleton	Quantitative, proof of concept	5	Rehabilitation	Analysis and cognition	Deep learning	Games
Nasri et al [45]; 2020	Patients (15)	Real-time hand gesture recognition	Case series	4	Rehabilitation	Direct intervention	Deep learning	Serious games
Burdea et al [42]; 2021	Healthy individuals (2)	Game controller–based telerehabilitation	Proof of concept	5	Rehabilitation	Direct intervention	AI	Game controller or periphery
Zhang et al [46]; 2021	Patients (5)	Gait analysis and waist motion capture	Case series	4	Rehabilitation	Direct intervention	Machine learning	Serious games
Disease or health topic: phantom limb pain or limb absence								
Ortiz-Catalan et al [47]; 2016	Patients (14)	Phantom motor execution	Quantitative clinical trial	4	Rehabilitation	Direct intervention	Machine learning	Games
Lendaro et al [48]; 2019	Patients (4)	Phantom motor execution	Quantitative clinical trial	4	Rehabilitation	Analysis and cognition	Machine learning	Serious games
Kristofferson et al [49]; 2021	Patients (4)	Prosthesis system	Explorative study	4	Rehabilitation	Direct intervention	Machine learning	Serious games
Disease or health topic: cognitive impairment								
Valladares-Rodriguez et al [50]; 2018	Healthy individuals or patients (16)	Early detection of mild cognitive impairment	Proof of concept	5	Prevention or diagnostics	Analysis and cognition	Machine learning	Serious games
Valladares-Rodriguez et al [51]; 2019	Patients (74)	Early detection of mild cognitive impairment	Case series	4	Prevention or diagnostics	Analysis and cognition	Machine learning	Serious games
Jung et al [37]; 2019	Patients (12)	Mini-Mental State Examination	Case series	4	Rehabilitation	Direct intervention	Machine learning	Serious games
Disease or health topic: cancer								
Good et al [39]; 2014	Registered players (1077)	Gene Selection for breast cancer survival prediction	Quantitative study	5	Prevention	Analysis and cognition	Machine learning	Serious games
Disease or health topic: attention-deficit/hyperactivity disorder								
Keshav et al [40]; 2019	Patients (7)	Digital attention-related augmented reality game	Case series	4	Prevention or diagnostics	Analysis and cognition	AI	Serious games
Disease or health topic: rheumatoid arthritis								
Varga et al [38]; 2021	Healthy individuals (7)	Virtual arthritis rehabilitation app	Proof of concept	5	Rehabilitation	Direct intervention	Machine learning	Serious games
Varga et al [58]; 2022	Patients (10)	Virtual arthritis rehabilitation app	Case series	4	Rehabilitation	Direct intervention	Machine learning	Serious games

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Authors; year	Target group (participants, n)	Subject	Study design	Level of evidence[a]	Level of care	Function type	AI[b] technology	Game variant
Disease or health topic: other								
Pinto et al [41]; 2019	Older adults (11)	Active and assisted living for monitoring daily life activities	Case series	4	Prevention or diagnostics	Analysis and cognition	Machine learning	Gamification

[a]According to the Oxford Centre for Evidence-Based Medicine: Levels of Evidence [54].

[b]AI: artificial intelligence.

Motion Impairment

Almost one-third of the studies (5/16, 31%) targeted the objective of motion impairment. Studies included upper- and lower-limb rehabilitation with a broad range of possible medical indications, ranging from poststroke to vestibular dysfunction. Games were used to enhance motivation and provide a user-friendly at-home training experience. Some of the studies (5/16, 31%) achieved this through an integration of virtual reality and artificial reality. AI was integrated in different ways. Some of the studies (4/16, 25%) used games as a training tool and then analyzed and classified the collected data with AI. Other studies (3/16, 19%) first processed sensor data via AI to improve the quality of an associated game. Direct interaction between the AI and the games component was shown in 2 (40%) of the 5 studies, in which AI adapted the game design and difficulty to the ability level of the patient.

Only 1 (20%) of the 5 studies tested the design using a control group analyzing patient improvements in clinical parameters. All other studies demonstrated the functionality and usability of their technical approach in pilot studies.

Phantom Limb Pain or Limb Absence

Of the 16 studies, 3 (19%) targeted the topic of phantom limb pain or limb absence, where a game environment can support at-home therapy and provide enhanced visual feedback. Of the 3 studies, 2 (67%) by the same research group targeted phantom motor execution with similar approaches. Machine learning was used to improve the quality of electromyography sensor data and thus provide better data input for training. Different training methods in the spectrum of virtual reality and augmented reality and serious games were tested. Of the 3 studies, 1 (33%) focused on ethnographic user–type analysis, and 1 (33%) effected a decrease in phantom pain. The third study tested a machine learning–aided prothesis, comparing 2 different training approaches—1 conventional and 1 via a serious game—to collect electromyography data. Testing was only conducted on 4 patients; however, the results were insignificant.

Cognitive Impairment

In cognitive impairment, the included studies used a set of games covering different cognitive functions as diagnostic instruments. Data were then processed by machine learning techniques to further improve outcome quality. Of the 3 studies, 1 (33%) focused on evaluating patients with cognitive impairment after stroke. Scores acquired from a game set were analyzed by AI and compared with the clinically widely used Mini-Mental State Examination (MMSE) [37]. Of the 3 studies, 2 (67%) used a game set for predicting the future development of mild cognitive impairment, using AI to automatically distinguish between healthy individuals and individuals who were possibly affected. In both fields, pilot studies were conducted with patients, showing high motivation to participate and good usability of the game sets.

Rheumatoid Arthritis

In rheumatoid arthritis, a serious game for hand rehabilitation was developed. Neural networks for processing data and machine learning for testing the accuracy of hand movements for individually adapting difficulty were integrated. Two small pilot studies, 1 with healthy individuals and 1 with patients, showed high accuracy of the machine learning algorithm and good usability, whereas clinical benefits have not yet been measured [38].

Cancer

In cancer, a crowdsourcing campaign was set up via an open web-based game that captured inputs from players regarding their estimation of 5 specific genes, which can be used as predictors of breast cancer survival. Gene selections were processed by machine learning to identify the best prediction models. When only including inputs from people with a self-proclaimed Doctor of Medicine degree, a Doctor of Philosophy degree, or expertise in cancer, the resulting models performed similarly to clinically established gene sets [39].

ADHD Severity

A set of smartglasses was developed to assess ADHD severity through playing an attention-related augmented reality game designed as a social-emotional communication aid. AI was used to analyze video and audio as well as affective and behavioral data and provided users with in-game rewards based on their performance. The study showed significant correlation of the game score to validated clinical gold standard assessments for ADHD [40].

Other

To improve the prevention of cognitive and physical decline, an at-home innovative system consisting of remote monitoring and neurocognitive games was developed. Feedback to the user, including badges or benefits for real-life events, is provided via machine learning analysis. Older adult users indicated “great acceptability” of the system [41].

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Discussion

Principal Findings

Currently, there are only a limited number of studies involving a combination of game-based methods and AI in health. Almost one-third of the included studies (5/16, 31%) were centered on addressing motion impairment. The primary emphasis of the research was on rehabilitation. In addition, most of the studies (9/16, 56%) focused on prevention and diagnostics. In terms of AI technology, machine learning was the most commonly used approach (12/16, 75%). Furthermore, serious games were used in most of the studies (11/16, 69%).

When analyzing the studies by disease category, most of the studies (5/16, 31%) used a rehabilitation approach for different aspects of motion impairment (eg, in poststroke conditions, phantom limb pain or limb absence, and rheumatoid arthritis). In this field, studies have a focus on providing individual, at-home, and complex training opportunities for improving motoric limb function, in which therapeutic concepts rely on long-term and self-guided exercising. Games take the role of a training tool, enhancing at-home training motivation and providing multidimensional and exercises compared with the current standard of care. In addition, in some of the studies (5/16, 31%), the integration of virtual reality and augmented reality provided an immersive experience. The role of AI in this context is diverse, sometimes to analyze and classify collected data to improve game setup and level, sometimes to analyze data resulting from game play itself.

In a second cluster, studies for neurological diseases, including those handling cognitive impairment in older adults as well as 1 study for ADHD in younger patients, there was a clear focus on diagnostic evaluations. Here, different sets of games were used to assess various cognitive subdomains, with AI processing these different data inputs and calculating scores and predictions. The advantages in this field are the wide range of possible game designs and the feasibility to play these games individually at home. This could reduce health professionals' time in assessing cognitive function during face-to-face visits or supplement them by enabling longitudinally acquired data sets and trajectories. The first results show promising results in comparison with standard clinical scores obtained using, for instance, the MMSE.

The direct interaction between the games approach and AI technology was only described in 3 (19%) of the 16 studies. Most of the time, the 2 entities follow each other, with the AI technology not analyzing live in-game playing data. However, direct interaction holds a promise of benefit through an AI-enabled assessment of the patient's ability during game play and individualized live adjustments of game design and difficulty. Examples using this approach showed good technical functioning and positive user feedback [42]. Even so, the limited number of published studies suggest that the potential of this integrated approach has so far not been fully used yet. This is rather surprising, given the fact that the direct link between AI and games is widely prevalent in the commercial games sector. The reasons for this are purely speculative. The transition of findings from 1 field to another is still pending, perhaps because studies in the commercial games field have a different scope than those in medicine and health. Another reason could be the resource-intensive nature of research. However, the future potential of this interaction seems promising, with the stimulation of user motivation by game design and gamification elements and with AI being used to process large and multimodal data sources and to perform individualized adaptations.

When analyzing further categories, our review shows that the studies so far have produced very limited quality evidence (all studies have an evidence level of 4 or 5, except for 1 study that has an evidence level of 3b), with most of the studies presenting either a rather technical proof of concept (15/16, 94%) or performing usability testing with a small sample size of healthy individuals and patients (14/16, 88%). Higher-quality studies with control groups and end points focusing on specific clinical outcomes are missing.

Of note, the research field is still young. All studies were conducted in the last 8 years, with 13 (81%) of the 16 studies being published in the last 3 years. All research settings however bear the potential of conducting higher-quality studies with bigger sample sizes and specific medical outcomes in the near future.

However, the studies in this review already show promising results, with overall well-functioning technical implementation of the game elements and high accuracy and usefulness of the AI integration. From the patients' and healthy individuals' perspective, generally high usability, motivation, and satisfaction were found, mostly assessed by established usability questionnaires and qualitative interviews. This is an encouraging perspective for the future because individualized patient-driven at-home diagnostic and therapeutic approaches are increasingly relevant in all fields of medicine.

All 16 studies identified in this review have a relatively low level of evidence (3b: n=1, 6%; 4: n=10, 63%; and 5: n=5, 31%). The risks of bias in these studies are multifaceted. Pilot studies, often conducted to assess the feasibility of a full-scale study, typically featured small sample sizes and often lacked rigorous methodology, randomization, and blinding procedures. As a result, they are susceptible to a range of biases, including selection bias, performance bias, and detection bias. Studies were characterized by weaker methodologies, which can lead to biases in data collection, analysis, and reporting. Nonrandomized studies were prone to selection bias, confounding, and other methodological flaws. The high heterogeneity of the identified studies encompassed a wide range of disease or health issues, populations, and interventions. This heterogeneity makes it challenging or impossible to integrate data and limits overall conclusions.

Limitations

First, as described earlier, the field of research is still very interdisciplinary, and the studies carried out are very diverse based on the vast variety of game-based approaches and therapeutic interventions.

This review only covered original studies in English, which were found in the PubMed, Scopus, IEEE Xplore, Cochrane Library, and PubPsych databases and published in the last 20

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years. Although these are widely recognized and commonly used databases in the field of health care research, restricting the review to these 5 databases may have resulted in the exclusion of relevant studies published in other databases owing to this high interdisciplinarity. However, efforts have been made to minimize this limitation using comprehensive search strings, snowballing, and asking colleagues to identify additional relevant literature. In addition, this review also includes interdisciplinary databases such as the more technical-oriented IEEE Xplore and the more pedagogical-oriented PubPsych.

It especially remains unclear whether all projects conducted especially with a more technical focus have been published in scientific journals at all. For future reviews, a more holistic approach should be taken to assess more results from projects that may not have been included in a publication.

In addition, there might be a lack of awareness that research in the engineering, gaming, and fitness spectrum has a direct connection with health-related issues. Thus, it seems possible that certain publications were not fully covered by our already broad search strategy or that promising interventions have not been related to health care yet. This should be mitigated in future studies, considering the growing attention to this young research field.

Another limitation is that this review focused on therapeutic medical interventions rather than on health interventions. AI and game-based approaches in the field of prevention and health promotion have not been included, although this is an important aspect of population health. Game-based approaches especially are used a lot in this field to reach the target groups [8,9,21,22,59-61].

Future Directions

In the near future, the potential of games, which is already established in the commercial games sector, should be applied to the field of serious games and AI. Adaptive game design can be suitable in health care to improve the intervention outcome via AI-driven health care games that assess the skills level of the patient and adapt the difficulty in feedback loops, which could lead to a better harmonization with traditional therapy sessions. NPCs could be used as virtual patients or other health care personnel or relatives to simulate the interprofessional working environment and to improve the interaction and communication with virtual patients [26,27,34].

Finally, the integration of AI and games should carefully consider the ongoing discussions regarding ethical, moral, and data protection issues. In particular, studies describing ethical issues using game-based approaches are scarce [62,63].

Analyzing the currently limited evidence with promising future possibilities in study design and quality, as well as a dynamic research field, it seems, at this stage, that another review should be conducted in the next few years to assess this rapidly growing research field.

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Authors' Contributions

All authors were responsible for conceptualization, methodology, validation, and visualization. DT and JJS were responsible for data curation and formal analysis. DT and SK were responsible for investigation. SK was responsible for funding acquisition, project administration, resources, software, and supervision. DT and JJS wrote the original draft; all authors reviewed and edited the manuscript (contributions of the authors are based on CRediT [contributor roles taxonomy] [64]).

Conflicts of Interest

SK is the founder and a shareholder of MED.digital. All other authors declare no other conflicts of interest.

Multimedia Appendix 1
Search term protocol.
[DOCX File , 31 KB - games_v12i1e48258_app1.docx]

Multimedia Appendix 2
Rayyan data of the review process of all studies.
[XLSX File (Microsoft Excel File), 320 KB - games_v12i1e48258_app2.xlsx]

Multimedia Appendix 3
Categorization of all eligible studies.
[XLSX File (Microsoft Excel File), 32 KB - games_v12i1e48258_app3.xlsx]

Multimedia Appendix 4
Detailed descriptions of all included studies.
[DOCX File , 25 KB - games_v12i1e48258_app4.docx]

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Multimedia Appendix 5
PRISMA-P-Checklist.
[DOCX File , 32 KB - games_v12i1e48258_app5.docx]

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
AI: artificial intelligence
MMSE: Mini-Mental State Examination
NPC: nonplayer character

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PRISMA-P: Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols

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Review

The Effects of Serious Games on Cardiopulmonary Resuscitation Training and Education: Systematic Review With Meta-Analysis of Randomized Controlled Trials

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Abstract

Background: Serious games have emerged as an innovative educational strategy with the potential to significantly enhance the quality and effectiveness of cardiopulmonary resuscitation (CPR) training. Despite their promise, there remains a degree of controversy when comparing the advantages of serious games with traditional CPR training methods. This study seeks to provide a comprehensive assessment of the impact of serious games on CPR training and education by systematically analyzing the results of previous research.

Objective: This study aimed to assess the effect of serious games on CPR training and education by summarizing and pooling the results of previous studies.

Methods: We conducted a thorough and systematic search across 9 prominent web-based databases, encompassing the period from the inception of these databases until April 1, 2023. The databases included in our search were PubMed, Cochrane Library, Wiley Online Library, EBSCO (PsycInfo), SpringerLink, Chinese Biology Medicine Disc, Vip Journal Integration Platform, Wanfang Database, and Chinese National Knowledge Infrastructure. The studies selected adhered to the following criteria: (1) being a randomized controlled trial comparing serious games and traditional methods for CPR training; (2) having participants aged 12 years or older in CPR; (3) having an experimental group using serious games and a control group using nongame methods for CPR instruction; and (4) having outcomes including theoretical and skill assessments, compression depth, and rate. The Cochrane risk of bias assessment tool was used to evaluate the risk of bias. Data analysis was performed using RevMan (version 5.3; Cochrane Training), and mean differences (MDs) and standardized mean differences (SMDs) with 95% CIs were used to calculate continuous variables.

Results: A total of 9 articles were included, involving 791 study participants, of whom 395 in the experimental group taught CPR training using serious games and 396 in the control group taught CPR training using traditional methods. The results of our meta-analysis indicate that the use of serious games in CPR training yields outcomes that are comparable in effectiveness to traditional training methods across several key areas. Specifically, serious games demonstrated equivalence to traditional formats

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in theory assessment (SMD –0.22, 95% CI – 0.96 to 0.51; *P*=.55), skill assessment (SMD –0.49, 95% CI –1.52 to 0.55; *P*=.36), compression depth (MD –3.17, 95% CI –0.18 to 6.53; *P*=.06), and compression rate (MD –0.20, 95% CI –7.29 to 6.89; *P*=.96).

Conclusions: In summary, serious games offer a viable and effective CPR education approach, yielding results comparable to traditional formats. This modality is a valuable addition to CPR training methodologies. However, caution is warranted in interpreting these findings due to limited controlled trials, small sample sizes, and low-quality meta-analyzed evidence.

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KEYWORDS

CPR; education; meta-analysis; serious game; training

Introduction

Background

Out-of-hospital cardiac arrest (OHCA) is a critical medical emergency characterized by the sudden cessation of heart function, resulting in an abrupt loss of blood flow. OHCA incidents frequently occur in community settings, schools, homes, and public places [1]. Despite sustained efforts, OHCA survival rates remain disheartening, largely due to modifiable factors such as bystander cardiopulmonary resuscitation (CPR), automated external defibrillator (AED) use, and the timing of emergency medical services (EMS) intervention [2,3]. In the United States, OHCA affects over 88.8 adults per 100,000 adults annually, with a mere 9.0% discharge survival rate, as reported by the American Heart Association [4]. Similarly, in Europe, the annual incidence of OHCA among adults ranges from 67 to 170 per 100,000, with discharge survival rates varying from 0% to 18% [5]. In China, more than 540,000 individuals experience OHCA each year, but the survival rate remains at approximately 2% [6]. These statistics underscore that OHCA, despite regional disparities, has emerged as a substantial public health challenge, imperiling the well-being of citizens [7]. OHCA is typified by sudden respiratory distress, pulse cessation, and loss of consciousness, necessitating immediate and effective first-aid measures within the critical 4-minute window [8]. However, current prehospital EMS services often struggle to reach the scene promptly to address emergencies in public spaces [9]. Consequently, first responders (FRs), nonmedical professionals in public areas, shoulder the responsibility of on-site rescue efforts [10]. Swift and efficient basic life support interventions administered by FRs not only create a vital time buffer for EMS teams to arrive but also substantially elevate the chances of patients with OHCA surviving [11].

CPR, encompassing artificial respiration and chest compressions, stands as one of the simplest and most universally applicable techniques for basic life support during OHCA emergencies [12]. The quality of chest compressions holds immense significance in preserving organ perfusion. Consequently, the timely and effective administration of CPR plays a pivotal role in determining both the survival rate and neurological outcomes for patients with OHCA [3]. To enhance the widespread adoption of CPR and ensure that more individuals are proficient in this vital first-aid technique, the World Health Organization and the International Liaison Committee on Resuscitation endorsed the “Kids Save Lives” statement, which calls for CPR training for students, adolescents, and adults aged 12 years or older who already have the physical fitness and learning ability to understand and remember CPR skills to empower young people, including children aged 12 years, with CPR skills. Develop a generation of proactive and empowered community members who are expected to make a difference in emergency situations, especially in the context of OHCA, with the goal of increasing survival and improving long-term outcomes for patients with OHCA [13,14].

Serious games are increasingly used in medical education, encompassing medical theory instruction, clinical skills training, cognitive rehabilitation exercises, and patient health education. The integration of serious games into medical simulation programs is seen as a means to enhance the efficiency and effectiveness of training programs [15,16]. Otero-Agra et al [17] used serious games to instruct middle school students in CPR, revealing that 61.7% of participants acquired correct CPR techniques, with 93.4% achieving an average chest compression depth exceeding 50 mm. These results endorse serious games as effective tools for knowledge acquisition and the mastery of high-quality CPR skills. To optimize their use as an educational strategy, serious games must possess robust content and cater to the target audience. Integrating learning theory with game requirements enhances student engagement and ensures the efficacy of learning [18]. High fidelity is crucial, especially for medical students, as the knowledge and skills acquired in serious games will be applied in future clinical practice involving real patients. High-fidelity serious games bridge the gap between virtual gaming scenarios and clinical reality, boosting rescue confidence and self-efficacy [19]. Creutzfeldt et al [20] used serious games based on massively multiplayer virtual worlds technology to train 36 high school students in CPR. After 90-120 minutes of game-based sessions, participants reported a significant increase in self-efficacy, endorsing the effectiveness of serious games for CPR instruction. Moreover, serious games can incorporate adaptive learning features, adjusting difficulty and content based on the learner’s proficiency, ensuring tailored learning for individuals with varying CPR skill levels [21].

The incorporation of serious games into CPR training aims to enhance the learning process by rendering it more engaging, interactive, and effective. Compared to conventional methods relying on lectures, videos, and hands-on practice, serious games make the learning experience more enjoyable, interactive, and motivation-driven, integrating features such as scores, levels, and rewards [21,22]. Notably, serious games for CPR training are user-facing, offering immediate training opportunities, flexible learning schedules, and detailed real-time feedback on CPR performance [23]. In contrast, traditional teaching models often limit training opportunities, providing delayed feedback,

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particularly in large-scale group activities where individual feedback is frequently overlooked [24]. A systematic review by Lim et al [25] underlines that the absence of regular retraining and effective feedback in traditional CPR education can impact skill retention. Serious games address these shortcomings by providing continuous opportunities for practice and feedback. Moreover, serious games support collaborative learning, enabling learners to respond jointly to virtual CPR scenarios and develop teamwork and communication skills. They also offer diverse immersive first aid scenarios with varying causes of cardiac arrest, an aspect unattainable in traditional teaching formats [16,26]. This multifaceted approach not only compensates for the deficiencies in traditional methods but also promotes a dynamic and engaging learning environment in CPR training. Considering the advantages mentioned above, the 2020 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care recommended the incorporation of serious games into CPR training and education to enhance teaching methods and improve instructional quality, taking into account advancements in training equipment and teaching formats [27]. However, Dankbaar [28] concluded that serious games have limitations in terms of time and their ability to provide learners with sufficient knowledge acquisition and complex skill improvement. In summary, there exists a degree of controversy regarding the impact of serious games on CPR training and education. Therefore, we aimed to conduct a meta-analysis to determine the effectiveness of serious games in CPR training and education.

Research Gap and Aim

While numerous researchers have explored and experimented with serious games for CPR training, published randomized controlled trial (RCT) studies have explored and experimented with the effect of serious games applied to CPR training, and their effectiveness has been proven and supported [16,29]. However, due to the limitations of research, the generalization of research conclusions is affected. Specifically, (1) these RCTs were single-center studies with small sample sizes; (2) specific serious games limit the reliability of the findings in different settings of serious games or target populations; (3) outcomes were mostly assessed by questionnaires, and there were a lack of reliable, automated, and repeatable methods to measure their efficacy; and (4) there is a lack of methodological specifications and standard protocols for the use of serious games. Furthermore, there is a lack of systematic evaluation or meta-analysis of the effectiveness of serious games-based CPR training. Consequently, it is necessary to quantitatively analyze the objective effect of serious games–based training through meta-analysis. In view of this, we conducted a meta-analysis to comprehensively evaluate the effect of serious games on CPR training and teaching.

Methods

Overview and Registration

This systematic review adheres to the guidelines set forth by the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) [30] and was registered in advance in the PROSPERO (International Prospective Register of Systematic Reviews) database (registration number CRD42023423089).

Search Strategy

Our search was conducted in several databases, including PubMed, Cochrane Library, Wiley Online Library, EBSCO (PsycInfo), and SpringerLink. Besides, Chinese databases, including the China National Knowledge Infrastructure (CNKI), China Biomedical Literature Database, VIP Journal Integration Platform, and Wanfang Database, were searched. The search was conducted from the inception of the databases until April 1, 2023. We limited the publication language to English and Chinese. English search terms included “serious game,” “gam*,” “cardiopulmonary resuscitation,” “CPR,” “basic life support,” “BLS,” “first aid training,” “resuscitation education,” “emergency skill,” etc. The search involved a combination of subject terms and free words, with a manual retrospective search of references and associated literature to ensure a comprehensive search of relevant studies. Multimedia Appendix 1 provides detailed information on the search strategies, including search terms, and the process used.

Eligibility Criteria for This Review

The eligibility of studies was assessed based on the following criteria: (1) the study type should be an RCT comparing the effectiveness of serious games with other traditional training methods for teaching CPR; (2) the study population should include participants aged 12 years or older who participated in CPR training or first aid training that covered basic life support for CPR; (3) interventions in the experimental group should involve the use of serious games for CPR training instruction, while the control group should receive other methods of CPR theory and skills training instruction excluding serious games, with no limitations on the types of games or software used; and (4) outcome measures should include one or more of the indicators of theoretical assessment, CPR skill assessment, compression depth, and compression rate. Additionally, duplicate or multiple manuscripts, literature in languages other than Chinese or English, literature with inaccessible full text, incomplete or missing data, improper data collection, or errors in statistical methods were excluded.

Screening Process

Two authors (PC and PY), who were trained in evidence-based methods, independently conducted the screening of literature and extraction of data. All references were managed using EndNote X9 (Clarivate), a reference management software. After removing duplicates, the remaining references were first screened based on titles and abstracts. Subsequently, full-text screening was performed independently by the authors in duplicate to determine the inclusion of literature. Disagreements were resolved through discussion or adjudication by a third author (HZ).

Quality Assessment

The Cochrane handbook’s criteria for assessing the risk of bias in RCTs were used to evaluate the methodological quality of the trials [31]. The assessment covered various aspects, including selection bias, concealment of the allocation scheme, implementation bias, measurement bias, missed visit bias,

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reporting bias, and other biases. Each item was categorized as "low risk of bias," "unclear," or "high risk of bias." In cases where differing opinions arose, a third author (HZ) was involved to reach a consensus.

Data Extraction

For data extraction, we used Excel (2010; Microsoft Corporation) to create a standardized form. The form included the following information: (1) basic details such as the first author, publication year, and country of the study; (2) population characteristics, sample size, and information about the serious games used in training and teaching; (3) specific interventions for the test and control groups; and (4) outcome measures and the tools used for measurement.

Statistical Analysis

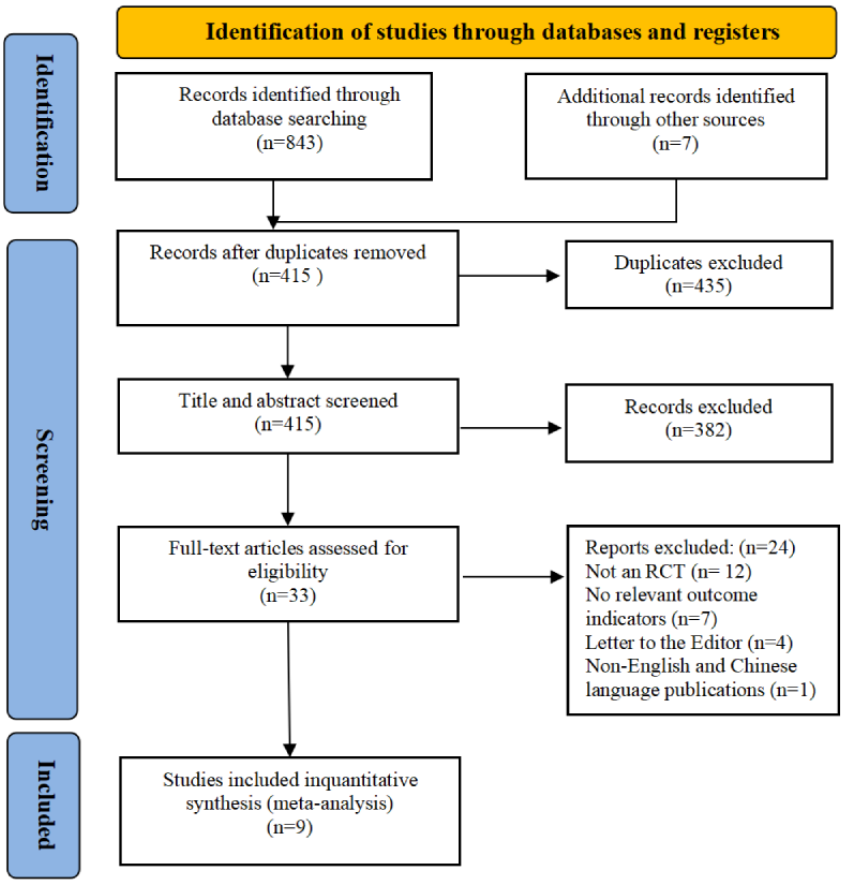
Data analysis was carried out using RevMan (version 5.3; Cochrane Training). To assess heterogeneity, the Q test and the I^2 test were used. If the resulting P value was greater than or equal to .1 and I^2 was less than or equal to 50%, it indicated low heterogeneity among the findings, leading to the selection of the fixed-effects model for meta-analysis. Otherwise, the random-effects model was used. When comparing groups, continuous variables were analyzed using mean difference (MD) if the same measurement instrument was used or standardized mean difference (SMD) if different instruments were used. Both effect measures were reported with 95% CIs. For continuous data that did not follow a normal distribution in the included studies and were expressed as medians, extreme values, or quartiles, a specific web-based formula calculator developed by Professor Luo et al [32] from Hong Kong Baptist University was used. This calculator, designed for meta-analysis data conversion, enabled statistical estimation of the data. Leave-one-out analysis was used to conduct sensitivity analysis, that is, omitting one study at a time from the meta-analysis and examining the impact on the overall effect size, then judging the robustness and reliability of the results and exploring the sources of heterogeneity [33]. Statistical significance was determined at a $P<.05$. The level of evidence was evaluated using the GRADEpro GDT web-based tool.

Results

Study Selection

After conducting a comprehensive search across various databases, a total of 843 RCTs were found. Additionally, 7 more studies were obtained by snowballing. Following the removal of duplicates, 415 articles were screened based on their titles and abstracts. Out of these, 382 articles were excluded, and the remaining 33 articles were examined in their entirety. Ultimately, a total of 9 full-text articles were considered for quantitative synthesis. This included 5 papers in English and 4 papers in Chinese. More specific information can be found in the study's PRISMA flowchart (Figure 1).

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart of the selection process. RCT: randomized controlled trial.



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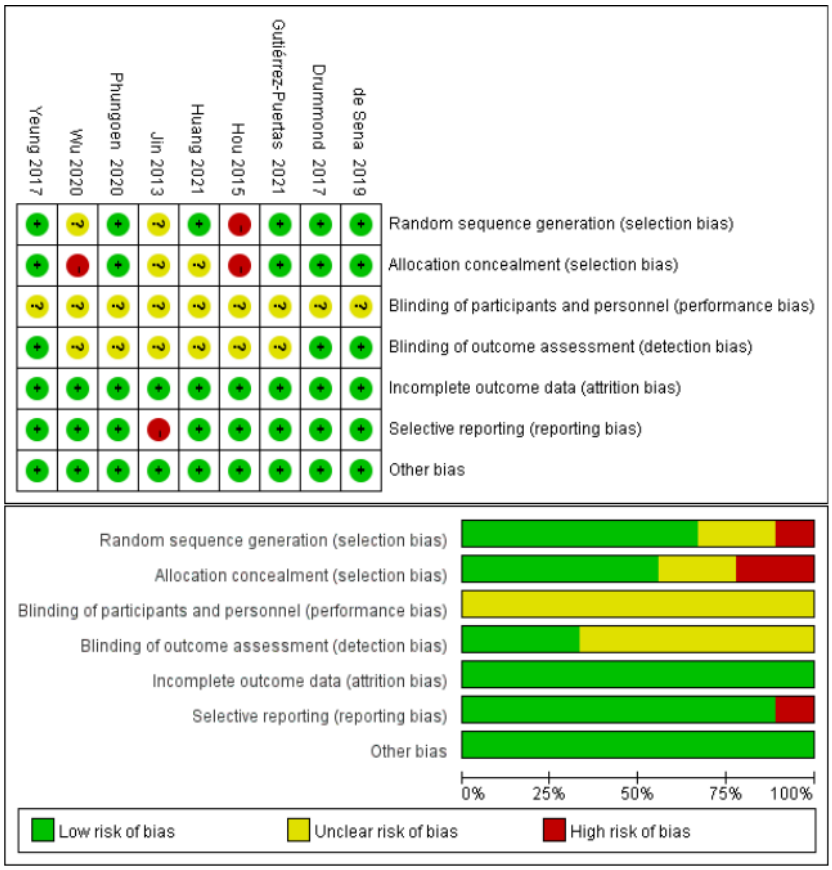
Characteristics of Included Studies

We included 9 RCTs [34-42] from 6 countries. There were no statistical differences in general information between the trial and control groups in each study. A total of 791 study participants were included, with 395 in the experimental group taught CPR training using serious games and 396 in the control group taught CPR training using traditional methods. Additional information can be found in Multimedia Appendix 2 [34-42].

Quality Assessment

The risk of bias evaluation of the included literature is presented in Figure 2 [34-42] (the colors green, yellow, and red in the figure mean "low risk of bias," "unclear risk of bias," and "high risk of bias," respectively). The quality of the included studies was found to be acceptable. In 6 RCTs [36-38,40-42], they described the generation of random sequences, of which 5 RCTs [36-38,40,41] described methods of allocation concealment. Due to CPR training and teaching, it was not possible to blind participants. In 3 RCTs [36-38], they applied the blinding method for researchers. Additionally, in 1 RCT [34], they had a high risk of reporting bias, and all 9 RCTs had complete data and did not have any other bias.

Figure 2. Methodological quality assessment of risk of bias for the included trials.

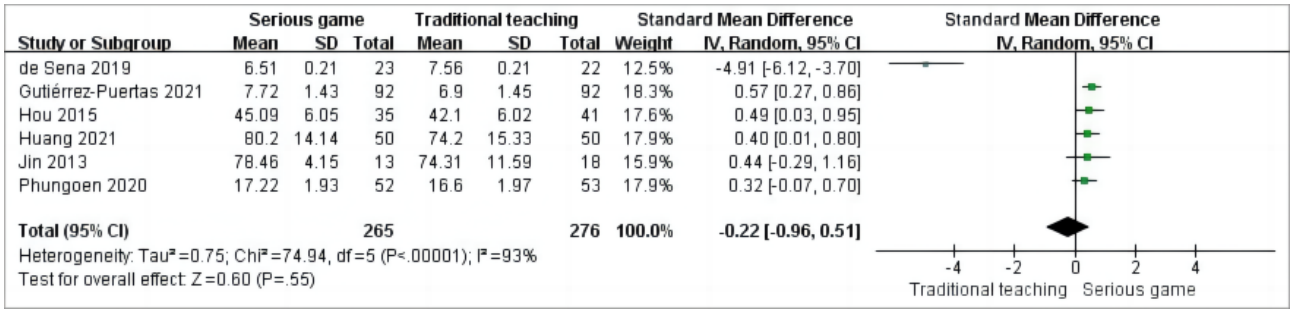


Meta-Analysis Results

The Effect of Serious Games Teaching on CPR Theory Performance

In the analysis, 6 out of the 9 studies [34,35,38,40-42] used posttraining CPR theory assessment as an outcome measure in RCTs. The pooled results revealed significant heterogeneity among the studies (P<.001; I^2=93%), necessitating the use of a random-effects model for the meta-analysis. Figure 3 [34,35,38,40-42] demonstrates that there was no significant disparity in the theory assessment between the 2 groups under investigation (SMD –0.22, 95% CI –0.96 to 0.51; P=.55).

Figure 3. Meta-analysis of the effect of serious games on theory assessment.



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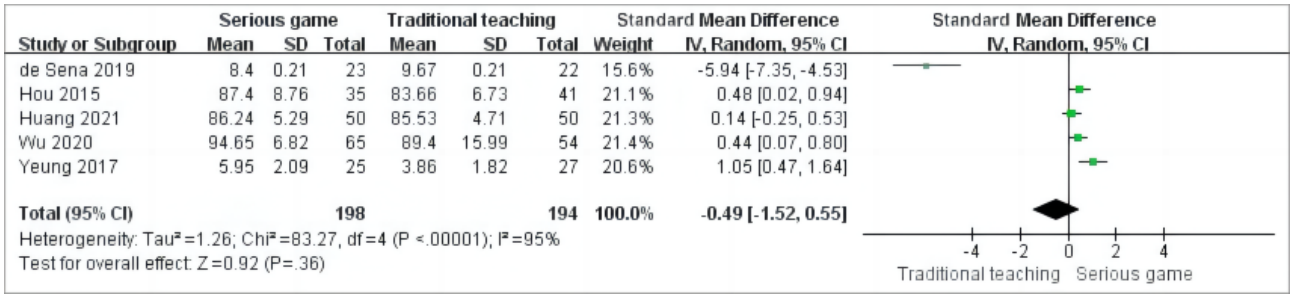
The Effect of Serious Games Teaching on the Performance of CPR Skills Operations

Posttraining CPR skill manipulation performance was assessed as an outcome indicator in 5 RCTs [35,36,38,39,42] out of the 9 studies included. Meta-analysis was conducted using a random-effects model due to heterogeneity among the studies (P<.001; I^2=95%). The results indicated that there was no significant difference in skills assessment between the 2 study groups (SMD –0.49, 95% CI –1.52 to 0.55; P=.36). This suggests that the use of serious games for CPR training did not lead to a significantly different skill level compared to other traditional training methods (Figure 4 [35,36,38,39,42]).

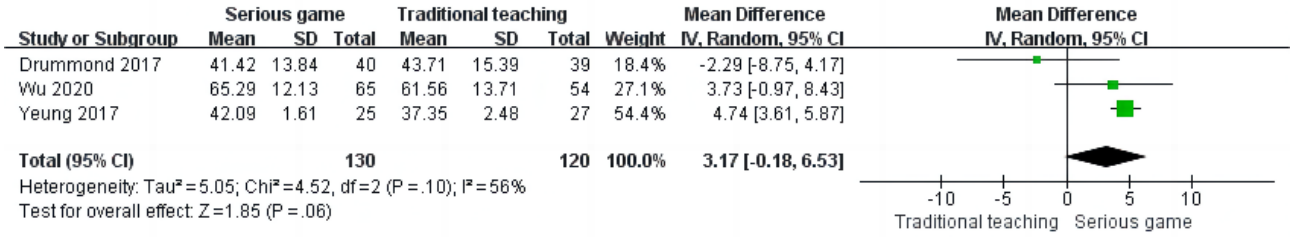
Figure 4. Meta-analysis of the effect of serious games on skill assessment.



The Effect of Serious Games Teaching on the Depth of CPR Compression

A total of 3 studies [36,37,39] presented findings on the impact of serious games on CPR compression depth. The assessment of heterogeneity demonstrated variability among the included studies (P=.10; I^2=56%), necessitating the application of a random effects model. The analysis depicted in Figure 5 [36,37,39] revealed that the disparity between the 2 groups did not reach statistical significance (MD 3.17, 95% CI –0.18 to 6.53; P=.06).

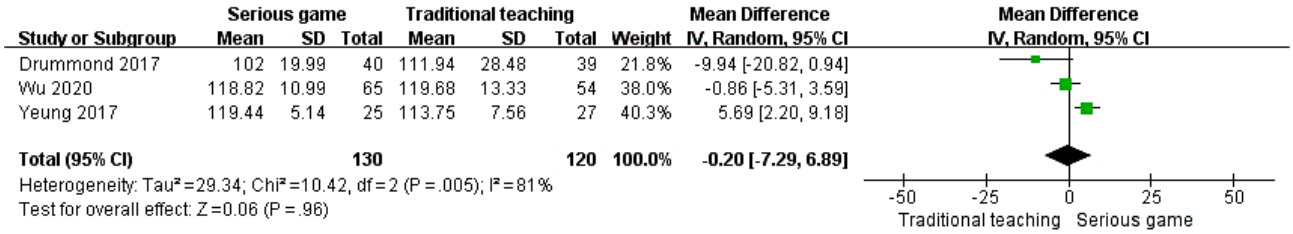
Figure 5. Meta-analysis of the effect of serious games on cardiopulmonary resuscitation (CPR) compression depth.



The Effect of Serious Games Teaching on the Frequency of CPR Compression

A meta-analysis was performed on 3 studies [36,37,39] that investigated the impact of serious games training on the frequency of CPR compression. Due to the variation among these studies (P=.005; I^2=81%), a random effects model was used. The results, as illustrated in Figure 6 [36,37,39], indicated that there was no significant difference in the theory of CPR compression rate between the 2 study groups (MD –0.20, 95% CI –7.29 to 6.89; P=.96).

Figure 6. Meta-analysis of the effect of serious games on cardiopulmonary resuscitation (CPR) compression frequency.



Sensitivity Analysis

We conducted separate analyses using both fixed effects and random effects models to examine the SMD, MD, and 95% CI of each model. By systematically excluding studies one by one, when the study by de Sena et al [38] was excluded, we observed a decrease in heterogeneity from 93% to 0% for theoretical assessment (Figure 7 [34,35,40-42]) and from 95% to 54% for skill assessment (Figure 8 [35,36,39,42]), respectively. This indicates that the study conducted by de Sena et al [38] may have contributed to the observed heterogeneity. In the meta-analysis of CPR compression depth, heterogeneity decreased from 56% to 0% after the exclusion of the study by Drummond et al [37], indicating that this study was the source of heterogeneity (Figure 9 [36,39]). After the exclusion of the study by Yeung et al [36], the heterogeneity of the meta-analysis on compression frequency of CPR decreased from 81% to 56%, indicating that this study was one of the sources of heterogeneity (Figure 10 [37,39]).

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Figure 7. Sensitivity analysis of meta-analysis of cardiopulmonary resuscitation (CPR) theory performance.

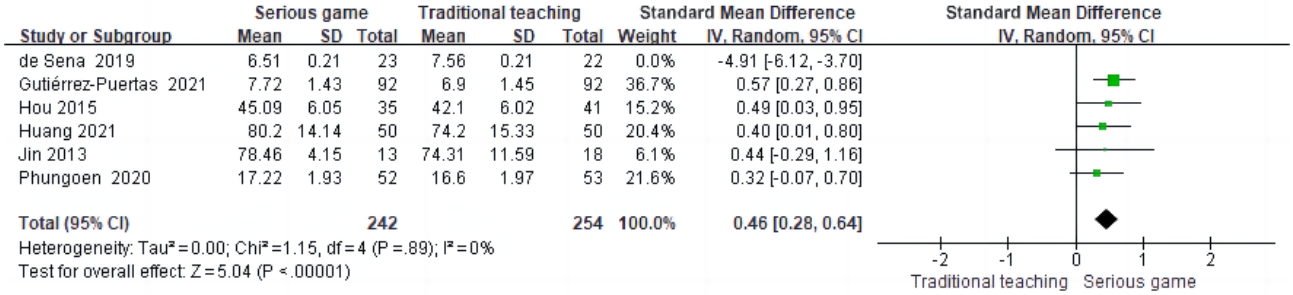


Figure 8. Sensitivity analysis of meta-analysis of cardiopulmonary resuscitation (CPR) skills operations.

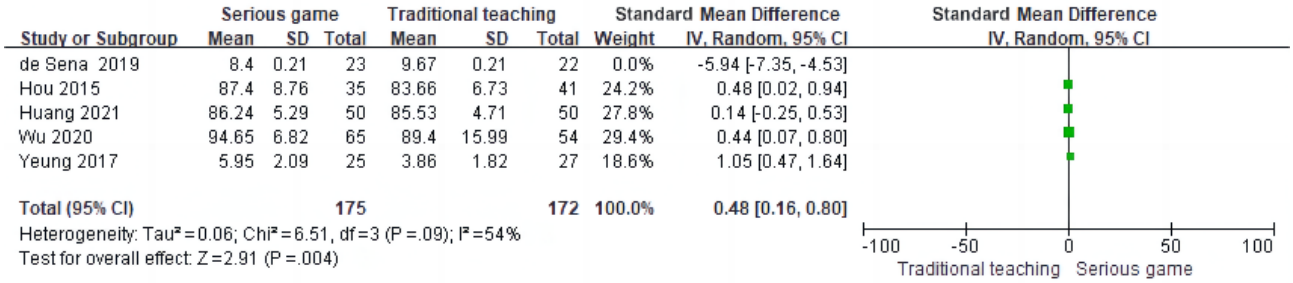


Figure 9. Sensitivity analysis of meta-analysis of cardiopulmonary resuscitation (CPR) compression depth.

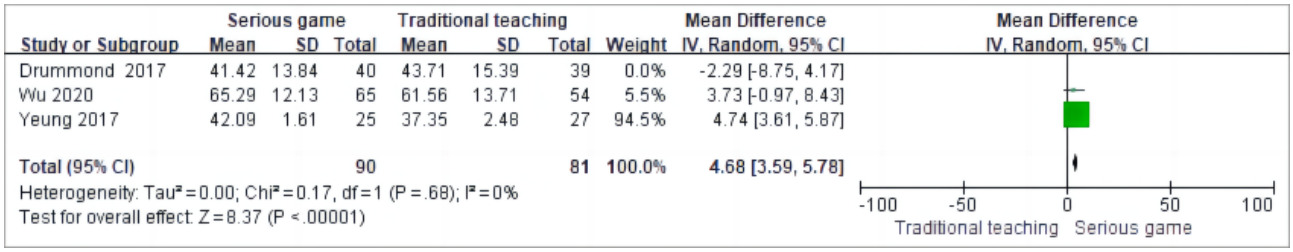
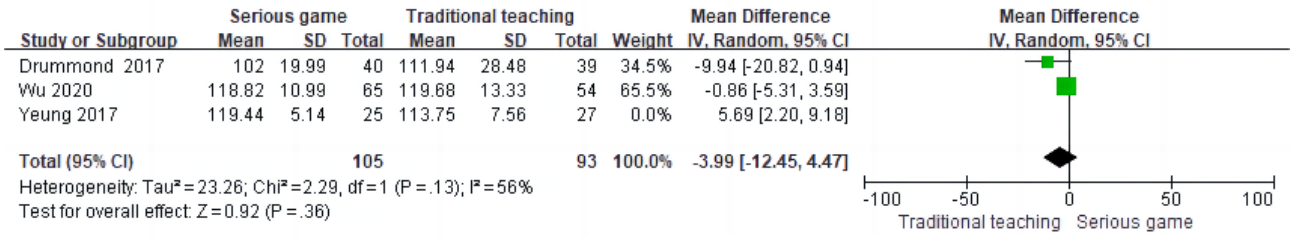


Figure 10. Sensitivity analysis of meta-analysis of cardiopulmonary resuscitation (CPR) compression frequency.



GRADE Evidence Quality Levels

Table S1 in Multimedia Appendix 3 presents the GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) system evidence level for each outcome indicator in the meta-analysis of this study. The 4 outcome indicators considered were theory assessment, skill assessment, compression depth, and compression frequency.

Discussion

Principal Findings

This study systematically evaluated the efficacy of serious games-based training in CPR education, drawing upon data from 9 studies with a total of 791 participants. Our findings reveal no significant differences in theoretical exam scores, skill assessment scores, compression depth, or compression frequency between serious games-based and traditional CPR training methods. This suggests that serious games offer a highly effective alternative for CPR education. In alignment with the 2020 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care [27], which recommend the incorporation of serious games into CPR education, our results underscore the positive impact of virtualized, gamified learning models on knowledge acquisition and CPR skill mastery. Theory and skills assessments are pivotal components of CPR training, serving as key indicators of training effectiveness and student proficiency. Our meta-analysis demonstrates that serious games-based CPR training is on par with traditional methods in enhancing both knowledge acquisition and skill levels. Consequently, serious games represent a valuable addition to the spectrum of CPR teaching and training methods, fostering innovation and aligning

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with the American Heart Association's guidelines for modernizing teaching tools and approaches.

Comparison With Previous Work

This study aligns with a previous meta-analysis [43], indicating that both lay and medical school students exhibit enhanced knowledge following web-based digital resuscitation training. Moreover, they demonstrate comparable cognitive outcomes to those undergoing traditional training sessions. The inclination of younger individuals toward serious games for acquiring new skills stems from their immersive and interactive nature, offering a secure trial-and-error environment [44]. This, coupled with engaging and positive learning experiences, reduces reliance on educational resources and fosters active, independent learning—especially when conventional training methods are inaccessible. This approach helps in sustaining knowledge levels, preventing decay over time, and attaining learning outcomes equivalent to traditional education forms [45]. Despite these benefits, serious games' applications for CPR training face challenges, presenting a mixed landscape concerning usability and enjoyment quality. Issues range from outdated guidelines and unupdated advice to overly detailed, professional information hindering learning efficacy. Such drawbacks may discourage public engagement with CPR learning [46]. For nonmedical learners, serious games must ensure acceptable usability, simplifying the comprehension and retention of CPR theoretical knowledge. Regular updates aligning with the latest guidelines can transform serious games into dynamic electronic textbooks [46,47]. To maximize the potential of serious games over traditional training, it is crucial to identify and evaluate functions that motivate learners to increase frequency and actively embrace knowledge updates. This strategic approach could position serious games as a superior alternative for enhancing the theoretical understanding of CPR, offering distinct advantages over traditional training methods [46,48].

Numerous guidelines [27,49-51] underscore the primary goal of CPR training: imparting participants with the skills necessary for high-quality CPR. This involves maintaining the correct compression rate and depth, ensuring thoracic recoil, and minimizing interruptions and hyperventilation. However, traditional training methods have presented challenges, particularly for nonmedical personnel [52,53], in mastering these vital competencies. Previous studies [52,54] have noted that simulated scenarios and repetitive practice often fall short of achieving adequate compression depth and frequency. Aksoy [55] and Siqueira et al [56] propose that a CPR teaching mode based on serious games could enhance learners' motivation and attitude, consequently improving compression quality. This study echoes Lau et al's [57] systematic review, indicating equivalence between serious games and traditional training methods in enhancing compression depth and frequency. However, electronic CPR training, including serious games, may not independently enhance skills without some influence from instructors, particularly for beginners. In other words, teacher involvement remains crucial to refining CPR skill performance through serious games training. Lim et al [25] discovered that content learned in serious games may not seamlessly transfer to skill operations during assessments, particularly for students with autonomous learning based on serious games. Scores in the pressing position, crucial for CPR quality, were notably worse than those in traditional training. Factors such as incorrect anatomical positions directly impact compression quality, making it challenging to achieve better performance in practical measures such as compression depth and frequency. While there was no significant difference in CPR compression skill or rate between the 2 training models, serious games-based CPR training revealed imperfections. To address this, integrating and emphasizing the impactful elements and advantageous attributes of traditional training into serious games may compensate for their shortcomings in skill practice. This approach has the potential to amplify the comparative advantages of serious games in CPR training.

In summary, the results of this study are similar to those of similar previous systematic reviews or studies. Nevertheless, given the limited number of studies included in this meta-analysis and the low GRADE evidence level, these results warrant cautious interpretation. Therefore, we recommend future CPR training efforts prioritize conducting high-quality, large-sample studies. This will enable a more comprehensive analysis of the effectiveness of serious games-based training, providing substantial evidence for the refinement of guidelines and the development of related teaching methodologies.

Strengths and Limitations

Strengths

This review compensates for the shortcomings of the previous literature in English by focusing on all types of serious games and conducting a comprehensive search of massive Chinese databases. Certainly, this study was conducted in strict accordance with highly recommended guidelines (ie, PRISMA), with early registration of the protocol for the systematic review and final grading of the evidence based on the GRADEpro GDT web-based tool, so it can be considered a robust, high-quality review. In addition, the meta-analysis conducted in this study involved 9 RCTs [34-42]. These RCTs provided detailed information on the study population, training protocol, serious games used, and measurement tools for outcome indicators. As for blinding implementation, it was challenging to blind interventionists due to the nature of CPR teaching training, which resulted in some degree of implementation bias. On the other hand, blinding the measurer effectively prevented measurement bias, particularly when assessing CPR theoretical knowledge and skills. Objective outcome indicators such as CPR compression depth and frequency, as recorded by the simulator, were less susceptible to measurement bias. The literature also addressed missed visits, had a low risk of selective reporting bias, and demonstrated baseline comparability between groups. Therefore, the included literature was of high quality, and the findings can be considered credible.

Limitations

This study acknowledges several limitations that merit consideration. First, our research only encompassed studies available in Chinese and English, which may introduce a linguistic bias. Second, heterogeneity in our meta-analysis results emerged due to variations in study populations, the use of different serious games, and diverse tools used to measure

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outcome indicators. Despite our efforts to explore the sources of heterogeneity through sensitivity analysis, a complete explanation remained elusive. In particular, it is worth noting that the use of different instruments by the included studies to evaluate training outcomes may have influenced the judgment of the results. Third, the relatively small number of included studies prevented us from conducting tests for publication bias. Additionally, some data underwent statistical transformations during the meta-analysis, potentially influencing the accuracy of the results. Lastly, this study focused primarily on CPR theory assessment, skill evaluation, compression depth, and compression rate as outcome indicators, without delving into knowledge and skill retention post-training, trainees' self-efficacy, or other facets of compression quality.

Implications for Future Research and Practice

Serious games, as an innovative model for CPR teaching and training, offer a promising avenue for first aid education, catering to diverse populations. However, this approach is still in its developmental and exploratory phases, and its cost-effectiveness warrants discussion. Future research should consider incorporating outcome indicators from the field of health economics to address economic barriers and promote the adoption of serious games in professional medical education and broader first aid training. Additionally, many studies lack standardized training specifications for serious games, including training duration, frequency, trainer intervention levels, and evaluation methods and tools for assessing training effectiveness. While serious games are recommended for CPR education, the specific details of this training mode require further standardization. Moreover, the quality of serious games, which serve as the platform for CPR training, significantly impacts training effectiveness. Developing serious games that align with international guidelines and cater to the diverse characteristics of trainees is undoubtedly challenging but essential. In conclusion, future research should prioritize conducting multicenter, large-sample RCTs to advance our understanding of the potential of serious games in CPR education.

Conclusion

This study conducted a meta-analysis of RCTs to assess the efficacy of serious games in CPR training. The findings indicate that serious games are equally effective as traditional training methods in enhancing CPR theory assessment and skill evaluation. Meanwhile, no significant differences emerged between serious games and traditional training methods regarding CPR compression depth and frequency. Notably, the current body of high-quality studies on serious games in CPR training is limited, often characterized by small sample sizes. Therefore, future research should prioritize conducting additional high-quality RCTs to provide further evidence and offer a more comprehensive understanding of the impact of serious games in CPR training and education.

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Data Availability

Data sharing is not applicable to this article as no data sets were generated or analyzed during this study.

Authors' Contributions

PC conceived the idea for the review. PC, YH, and PY conducted the data curation, methodology, validation, and formal analysis and wrote the first draft of the manuscript. PC, YH, PY, HW, and BX were involved in the study selection, quality assessment, and data extraction. PC, BX, and CQ conducted the statistical analysis. HZ is responsible for the writing, methodology, conceptualization, supervision, and editing of this manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[DOCX File , 19 KB - games_v12i1e52990_app1.docx]

Multimedia Appendix 2
Detailed characteristics of the included trials.
[DOCX File , 22 KB - games_v12i1e52990_app2.docx]

Multimedia Appendix 3
Supplementary table S1.
[DOCX File , 15 KB - games_v12i1e52990_app3.docx]

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Multimedia Appendix 4
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[PDF File (Adobe PDF File), 101 KB - games_v12i1e52990_app4.pdf]

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Abbreviations

AED: automated external defibrillator
CPR: cardiopulmonary resuscitation
EMS: emergency medical services
FR: first responder
MD: mean difference
OHCA: out-of-hospital cardiac arrest
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO: International Prospective Register of Systematic Reviews
RCT: randomized controlled trial
SMD: standardized mean difference

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Review

Electronic Interactive Games for Glycemic Control in Individuals With Diabetes: Systematic Review and Meta-Analysis

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Abstract

Background: Several electronic interventions have been used to improve glycemic control in patients with diabetes. Electronic interactive games specific to physical activity are available, but it is unclear if these are effective at improving glycemic control in patients with diabetes.

Objective: This study aimed to determine the effects of electronic game–based interventions on glycemic control in patients with diabetes.

Methods: Relevant studies that were published before April 1, 2023, were searched from 5 databases: PubMed, Embase, Web of Science, Scopus, and Cochrane Library. Eligibility criteria included prospective studies examining the relationship between electronic games with physical activities or diet education and glycemic control as the outcome. The risk of bias was assessed using the Cochrane risk-of-bias tool. All analyses were conducted using RevMan5.4.1. Depending on the heterogeneity across studies, the pooled effects were calculated using fixed-effects or random-effects models.

Results: Participants from 9 studies were included and assessed. Glycated hemoglobin (HbA_{1c}) and fasting blood glucose improved in the intervention group, although the analysis revealed no significant reduction in HbA_{1c} (−0.09%, 95% CI −0.29% to 0.10%) or fasting blood glucose (−0.94 mg/dL, 95% CI −9.34 to 7.46 mg/dL). However, the physical activity of individuals in the intervention group was significantly higher than that of those in the control group (standardized mean difference=0.84, 95% CI 0.30 to 1.38; P=.002). Other outcomes, such as weight and blood lipids, exhibited no significant improvement (all P>.05).

Conclusions: Electronic games had a good impact on participants' physical activity and offered an advantage in glycemic control without reaching statistical significance. Electronic games are convenient for reminders and education. Low-intensity exercise games may not be considered a better adjuvant intervention to improve diabetes self-management care.

(JMIR Serious Games 2024;12:e43574) doi:10.2196/43574

KEYWORDS

electronic game; physical activity; diet; diabetes mellitus; glycemic control

Introduction

Diabetes mellitus is one of the 4 major noncommunicable diseases and is also among the top 10 global causes of death. Throughout the world, the number of patients with diabetes mellitus is increasing, probably due to changes in lifestyle. According to the International Diabetes Federation, in 2021, approximately 536.6 million adults (aged 20-79 years) were living with diabetes; this is expected to rise to 12.2% in 2045 [1]. Because of the rise in type 1 and type 2 diabetes, the burden of health care expenditures and its complications continues to increase, whereas the complications are the main causes of

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morbidity and mortality [2]. To address the health challenge resulting from diabetes, effective and efficient management is needed [3-5].

Lifestyle management, an efficacious method for diabetes prevention [6], is a fundamental aspect of diabetes care. It includes diabetes self-management education and support, medical nutrition therapy, physical activity, smoking cessation counseling, and psychosocial care [7]. Food intake and physical activity are associated with significantly improved control of diabetes [8]. With advances in technology, lifestyle management incorporating novel technologies and formats meets the needs of various populations for diabetes treatment [9]. New methods, such as electronic games and wearable devices, aim to contribute to better patient compliance [10].

It has been reported that electronic games can help players learn more about healthy diets and encourage exercise [11,12]. Although they play a role as facilitators in motivating and accelerating physical activity, they offer little benefit to patients with chronic disease [13]. Previous systematic reviews have evaluated the impact of app-based or electronic health interventions to support changes in blood glucose management, physical activity, or diet [9,14,15]. However, previous papers analyzed relatively few articles or articles that were not solely on using games. They also used educational or regulation applications, robots, or virtual worlds that do not contain game elements. Electronic games specific to physical activity and dietary education are available; however, we currently lack an understanding of how effective electronic games can be for glycemic control.

In this study, we performed a comprehensive literature search to select studies on the effects of electronic game–based interventions on glycemic control in patients with diabetes for meta-analysis. Electronic gaming interventions are defined as containing an element of gaming that involves virtual reality, serious gaming, or exergaming [15].

Methods

Data Sources and Search Strategy

This review was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement and its associated checklist (Multimedia Appendix 1). Relevant studies that were published before April 1, 2023, were searched from 5 databases: PubMed, Embase, Web of Science, Scopus, and Cochrane Library. The references of the included studies were hand-searched to identify any additional articles. The following terms were used during the search: (“Diabetes” OR “diabetic” OR “diabetes mellitus” OR “glycemic control” OR “glucose control” OR “glucose”) AND (“game” OR “gamification” OR “exergaming” OR “avatar” OR “wii” OR “virtual” OR “konami” OR “wii-fit” OR “kinect” OR “tierone” OR “video-game” OR “serious-games” OR “serious video-games” OR “Augmented reality” OR “mixed reality” OR “second life” OR “TierOne” OR “Konami Dance Dance Revolution” OR “Sony Eyetoy” OR “Microsoft Kinec”). Detailed search strategies for each database are given in Multimedia Appendix 2. The reference lists of the searched articles and the relevant reviews were then screened to identify any pertinent studies.

Study Selection

Studies included in this meta-analysis met the following criteria: (1) participants were diagnosed as having type 1 diabetes or type 2 diabetes; (2) the articles were published in English or Chinese; (3) the articles presented the electronic management intervention with a gaming element, such as a virtual reality game, serious game, or exergame; and (4) the outcome indicators were blood glucose and glycated hemoglobin (HbA_{1c}).

Studies that met the following criteria were excluded: (1) participants had gestational diabetes mellitus, had other special types of diabetes mellitus, underwent surgery, had an operation, or were in the emergency department; (2) participants had a previous history of mental illnesses, eating disorders, or cancer; (3) the management intervention was only based on an online, mobile, or virtual application but did not use a gaming element; and (4) articles that were protocols, conference abstracts, case reports, reviews, or meta-analyses.

Articles were screened in a 2-step process. First, all titles and abstracts were examined by 2 investigators. Any citations that clearly did not meet the inclusion criteria were excluded. Second, all abstracts and full-text articles were examined independently by 2 investigators. Any disagreements in the selection process were resolved through discussion with a third investigator.

Risk of Bias

The included trials were independently assessed by 2 investigators for the risk of bias using the Cochrane risk-of-bias tool [16]. An assessment was performed across 5 domains of bias (sequence generation, allocation concealment, blinding, incomplete outcome data, and selective reporting). The risk of bias was assessed as either low (proper methods taken to reduce bias), high (improper methods creating bias), or unclear (insufficient information provided to determine the bias level). All discrepancies and disagreements were resolved through consensus or, where necessary, by a third author.

Data Extraction

A Microsoft Excel table was used to extract data on the year of publication, country, sample size, participant characteristics, study setting and design, intervention and control arms, duration, and outcome data. The main outcomes included HbA_{1c} or fasting blood glucose (FBG). The secondary outcomes included daily steps (regarded as a physical activity outcome), blood pressure, and weight, among others. The data were obtained from the original text and attachments supplied. Data from different studies were converted to common units. Data extraction was carried out by 2 reviewers independently. All discrepancies and disagreements were resolved through consensus.

Missing Data

Study authors were contacted by email where there were missing or unclear data (for instance, relating to the primary outcome). Studies for which insufficient primary data were available (eg,

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missing data cannot be obtained) were excluded from analysis but not from the review.

Data Synthesis and Quality Assessment

All analyses were conducted using RevMan5.4.1 (Cochrane). Data were expressed as the mean difference (MD) and 95% CI and pooled using fixed-effect or random-effects models according to the heterogeneity. A random-effects model assumes that the study estimates are estimating different, yet related, intervention effects and thus incorporates the heterogeneity among studies. This is a more appropriate method to pool studies that may differ slightly in the distribution of risk factors, population, size, and outcomes.

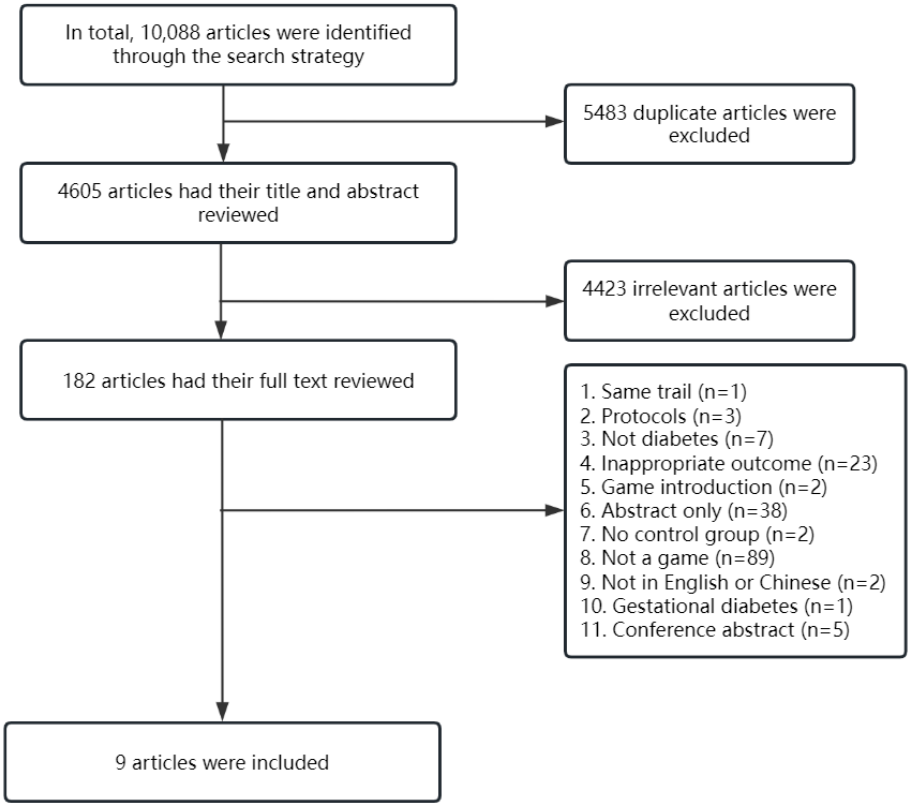
Heterogeneity was assessed using a χ^2 test and quantified using the I^2 statistic. Significance for the heterogeneity was set at $P<.05$, with an $I^2>50\%$ considered to be evidence of high heterogeneity, which prompted us to use the random-effects model to pool the data.

Results

Overview

Our search identified 10,088 articles, of which 4605 were screened after removing duplicate records. Of these, 182 were identified for further evaluation. Of these, 173 were excluded, resulting in 9 included studies (Figure 1). Of the excluded articles, 18 were excluded because they only had abstracts and we could not access the original text and data.

Figure 1. Flowchart of the study selection process.



The results of the remaining 9 studies, comprising 913 participants and 747 cases of type 2 diabetes, were included in the meta-analysis [17-25]. The characteristics of all 9 studies are shown in Multimedia Appendix 3 [17-25]. The duration of trials ranged from 1 month to 1 year. Of the 9 studies, 4 were undertaken in the United States [18,21,23,25], 2 in Europe [17,20], and 3 in Asia [19,22,24]. Of the 9 studies, 3 assessed FBG and 8 assessed HbA_{1c}.

The studies included 2 non–randomized controlled trials (RCTs) and 7 RCTs, the quality of which was assessed using the Cochrane risk-of-bias tool. We determined that 3 studies were of high quality, whereas 4 were of moderate quality and 2 were of low quality (Figures 2 and 3 [17-25]). The 2 non-RCTs were not random and the allocations were unclear. Blinding was difficult in game interventions; 1 study was unblinded [25] and 4 were unclear, but the studies made an effort to blind either patients or personnel. One study was not blinded to the outcome assessment, but it was still analyzed as low risk, considering its main outcome was the objective index. The 9 studies had no elective outcome reporting.

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Figure 2. Risk-of-bias graph showing the authors' judgments about each risk-of-bias item presented as percentages across all the included studies. A total of 9 trials were assessed for risk of bias.

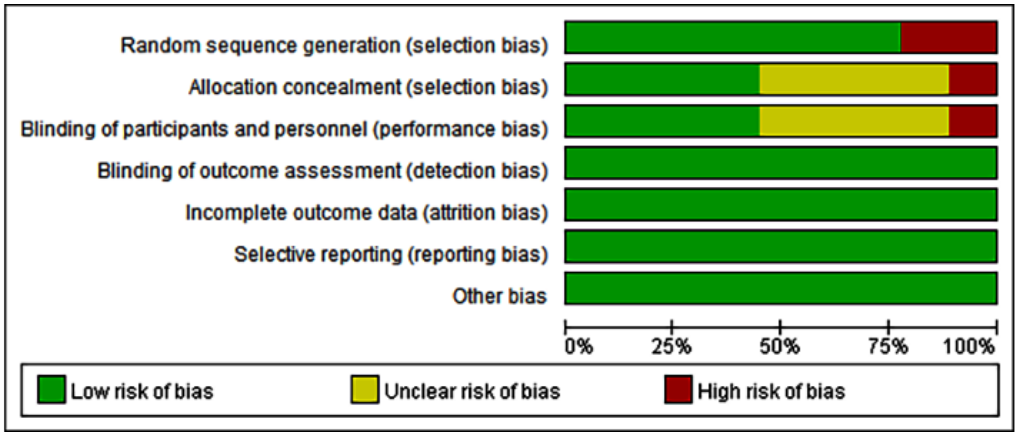
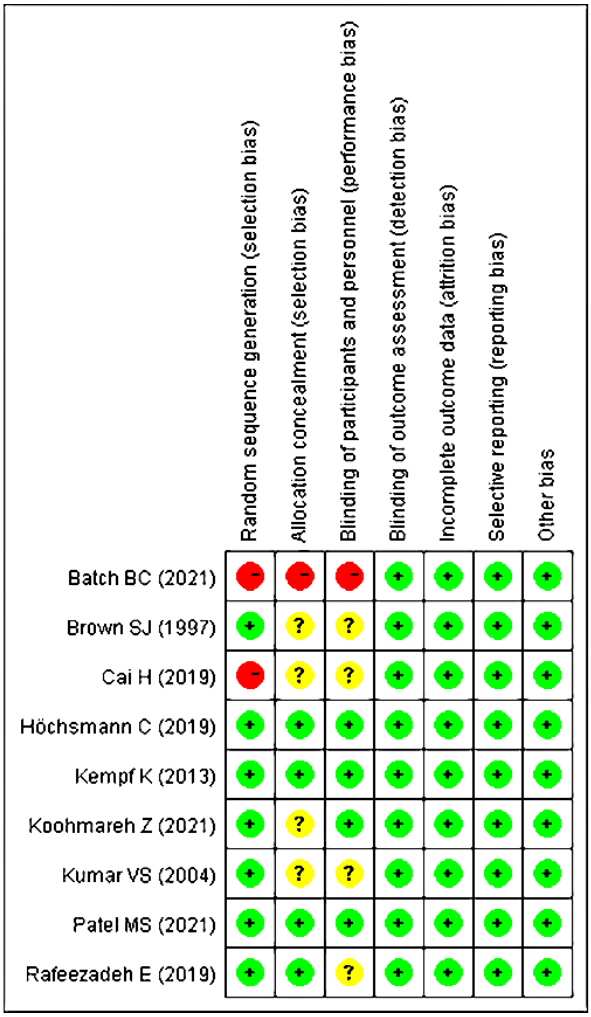


Figure 3. Risk-of-bias summary showing the authors' judgments about each risk-of-bias item for each included study. Green "+": low risk of bias; red "−": high risk of bias; yellow "?": unknown risk of bias.



Publication bias was not assessed for any outcome as <10 trials were available.

Meta-Analysis

HbA_{1c} Level

A total of 8 articles had HbA_{1c} testing but 1 did not provide postintervention data [25]. We sent an email to the author with a request to provide the raw data but received no reply.

As shown in Figure 4A [17,21,23-25], this analysis showed a clinically important improvement in HbA_{1c}, but there was no significant reduction after the intervention among individuals with diabetes mellitus (7 studies; n=607; MD=−0.09%, 95% CI −0.29% to 0.10%; I^2=37%; P=.36). Figure 4B shows the change in HbA_{1c} after a diet-based game intervention (3 studies; n=167; MD=−0.09%, 95% CI −0.48% to 0.30%; I^2=2%; P=.65). Figure 4C shows the change in HbA_{1c} after a physical

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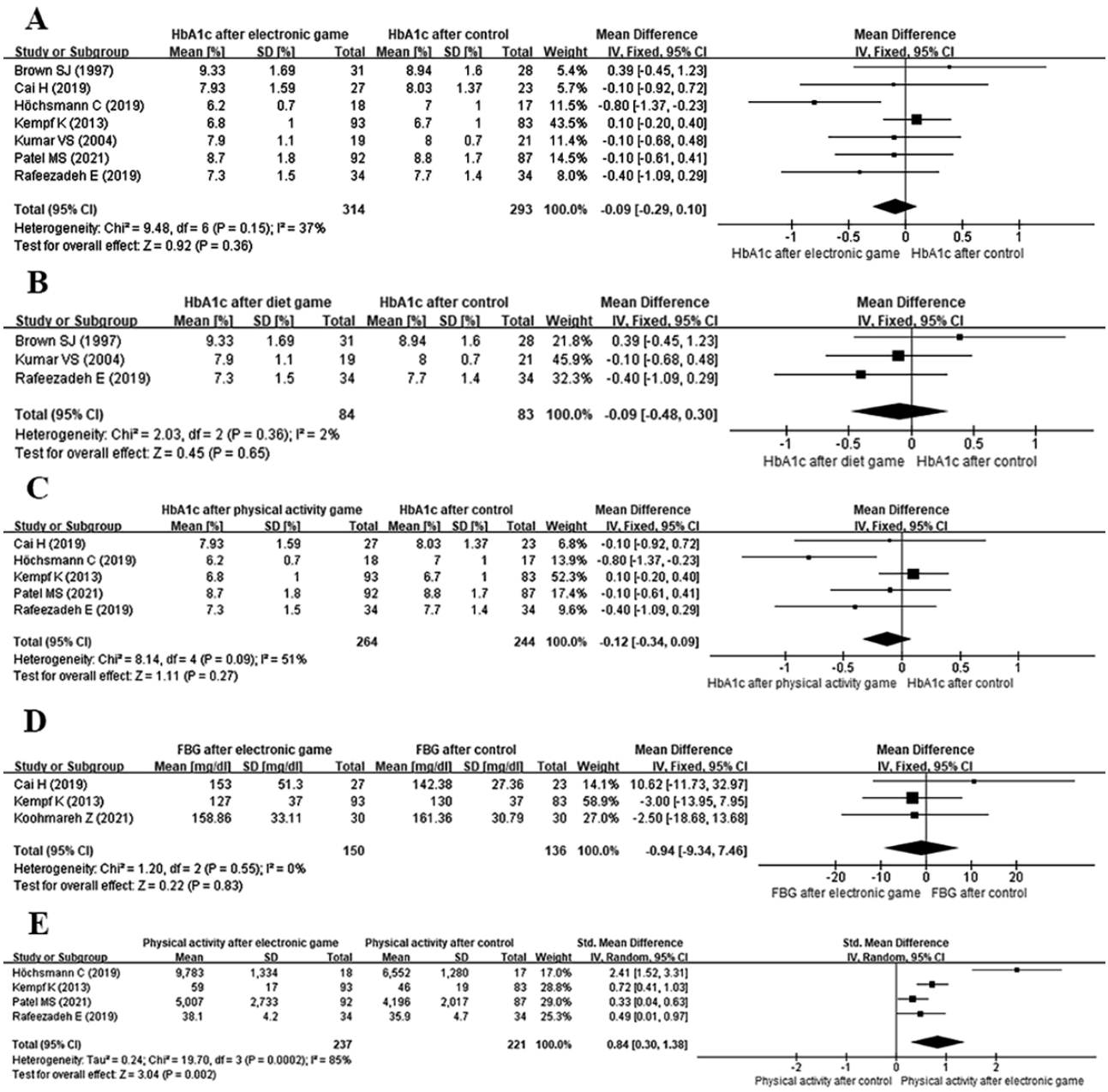
activity–based game intervention (5 studies; n=508, MD=−0.12%, 95% CI −0.34% to 0.09%; I^2=51%; P=.27).

Figure 4. Meta-analysis of the effect of electronic games on HbA_{1c}, FBG, and physical activity. (A) HbA_{1c} after a diet intervention or physical activity intervention; (B) HbA_{1c} after a diet intervention; (C) HbA_{1c} after a physical activity game intervention; (D) FBG after an electronic game intervention; and (E) physical activity after an electronic game intervention. FBG: fasting blood glucose; HbA_{1c}: glycated hemoglobin; IV: inverse variance; Std.: standardized.



Fasting Blood Glucose Level

The meta-analysis showed that the FBG level of the intervention groups was not statistically different from that of the control groups (3 studies; n=286; MD=−0.94 mg/dL, 95% CI −9.34 to 7.46 mg/dL; I^2=0%, P=.83; Figure 4D).

Physical Activity

Of the 7 RCTs, 2 assessed self-reported physical activity and 2 counted participants' daily steps during the intervention to assess the patients' physical activity. Because of the differences in measurement instruments, we calculated standardized mean differences (SMDs). These results were statistically heterogeneous with respect to the effect (χ^2_3=19.70; P<.001; I^2=85%); we found a significant increase in physical activity above baseline in the intervention groups. Moreover, participants assigned to the intervention groups increased their physical activity significantly more than participants in the control groups (SMD=0.84; 95% CI 0.30 to 1.38; P=.002; Figure 4E).

Weight

Weight also trended toward decreases in the intervention groups, with an MD of −1.46 kg (95% CI −4.71 to 1.80 kg; Figure 5A

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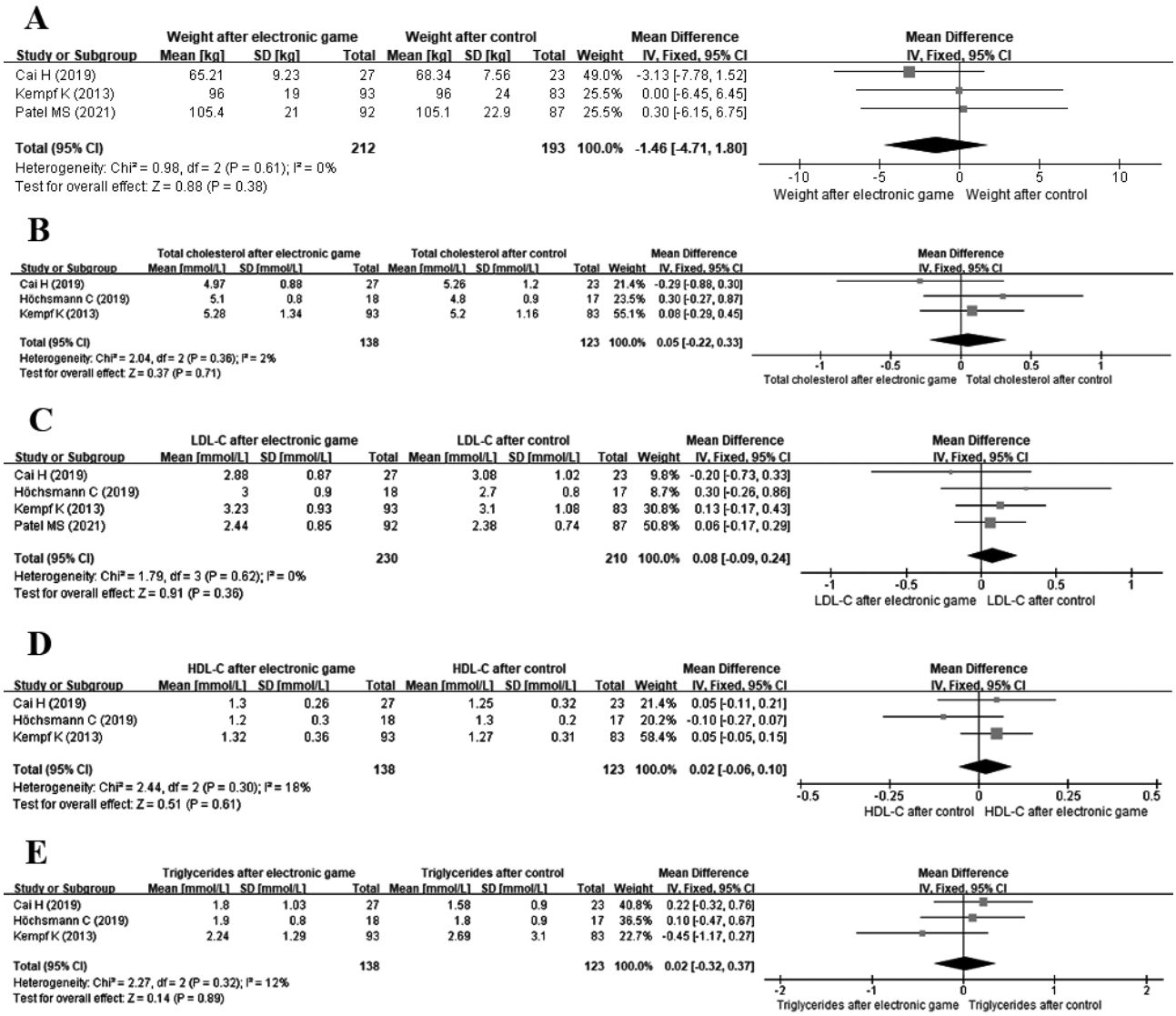
[17-19]). However, the decreases did not reach statistical significance (*P*=.38).

Figure 5. Meta-analysis of the effect of electronic games on (A) weight, (B) total cholesterol, (C) LDL-C, (D) HDL-C, and (E) triglycerides. HDL-C: high-density lipoprotein cholesterol; IV: inverse variance; LDL-C: low-density lipoprotein cholesterol; Std.: standardized.



Blood Lipids

There was no significant reduction in total cholesterol (3 studies; n=261; MD=0.05 mmol/L, 95% CI −0.22 to 0.33 mmol/L; I^2=2%; *P*=.71; Figure 5B), low-density lipoprotein cholesterol (4 studies; n=440; MD=0.08 mmol/L, 95% CI −0.09 to 0.24 mmol/L; I^2=0%; *P*=.36; Figure 5C), high-density lipoprotein cholesterol (3 studies; n=261; MD=0.02 mmol/L, 95% CI −0.06 to 0.10 mmol/L; I^2=18%; *P*=.61; Figure 5D), or triglycerides (3 studies; n=261; MD=0.02 mmol/L, 95% CI −0.32 to 0.37 mmol/L; I^2=12%; *P*=.89; Figure 5E) after the intervention among patients with diabetes mellitus.

Discussion

Principal Findings

This study demonstrated that electronic interactive games were associated with a good impact on participants' physical activity. However, we found that electronic interactive games did not present a significant benefit for HbA_{1c} levels, FBG levels, weight, or blood lipids compared to the control group. The game interventions were intended for education to manage diabetes through games.

Effects of Diet Education Games on Blood Glucose

Plant-based diets and exercise are major diabetes-protective factors [26]. The Da Qing Diabetes Prevention Study showed an overall 51% reduction in diabetes incidence in participants after a 6-year intervention with diet, exercise, or both; its 30-year follow-up showed that lifestyle interventions reduced the incidence of serious diabetes complications and diabetes-related mortality [27]. However, Hemmingsen et al [28] did not find firm evidence that diet alone or physical activity alone influences the risk of type 2 diabetes mellitus or its associated complications in people at increased risk of developing type 2 diabetes mellitus compared to standard treatment [28]. The trials included in this study had little data on the impact of games on

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diet, and only 3 articles evaluated participants' postintervention diet. From the results, education through games was effective, although the improvements in glycemic control were not statistically significant. The most important reason was that the 3 trials studied patients with type 1 diabetes mellitus aged 8 to 18 years. The games provided diabetes-related diet education to the patients, but family-based diet intervention may also not impact glycemic control [29].

Effects of Games Related to Physical Activity on Blood Glucose

Physical activity with different intensities impacts glycemic control in individuals with diabetes. Of the included studies, 4 trials [17,18,20,24] assessed physical activity by daily steps or self-reported activity, and this analysis found a significant increase. These results are consistent with findings from other meta-analyses showing increased physical activity among patients with chronic disease [30-32]. Some studies find positive effects with low-intensity physical activity, although these are not reflected by a decrease in HbA_{1c} or FBG in patients with type 2 diabetes [33-35]. A meta-analysis showed that high-intensity interval exercise significantly reduced HbA_{1c} levels compared to no or low-intensity exercise [36]. Low exercise intensity in the 9 studies we included may be the reason why there was no significant difference in HbA_{1c} and FBG in patients with diabetes between the groups. However, the games in the virtual reality group were relatively novel, which was very helpful for improving cognition, physical skills that are directly involved in functional abilities, and enthusiasm for sports [19].

The study by Höchsmann et al [20] contributed a substantial amount of heterogeneity; without this study, I^2 was 11%. The high heterogeneity may have been caused by the baseline of the participants in this trial being better than those in the other trials. In their trial, Höchsmann et al [20] used a dilapidated garden to symbolize the patient's physical condition, and exercise and daily physical activity execution were tracked by mobile phones, allowing for feedback. After 24 weeks of intervention, there was no significant change in HbA_{1c} levels in the intervention group, while HbA_{1c} levels in the control group receiving 1-time lifestyle counseling increased. In the trial, the intervention group had a higher increase in daily steps than the control group, providing evidence that physical activity can be encouraged by electronic games.

Effects of Games on Blood Lipids, Blood Pressure, and BMI

In our study, game-based intervention resulted in no significant decrease in blood lipids in patients with diabetes. Only 2 trials reported the outcomes of blood pressure [17,20] and BMI [17,19], and the 2 indexes were both reduced. Systolic blood pressure was below 140 mm Hg but above 130 mm Hg, which is still high for patients with diabetes. Treatment with medication may be indispensable.

Effects of Games on Weight

Lifestyle intervention can be effective for achieving clinically important reductions in body weight [37,38]. It has been demonstrated that electronic game activities are engaging, which encourages their use on a regular basis, improving the long-term outcome of a treatment for obesity [39,40]. However, an intervention using a different avatar did not improve physical activity practice or self-efficacy expectations [41]. Gomez et al [42] showed that high exercise intensity from active electronic games elicited significant increases in energy expenditure. In this study, electronic games did not result in significant weight reduction, and BMI was reduced slightly in 2 trials. Possible reasons include insufficient physical activity and that participants did not strictly control their diet. Whether electronic games are beneficial for weight control by encouraging appropriate intensity exercise in patients with diabetes requires more clinical evidence in the future.

The reasons for the lack of significant results in this meta-analysis may be as follows. First, participants in the control groups were also familiar with what the game taught. Second, patients with type 2 diabetes mellitus in the intervention groups, who were all older than 40 years, could not make full use of electronic devices and adapt to the games. Third, for exercise-based interventions, not all studies involved regular exercise monitoring for participants and established appropriate feedback or interaction mechanisms.

Limitations and Future Directions

This study had several limitations. First, not every included study reported the HbA_{1c} and FBG levels. Some excluded studies had relevant interventions but did not observe blood glucose changes or failed to give detailed trial data results. Second, the studies that were included in this meta-analysis were not homogeneous. Different games or game mechanisms were used in different patient populations. The number of participants was not large in several of the included studies, and each study used different games. Therefore, it is difficult to conduct detailed hierarchical verification of the effects of different games on blood glucose. We strived to ensure that the included studies were high-quality RCTs with strict inclusion and exclusion criteria, excluding nongaming electronic interventions. Existing studies have evaluated the effectiveness of electronic games as an alternative for traditional diabetes education. As diabetes continues, it is necessary to promote this management model. However, future studies should not only design the game in terms of increased knowledge and improved self-management but should encourage enhanced physical activity intensity.

Conclusion

As an alternative treatment tool in diabetes management, the studies on electronic games explored in this study showed a clinical improvement in glycemic control and weight control, although this improvement was not superior to that observed in the control participants. Thus, such interventions may complement existing treatment courses for diet, self-management education, and high-intensity physical activity to potentially increase the compliance of patients with diabetes. More new technologies can be used for diabetes control, and electronic games can be designed for different groups of patients with diabetes. For example, immersive virtual reality is an emerging strategy to enhance exercise performance for young

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patients with diabetes, and the metaverse may be a new community enabling older patients to form new social connections and share their experiences of living with diabetes. Interactive exercise games can be used in children to increase interest in education and family companionship time, and thus improve exercise compliance.

Acknowledgments

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Authors' Contributions

Y Cheng conceived the idea of the overview and wrote the protocol and full overview. WY and YH developed the concept and details of the overview (ie, participants, intervention, comparison, outcomes). WY and Y Chen carried out searches and selected reviews for inclusion (YH acted as an arbitrator). WY and SY carried out the assessment of methodological quality (YH acted as an arbitrator). WY and SY extracted the data and interpreted the initial findings. YH and Y Chen directed data analyses. WY, YH, LY, and Y Cheng formulated the focus of the discussion and made suggestions for future studies. All authors were involved in the interpretation of the results and in approving the final review.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 checklist.
[DOCX File , 28 KB - games_v12i1e43574_app1.docx]

Multimedia Appendix 2
Search strategy.
[PDF File (Adobe PDF File), 116 KB - games_v12i1e43574_app2.pdf]

Multimedia Appendix 3
Basic characteristics of the included studies.
[DOCX File , 21 KB - games_v12i1e43574_app3.docx]

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Abbreviations

FBG: fasting blood glucose
HbA_{1c}: glycated hemoglobin
MD: mean difference
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial
SMD: standardized mean difference

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Review

Virtual Reality Therapy for the Management of Chronic Spinal Pain: Systematic Review and Meta-Analysis

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Abstract

Background: The effectiveness of virtual reality (VR) therapy in adults with chronic spinal pain (CSP) is unclear.

Objective: This study was conducted to compare the effectiveness of VR therapy and other therapies in adults with CSP, especially patients with inflammation-related pain.

Methods: PubMed, Web of Science, Cochrane Library, Embase, and CINAHL databases were searched up to November 11, 2023. Randomized controlled trials (RCTs) comparing adults with CSP receiving VR therapy with those receiving other therapies were included. The trial registration platform as well as the reference lists of included studies and previous systematic reviews and meta-analyses were manually searched. Two independent reviewers performed study selection, data extraction, risk-of-bias assessment, and evaluation of the quality of the evidence. The weighted mean difference (WMD) was used as the effect size used to synthesize the outcome measure.

Results: In total, 16 RCTs involving 800 participants were included in this meta-analysis. The pooled data from 15 (94%) RCTs including 776 (97%) participants showed that VR therapy was superior in improving pain intensity (WMD=–1.63, 95% CI –2.11 to –1.16, $P<.001$, $I^2=90\%$) and reducing inflammatory markers, including C-reactive protein (WMD=–0.89, 95% CI –1.07 to –0.70, $P<.001$, $I^2=0\%$), tumor necrosis factor-alpha (WMD=–6.60, 95% CI –8.56 to –4.64, $P<.001$, $I^2=98\%$), and interleukin-6 (WMD=–2.76, 95% CI –2.98 to –2.53, $P<.001$, $I^2=0\%$). However, no significant differences were found in terms of the spinal range of motion (ROM), disability level, or fear of movement. In addition, 10 (63%) of the included RCTs had a high risk of bias.

Conclusions: VR therapy may be an effective and safe intervention for reducing symptoms in patients with CSP, as it is shown to exert significant analgesic effects and beneficial improvements in inflammatory factor levels. However, this approach may not have significant effects on the spinal ROM, disability level, or fear of movement. Notably, the quality of the evidence from the RCTs included in this study ranged from moderate to low. Therefore, we recommend that readers interpret the results of this study with caution.

Trial Registration: PROSPERO CRD42022382331; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=382331

(JMIR Serious Games 2024;12:e50089) doi:10.2196/50089

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KEYWORDS

virtual reality; chronic spinal pain; inflammation-related pain; systematic review; meta-analysis

Introduction

Chronic spinal pain (CSP), which most commonly includes chronic low back pain (CLBP) and chronic neck pain (CNP), is the leading cause of years with disability worldwide [1,2] and constitutes the most frequent reason for patients to seek medical care in any given year. The lifetime prevalence of low back pain (LBP) is 84%; more specifically, the lifetime prevalence of CLBP is 23%, and LBP accounts for approximately 11%-12% of cases of disability [3]. CSP is recognized as a biopsychosocial syndrome [4]. Prolonged pain can lead to anxiety, depression, and other negative emotions and is particularly significant in patients with CSP, as it is associated with decreased quality of sleep and reduced physical activity, thus placing tremendous strain on health care systems and world economies [5].

Previous studies have reported that an intervertebral disc undergoes aging or pathological changes in the adjacent region in patients with CSP, exposing cells within the nucleus pulposus to macrophages, resulting in an inflammatory response that might trigger pain [6,7]. The guidelines recommend that nonsteroidal anti-inflammatory drugs (NSAIDs) be the primary choice for patients with chronic pain [8]. However, compared with a placebo, NSAIDs can reduce CSP by controlling the level of inflammation but do not achieve clinically important efficacy [9]. Additionally, long-term use may be associated with adverse effects (eg, gastrointestinal reactions, hepatic and renal damage, and cardiovascular risk) [10]. Several studies have shown that conventional nonpharmacological therapies, such as spinal manipulation, acupuncture, exercise therapy, yoga, and cognitive-behavioral therapy, are beneficial for reducing CSP and improving psychological symptoms but have limited effects (small to moderate) [11-14]. Effective cognitive-behavioral therapies are not widely accessible due to the reliance on therapist experience, and the long-term effectiveness of these therapies remains unclear [15]. Notably, the majority of patients with CSP have goals of pain management (using ongoing care) rather than “curing” (care with a specific end) for their therapeutic care because of the complexity of the causes of chronic pain [16]. Thus, pain management is as important as the control of inflammation levels for patients with CSP. There is an urgent need for an alternative analgesic nonpharmacological and anti-inflammatory strategy for patients with CSP.

Virtual reality (VR) is typically characterized by low cost, easy availability, reusability, and personalized customization; VR therapy has been used as an alternative approach for pain management in various populations, such as individuals with spinal cord injuries, burns, and phantom limb pain [17-19]. VR can be categorized into 2 types: nonimmersive virtual reality (NIVR) and immersive virtual reality (IVR). NIVR is managed using a computer or console gaming system and a 2D interface device (mouse, keyboard, or gamepad, joystick), and patients do not need to be fully immersed in a virtual environment for experience [20].With the use of professional equipment, hardware, and configuration of the corresponding software, IVR can mimic reality by enabling the user to interact with the virtual environment [21]. A recent study demonstrated that regular exercise with the use of VR might be related to a decrease in inflammation in participants undergoing chronic hemodialysis [22], and inflammatory arthritis–targeting innovative teaching approaches based on VR technology are considered feasible [23]. There is limited evidence regarding the beneficial effects of VR therapy on pain in patients with CNP [24] and CLBP [25,26]; furthermore, there is insufficient focus on inflammatory factors. Therefore, this study aimed to investigate the potential efficacy of VR in reducing pain intensity and the levels of inflammatory factors in patients with CSP, thereby providing an updated summary of the existing evidence.

Methods

Study Protocol and Registration

This systematic review and meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. The PRISMA checklist is given in Multimedia Appendix 1. The study protocol was registered in the PROSPERO database (CRD42022382331). The *Cochrane Handbook for Systematic Reviews of Interventions* (version 5.1.0) was followed [27].

Search Strategy

Search Sources

PubMed, Web of Science, Cochrane Library, Embase, and CINAHL electronic databases were searched from inception to November 11, 2023, to identify relevant studies. The reference lists of the included studies, as well as systematic reviews and meta-analyses that examined the efficacy of VR in patients with CSP, were manually searched for additional eligible studies. The trial registration platform ClinicalTrials was also searched for ongoing studies that reported sufficient data on the efficacy of VR for CSP.

Search Terms

The studies on VR for CSP were identified by formulating appropriate search terms. These terms were selected based on the target population (spinal pain, neck pain, thoracic pain, back pain, LBP, sacral pain, and intervertebral disc pain), target intervention (eg, VR), and target study design (eg, randomized controlled trial [RCT]). The detailed search strategy is shown in Multimedia Appendix 2.

Study Eligibility Criteria

The inclusion criteria were as follows:

- Participants: adults older than 18 years with chronic pain (more than 12 weeks) in the spinal region were included, except those who were receiving analgesic medication and who had cancer-related pain or neuropathic pain (eg, neuropathic pain after spinal cord injury, herniated disc with compression, sciatica, or lumbosacral radiculitis).

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- Intervention: VR therapy.
- Comparisons: sham stimulation, usual care, and conventional treatment.
- Outcomes: pain intensity, inflammatory markers (eg, C-reactive protein [CRP], tumor necrosis factor-alpha [TNF-α], and interleukin [IL]-2, IL-4, and IL-6), fear of movement, spinal range of motion (ROM), and disability level.
- Study design: RCT.

No restrictions were imposed on language or publication date.

Study Selection

The retrieved studies were imported into Endnote X9 software (Clarivate), which was used to eliminate duplicate studies. Two independent reviewers (authors TTZ and FW) performed the initial screening of the literature by reading the titles and abstracts of all retrieved studies, and studies that did not meet the inclusion criteria were excluded. Next, the full texts of the remaining studies were screened. Any disagreements were resolved by negotiation and discussion with a third reviewer (author XZ).

Data Extraction

Two independent reviewers (authors FW and XL) extracted detailed information, including the name of the first author, the year and country of publication, the language of publication, study design, the number of included subjects (% female), diagnosis, and outcome indicators. Information about the characteristics of the interventions, including dose, frequency, and duration, was also collected for both the VR group and the control group. The sample size and mean (SD) of the outcome indicators in each group were collected. When the same group of participants was reported in different studies, the group with the largest sample size was selected for inclusion in this review to avoid duplicate publications [28]. For information that could not be confirmed, the authors were contacted by email. The 2 reviewers cross-checked the data at the end of the extraction, and any disagreements were resolved by negotiation.

Risk-of-Bias Assessment

The methodological quality of the included studies was independently assessed by 2 reviewers (authors XL and ZFH) using the Cochrane Risk of Bias tool, and the studies were classified as having a low, unclear, or high risk of bias [29]. Disagreements were resolved by consulting a third reviewer (author QD). The Egger test and funnel plots generated with Stata 14.0 software (StataCorp) were used to evaluate potential publication bias. The trim-and-fill method was used to adjust for funnel plot asymmetry due to publication bias [30]. Sensitivity analyses were performed by removing each study separately to assess the robustness of the results [29]. The overall strength of the evidence was assessed using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) criteria [31].

Meta-Analysis and Subgroup Analysis

This systematic review and meta-analysis were performed using Review Manager software 5.4 (Informer Technologies) and Stata 14.0 software. Heterogeneity was tested using the I^2 statistic. A fixed effects model was selected for the outcome indicators if I^2<50%, while a random effects model was used when there was significant statistical heterogeneity (I^2>50%, P<.05). The effect size used to synthesize the outcome measure was the weighted mean difference (WMD). Three subgroup analyses were performed to explore the possible causes of heterogeneity among the studies: the region of CSP (CNP vs CLBP), VR types (IVR vs NIVR), and treatment duration (<4 weeks vs ≥4 weeks).

Results

Search Results

A total of 924 records were obtained from the 5 databases and the trial registration platform. A total of 394 (42.6%) duplicates were identified and removed using Endnote X9 software. After screening the titles and abstracts, 40 (7.5%) of the remaining 530 RCTs were retained, and 490 (92.5%) were excluded for the following reasons: (1) the study population included patients without CSP, (2) the intervention did not use VR therapy, (3) the type of study was a non-RCT, (4) the information was incomplete, and (5) the patients also received analgesic medication. Of the 40 studies, 15 (38%) were retained after reading the full text and 25 (62%) were excluded for the following reasons: (1) the study population included patients without CSP, (2) the intervention did not use VR therapy, (3) the type of study was a non-RCT, (4) the information was incomplete, and (5) the patients also received analgesic medication. Two additional RCTs were retrieved from the reference lists of the included studies. One RCT was retained after the full text was read, and the other was excluded due to incomplete information. A total of 16 studies were included in this review, 15 (94%) of which reported sufficient data (eg, mean [SD], sample size) on the analgesic effect of VR for CSP. Therefore, 15 studies were included in the meta-analysis. The PRISMA flowchart of selecting the included studies is shown in Figure 1.

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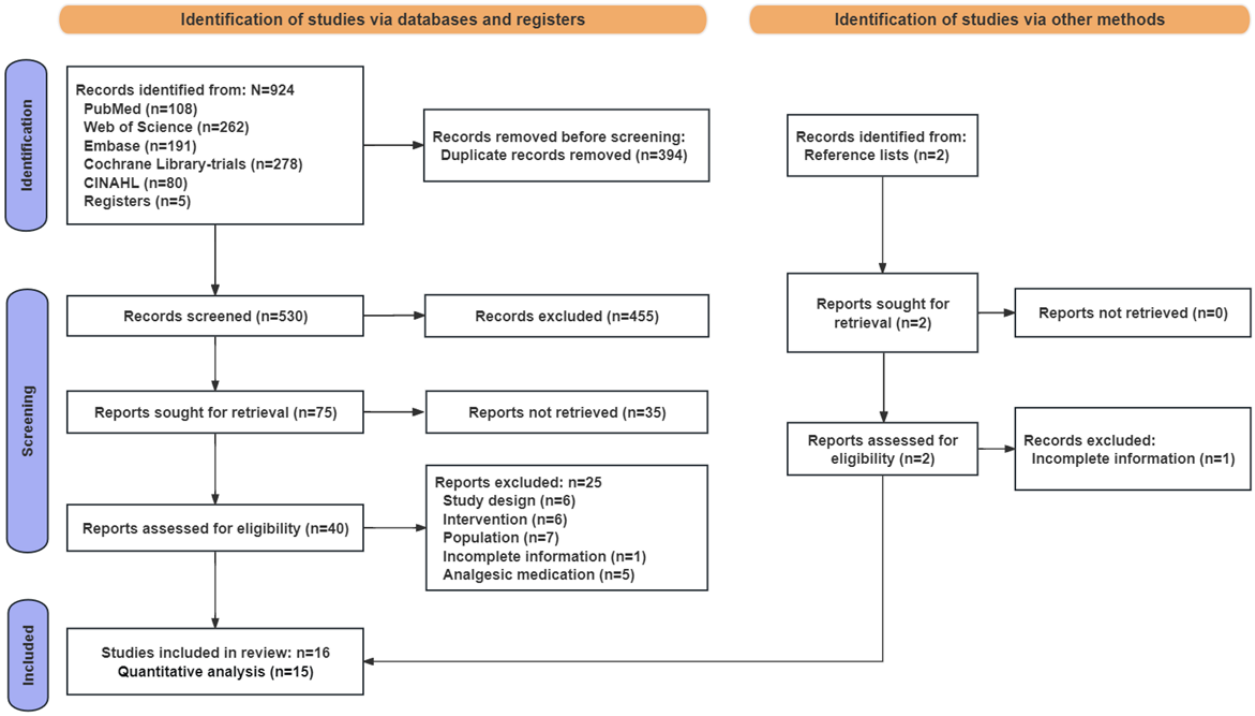
Figure 1. PRISMA flowchart: database and clinical trial register search and other sources. PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analysis.



The CSP reported in the included studies included CLBP [32-43] and CNP [44-47]. All patients had chronic pain that persisted for more than 3 months. The sample size varied from 8 to 90 participants, and the mean age ranged from 18 to 85 years. The characteristics of all the studies are summarized in Table 1.

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Table 1. Characteristics of the included studies [32-47].

First author	Patient characteristics			Outcome measures	Time points	Dropout rate (%)	Country, language
	Participants, n (% female)	Age (years), mean (SD)	Diagnosis				
Garcia et al [32]	T[a]: 179 I[b]: 89 (75) C[c]: 90 (78)	I: 51.5 (13.5) C: 51.4 (12.9)	CLBP[d]	DVPRS[e], Pain Catastrophizing Scale (PCS), 8-item Chronic Pain Acceptance Questionnaire (CPAQ-8)	Baseline, –7, 0, 4, 7, 11, 14, 18, 21, 25, 28, 32, 35, 39, 42, 46, 49, 53, 56 days	I: 0 C: 0	United States, English
Nambi et al [33]	T: 60 I (VR[f]): 20 I (core stabilization [CS]): 20 C: 20	I (VR): 21.45 (1.50) I (CS): 21.39 (1.40) C: 20.97 (1.50)	CLBP	NPRS[g], quality of life (physical fitness index)	Baseline, 4 weeks, 8 weeks, 6 months	I (VR): 0.05 I (CS): 0.05 C: 0	Saudi Arabia, English
Nambi et al [34]	T: 45 I (VR): 15 I (isokinetic training [IKT]): 15 C: 15	I (VR): 20.23 (1.60) I (IKT): 21.25 (1.20) C: 20.78 (1.60)	CLBP	NPRS	Baseline, 4 weeks	I (VR): 0 I (IKT): 0 C: 0	Saudi Arabia, English
Yalfani et al [35]	T: 25 I: 13 C: 12	I: 68.00 (2.94) C: 67.08 (2.90)	CLBP	VAS[h], 36-item Short Form Health Survey (SF-36)	Baseline, 8 weeks	I: 0 C: 0	Iran, English
Park et al [36]	T: 24 I (NWE[i]): 8 I (lumbar stabilization exercise [LSE]): 8 C: 8	I (NWE): 44.12 (5.48) I (LSE): 43.37 (5.42) C: 45.50 (5.34)	CLBP	VAS	Baseline, 8 weeks	I: 0 C: 0	South Korea, English
Afzal et al [37]	T: 90 I: 45 (64.28) C: 45 (69.04)	I: 37.5 (12.5) C: 38.2 (11.8)	CLBP	VAS, Modified Oswestry Disability Index	Baseline, 4th, 8th 12th sessions	I: 0.07 C: 0.07	Pakistan, English
Nambi et al [38]	T: 60 I (VRE[j]): 20 I (isokinetic exercise [IKE]): 20 C: 20	I (VRE): 23.2 (1.6) I (IKE): 22.9 (1.7) C: 22.8 (1.8)	CLBP	VAS, inflammatory biomarkers	Baseline, 4 weeks	I (VRE): 5 I (IKE): 5 C: 0	Saudi Arabia, English
Nambi et al [39]	T: 36 I (VR): 12 I (combined physical rehabilitation [CPR]): 12 C: 12	I (VR): 21.3 (2.6) I (CPR): 21.8 (2.2) C: 20.9 (2.8)	CLBP	Inflammatory biomarkers	Baseline, 4 weeks	I (VR): 0 I (CPR): 0 C: 0	Saudi Arabia, English
Nambi et al [40]	T: 54 I (VR): 18 I (CPR): 18 C: 18	I (VR): 22.3 (1.6) I (CPR): 21.4 (1.8) C: 21.9 (1.8)	CLBP	VAS, TSK-17	Baseline, 4 weeks	I (VR): 0 I (CPR): 0 C: 0	Saudi Arabia, English

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First author	Patient characteristics			Outcome measures	Time points	Dropout rate (%)	Country, language
	Participants, n (% female)	Age (years), mean (SD)	Diagnosis				
Matheve et al [41]	T: 84 I: 42 (64) C: 42 (64)	I: 42.1 (11.5) C: 44.2 (11.9)	CLBP	NPRS, Roland-Morris Disability Questionnaire (RMDQ), PCS	Baseline, postintervention	I: 0 C: 0	Belgium, English
Stamm et al [42]	T: 22 I: 11 (73) C: 11 (55)	I: 75.00 (5.80) C: 75.50 (4.39)	CLBP	NRS[k], Chronic Pain Grade Questionnaire (CPGQ), 12-item Short Form Health Survey (SF-12), Hannover Functional Ability Questionnaire for Measuring Back Pain–Related Disability (Ffb-H-R), TSK[l]-11	Baseline, 4 weeks	I: 0 C: 0	Germany, English
Monteiro-Junior et al [43]	T: 34 I: 17 (100) C: 17 (100)	T: 68 (4)	CLBP	NRS	Baseline, 8 weeks	I: 17.6 C: 5.8	Brazil, English
Cetin et al [44]	T: 41 I: 21 C: 20	I: 40.00 (11.88) C: 41.94 (10.76)	CNP[m]	Joint position sense error (JPSE), VAS, pressure pain threshold (PPT), SF-36	Baseline, 6 weeks	I: 19 C: 15	Turkey, English
Bahat et al [45]	T: 90 I (VR): 30 (63) I (laser): 30 (70) C: 30 (77)	I (VR): 48.00 (14.07) I (laser): 48.00 (17.41) C: 48.00 (17.76)	CNP	NDI[n], VAS, EQ-5D, TSK-17, cervical range of motion (CROM), kinematic measures	Baseline, 4 weeks	I (VR): 16.6 I (laser): 13.3 C: 16.6	Israel, English
Nusser et al [46]	T: 55 I (VR): 17 (53) I (sensorimotor group [SM]): 16 (69) C: 18 (66)	I (VR): 51.2 (8.8) I (SM): 53.1 (5.7) C: 49.8 (8.1)	CNP	NRS, active cervical range of motion (ACROM), NDI	Baseline, 3 weeks	I (VR): 0 I (SM): 11 C: 10	Germany, English
Tejera et al [47]	T: 44 I: 22 (50) C: 22 (54.5)	I: 32.72 (11.63) C: 26.68 (9.21)	CNP	VAS, conditioned pain modulation (PPT), ACROM device, NDI, PCS, 11-item Spanish version of the TSK	Baseline, 4 weeks, 1 month, 3 months	I: 0 C: 0	Spain, English

[a]T: total participants.
[b]I: intervention group.
[c]C: control group.
[d]CLBP: chronic low back pain.
[e]DVPRS: Defense and Veterans Pain Rating Scale.
[f]VR: virtual reality.
[g]NPRS: Numerical Pain Rating Scale.
[h]VAS: Visual Analogue Scale.
[i]NWE: Nintendo Wii exercise.
[j]VRE: virtual reality exercise.
[k]NRS: Numeric Rating Scale.
[l]TSK: Tampa Scale for Kinesiophobia.
[m]CNP: chronic neck pain.
[n]NDI: Neck Disability Index.

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The types of VR interventions included IVR [32,35,42,44-47] and NIVR [33,34,36-41,43], which were classified based on the degree of isolation participants experienced when interacting with the virtual environment during VR therapy. NIVR uses a wall-mounted screen or a computer monitor as the vehicle for VR content, while IVR uses a headset or head-mounted display [48]. Compared to NIVR, IVR can increase the user's sense of presence by improving immersion through the addition of auditory or haptic feedback [49]. The duration of a single VR session ranged from 2 to 40 minutes, and the frequency of treatment ranged from 5 to 7 times a week; all the included studies ranged in duration from a single exercise session to 8 weeks. For the control groups, 5 (31%) studies performed conventional balance function training [33,34,38-40], 5 (31%) performed conventional physical therapy [36,37,41,46,47], 2 (13%) performed core training [43,44], and the remaining conducted treatments, including sham VR [32], conventional multimodal pain therapy [42], waiting lists [45], and standard care [35]. The intervention details are summarized in Table 2.

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Table 2. Characteristics of the intervention protocols used in the included studies [32-47].

First author	Intervention group	Control group	Device	Duration
Garcia et al [32]	Ease VR[a], IVR[b], interactive, pain education, relaxation/interception, mindful escape, pain distraction games, dynamic breathing performed 56 times (2-16 minutes each time, average of 6 minutes, 1 time/day)	Sham VR, NIVR[c], not interactive, displayed 2D nature footage with neutral music, 20 videos rotated over 56 sessions, performed 56 times (2-16 minutes each time, average of 6 minutes, 1 time/day)	Pico G2 4K all-in-one head-mounted VR device	8 weeks
Nambi et al [33]	VR group: sit in the virtual platform and select firing game executed by trunk movements (flexion, extension, and lateral flexion; 30 minutes/day, 5 times/week, for 4 weeks); heat modality (20 minutes); therapeutic ultrasound (25 minutes)	Conventional balance function training, traditional active balance exercise for abdominal and back muscles (5 times/week for 4 weeks); heat modality (20 minutes); therapeutic ultrasound (25 minutes)	VR group: Pro-Kin system PK 252 N (TecnoBody)	4 weeks
Nambi et al [34]	VRT: shooting game (30 minutes, 5 days/week, for 4 weeks); home-based exercise; hot-pack therapy (20 minutes); ultrasound (frequency 1 MHz, intensity 1.5 W/cm^2 in continuous form for 5 minutes)	Conventional balance function training: standardized conventional exercises actively involving abdominal, deep abdominal, and back muscles (30 minutes/session, 5 days/week, for 4 weeks); hydrocollator packs (20 minutes/session); continuous ultrasound (frequency 1 MHz, intensity 1.5 W/cm^2) at the low back region (5 minutes, 5 days/week, for 4 weeks)	VRT: Pro-Kin system (TecnoBody)	4 weeks
Yalfani et al [35]	Fishing, boxing, tennis, football, bowling, beat saber, audio shield, and skiing (30 minutes, 3 times/week, for 8 weeks)	Standard care.	VR: HTC Vive virtual reality system	8 weeks
Park et al [36]	NWE[d]: using the Nintendo Wii exercise program, including the wakeboard, Frisbee dog, jet ski, and canoe games. Participants chose which Nintendo Wii sports program to perform and took a 2-minute break every 10 minutes (30 minutes/session, 3 times/week, for 8 weeks)	Conventional physical therapy: using physical agent modalities, such as a hot pack (30 minutes); interferential current therapy (15 minutes); deep heat with ultrasound (5 minutes)	VR: Nintendo	8 weeks
Afzal et al [37]	Kinetic exergames (trunk slide flexion, sitting to avoid obstacles, jumping and combined movement of arms, for 5 minutes); after 30 seconds of rest, play body ball game for 5 minutes (3 sessions/week for a total of 12 sessions); routine physical therapy	Conventional physical therapy: heat therapy for 10 minutes, hamstring stretching, back-strengthening exercises (3 sessions/week for a total of 12 sessions)	VR: nonimmersive system with a kinetic device (model V.2), incorporated with red-green-blue (RGB) cameras and time-of-flight (TOF) sensor, attached with a liquid crystal display (LCD) screen	4 weeks
Nambi et al [38]	VRE[e]: virtual training exercises performed in the upright position, a car race game chosen from the list of games, and training given to focus on the back muscles. The participant was asked to sit on the moving game chair and instructed to watch the game on the desktop monitor (30 minutes/session, 5 days/week, for 4 weeks); hydrocollator packs (20 minutes/session); continuous ultrasound (frequency 1 MHz, intensity 1.5 W/cm^2) at the low back region (5 minutes, 5 days/week, for 4 weeks)	Conventional balance function training: standardized conventional exercises actively involving abdominal, deep abdominal, and back muscles (30 minutes/session, 5 days/week, for 4 weeks); hydrocollator packs (20 minutes/session); continuous ultrasound (frequency 1 MHz, intensity 1.5 W/cm^2) at the low back region (5 minutes, 5 days/week, for 4 weeks)	VRE: Pro-Kin system (TecnoBody)	4 weeks

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First author	Intervention group	Control group	Device	Duration
Nambi et al [39]	Virtual reality training (VRT): shooting game, sitting on a virtual platform and visualizing the game on the computer display screen (30 minutes each time, 5 times/week, for 4 weeks); heat modality (20 minutes); therapeutic ultrasound (frequency 1 MHz, intensity 1.5 W/cm^2; 5 minutes); home-based exercise (10 repetitions, bottom-to-heel stretch, opposite arm/leg raise, back extension, bridging, knee rolling; 2 times/day for 4 weeks)	Conventional balance function training: active isotonic and isometric exercises for abdominal, deep abdominal, and back muscles (10-15 repetitions/day, 5 days/week for 4 weeks; stretching focused on each muscle group for 3 repetitions for 10 seconds per muscle group); heat modality (20 minutes); therapeutic ultrasound (frequency 1 MHz, intensity 1.5 W/cm^2; 5 minutes); home-based exercise (10 repetitions, bottom-to-heel stretch, opposite arm/leg raise, back extension, bridging, knee rolling; 2 times/day for 4 weeks)	VR: Pro-Kin system PK 252 N (Pelvic Module balance trunk MF; TecnoBody)	4 weeks
Nambi et al [40]	VRT: shooting game, sitting on a virtual platform and visualizing the game on the computer display screen (30 minutes each time, 5 times/week, for 4 weeks); heat modality (20 minutes); therapeutic ultrasound (frequency 1 MHz, intensity 1.5 W/cm^2; 5 minutes)	Conventional balance function training: active isotonic and isometric exercises for abdominal, deep abdominal, and back muscles (10-15 repetitions/day, 5 days/week for 4 weeks; stretching focused on each muscle group for 3 repetitions for 10 seconds per muscle group); heat modality (20 minutes); therapeutic ultrasound (frequency 1 MHz, intensity 1.5 W/cm^2; 5 minutes)	VR: Pro-Kin system PK 252 N (Pelvic Module balance trunk MF; TecnoBody)	4 weeks
Matheve et al [41]	2 different games (2 minutes each); single-session intervention, 2 × 2 minutes of pelvic tilt exercises in the sagittal plane, with 30 seconds of rest in between, through a wireless motion sensor	Conventional physical therapy: 2 different games (2 minutes each); single-session intervention, 2 × 2 minutes of pelvic tilt exercises in the sagittal plane, with 30 seconds of rest in between	VR: wireless motion sensor (Valedo Pro, Hocoma)	Single exercise session
Stamm et al [42]	Multimodal pain therapy in VR (movement therapy and psychoeducation), training session including 12 exercises, structured as follows: (1) warm-up (training of upper and lower extremities), (2) main part (strengthening of abdominal and back muscles, core stability), (3) cool-down (stretching, progressive muscle relaxation), (4) psychoeducative units (topics: physiology of pain, pain management, stress management, everyday training), 3 times/week for 30 minutes	Conventional multimodal pain therapy: chair-based group exercises and psychoeducation in a group setting), 3 times/week for 30 minutes	VR: head-mounted display headset using the ViRST VR app	4 weeks
Monteiro-Junior et al [43]	Virtual physical training (8 exercises, 30 minutes each time, with 3 weekly sessions lasting 90 minutes each), lasted 8 weeks, 3 times weekly/session	Core training: postures adopted by participants for 15-30 seconds or according to the capacity of each; 10-15 seconds between postures (ie, bridges), with each performed 3 times, lasted 8 weeks, 3 times weekly/session	VR: Wii Balance Board (WBB; Nintendo)	8 weeks
Cetin et al [44]	VR exercises: VR apps that allowed neck movements in all directions, motor control (MC) exercises (20 minutes and then VR for 20 minutes, 5 repetitions for each exercise; 40 minutes/session, 3 sessions/week, for 6 weeks, total of 18 sessions)	Core training: strengthening of deep cervical flexors (DCFs), deep cervical extensors (DCEs), and axioscapular muscles; stretching exercises; and postural correction exercises (40 minutes, 10 repetitions for each exercise, 3 sessions/week, for 6 weeks, total of 18 sessions)	VR: Oculus Go VR glasses, 2 VR apps installed: “Ocean Rift” and “Gala 360”	6 weeks

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First author	Intervention group	Control group	Device	Duration
Bahat et al [45]	VR group: kinematic home training and customized software with the virtual airplane controlled by head motion (5 minutes, 4 times/day, 20 minutes/day, 4 times/week, for 4 weeks)	Waiting list	VR: customized neck VR system (hardware including Oculus Rift DK1 head-mounted display equipped with 3D motion tracking; software developed using Unity-pro, version 3.5, Unity Technologies)	4 weeks
Nusser et al [46]	VR group: neck-specific sensorimotor training (NSST)— head-repositioning test (HRT), head-to-target test (HTT), dynamic exercise including 5 different trajectories (3 minutes given between tasks), training divided into 6 20minute sessions for a total of 120 minutes); standard rehabilitation program	Conventional physical therapy: different forms of general and neck-specific exercise therapies (strengthening, mobilization, relaxation, medical training therapy, functional gymnastics, aqua therapy, physical therapy, and traditional "back school")	VR: modified VR system (Fraunhofer Institute für Graphische Datenverarbeitung), helmet (Schutz helm uvex pheos alpine, Fürth), 3Space Fastrak System (Polhemus Inc)	3 weeks
Tejera et al [47]	VR mobile apps "Full Dive VR," only lateral flexion movements of the neck; "VR Ocean Aquarium 3D": flexion, extension, and rotation movements (3 series of 10 repetitions, with 30 seconds of rest between exercises)	Conventional physical therapy: flexion, extension, rotation, and tilt exercises (3 series of 10 repetitions, with 30 seconds of rest between exercises)	VR: VR Vox Play glasses with a head-mounted display clamping system (weight 330 g) with an LG Q6 smartphone attached, 2 VR mobile apps installed	4 weeks

[a]VR: virtual reality.

[b]IVR: immersive virtual reality.

[c]NIVR: nonimmersive virtual reality.

[d]NWE: Nintendo Wii exercise.

[e]VRE: virtual reality exercise.

The risk of bias in the 16 (100%) studies included in the meta-analysis is presented in Figure 2. Overall, 10 (63%) studies showed a high risk of bias. In addition, 15 (94%) RCTs generated an adequately randomized sequence, and 9 (60%) of them were analyzed using a blinded method for outcome measurement. Ratings using the GRADE methodology for all outcome measurements were inconsistent and ranged from moderate to low quality (Multimedia Appendix 3). Therefore, the quality of evidence from most studies was classified as fair.

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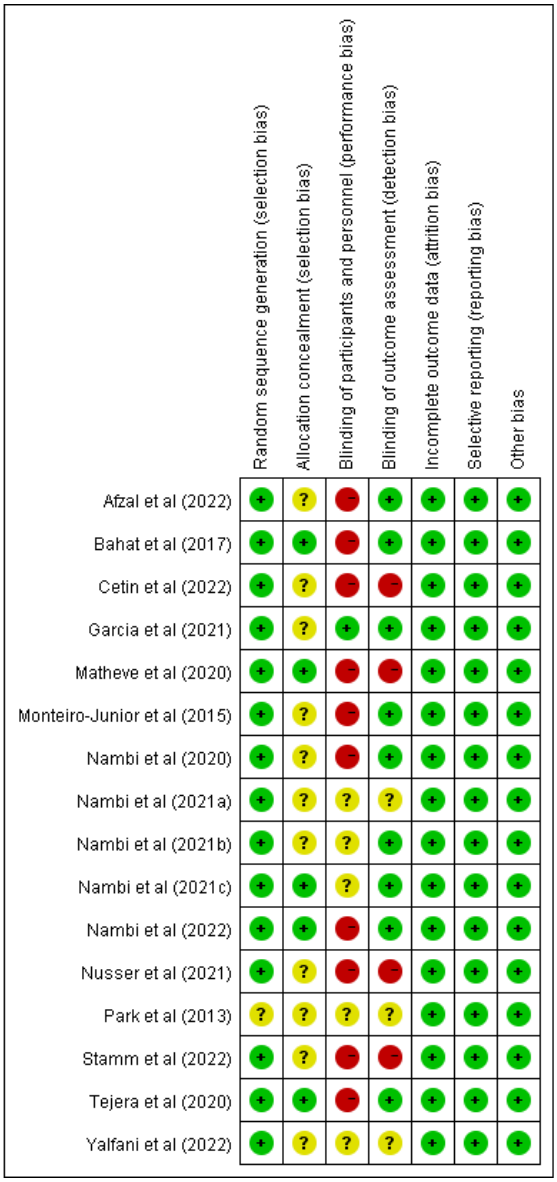
Figure 2. Cochrane risk-of-bias summary for included studies.



Primary Outcome

Pain Intensity

All 16 (100%) studies (800 patients) reported pain intensity: 9 (56%) used the Visual Analogue Scale (VAS) [34-38,40,44,45,47], 2 (13%) used the Numerical Pain Rating Scale (NPRS) [33,41], 3 (19%) used the Numeric Rating Scale (NRS) [42,43,46], and 1 (6%) used the Defense and Veterans Pain Rating Scale (DVPRS) [32]. The random effects model revealed that compared with the control treatment, the VR intervention significantly reduced pain intensity (WMD=–1.63, 95% CI –2.11 to –1.16, P<.001, I^2=90%). Clinical differences between groups were significant, and as suggested, the minimal clinically important difference (MCID) threshold on the VAS for LBP was set at a 1.5-point reduction [50]. Given the significant heterogeneity observed (I^2=90%), we performed subgroup analyses to investigate the source of heterogeneity based on the different regions, VR types, and treatment durations.

VR had a good analgesic effect on both CNP and CLBP groups compared with the control group. The results did not significantly differ among the subgroups (WMD=−1.63, 95% CI −2.11 to −1.16); see Figure 3. Moreover, a total of 7 (44%) studies demonstrated that IVR significantly improved CSP (WMD=–1.50, 95% CI –2.45 to –0.55, P<.001, I^2=80%) [32,35,42,44-47]. Another 8 (50%) studies showed that NIVR improved CSP substantially (WMD=–1.50, 95% CI –2.45 to –0.55, P<.001, I^2=90%) [33,34,36-38,40,41,43]; see Figure 4. The subgroup analyses also revealed significant differences between treatment durations of <4 weeks (WMD=–1.41, 95% CI –2.12 to –0.69, P=.001, I^2=0%) and ≥4 weeks (WMD=–1.65, 95% CI –2.16 to –1.14, P<.001, I^2=91%) in terms of the analgesic effect of VR treatment on CSP (Multimedia Appendix 4).

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Figure 3. Forest plots of the effect of VR compared with other treatments on pain intensity in patients with CSP: subgroup analysis of posttreatment effectiveness for different regions of spinal pain. CSP: chronic spinal pain; VR: virtual reality.

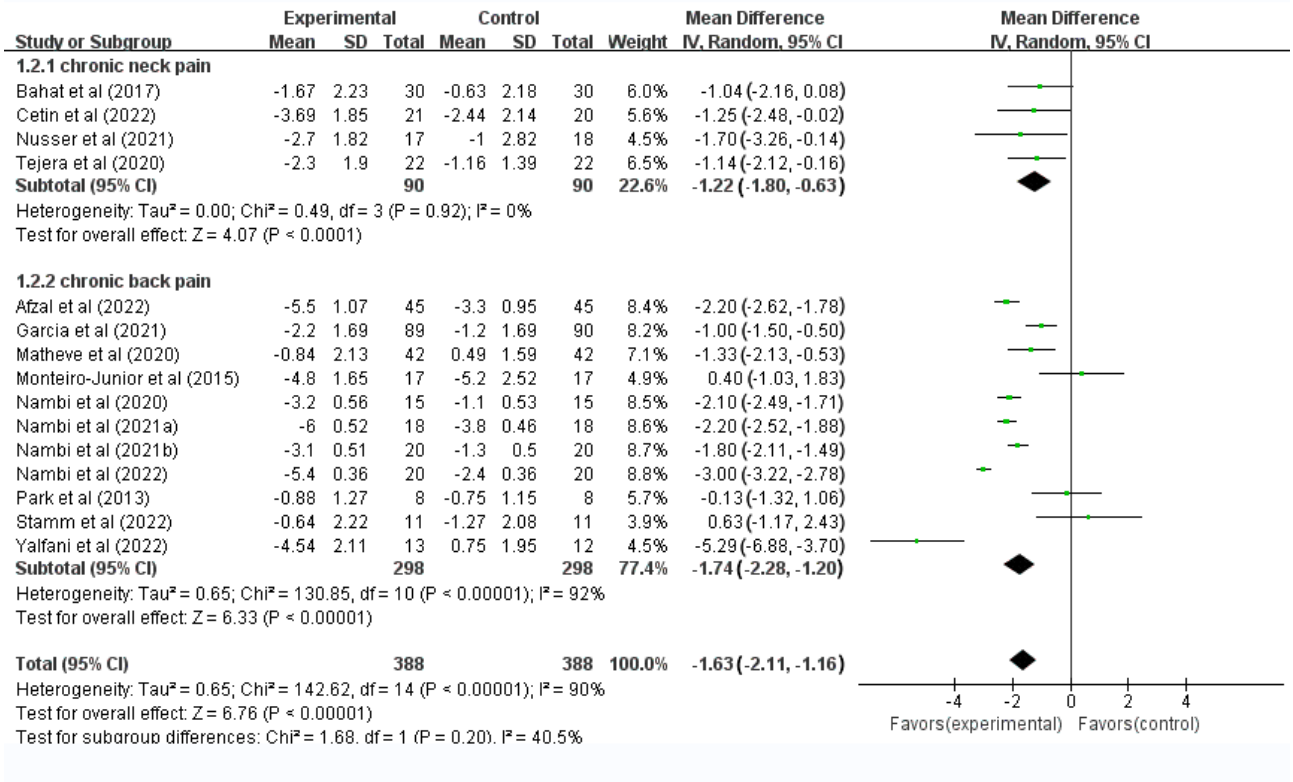
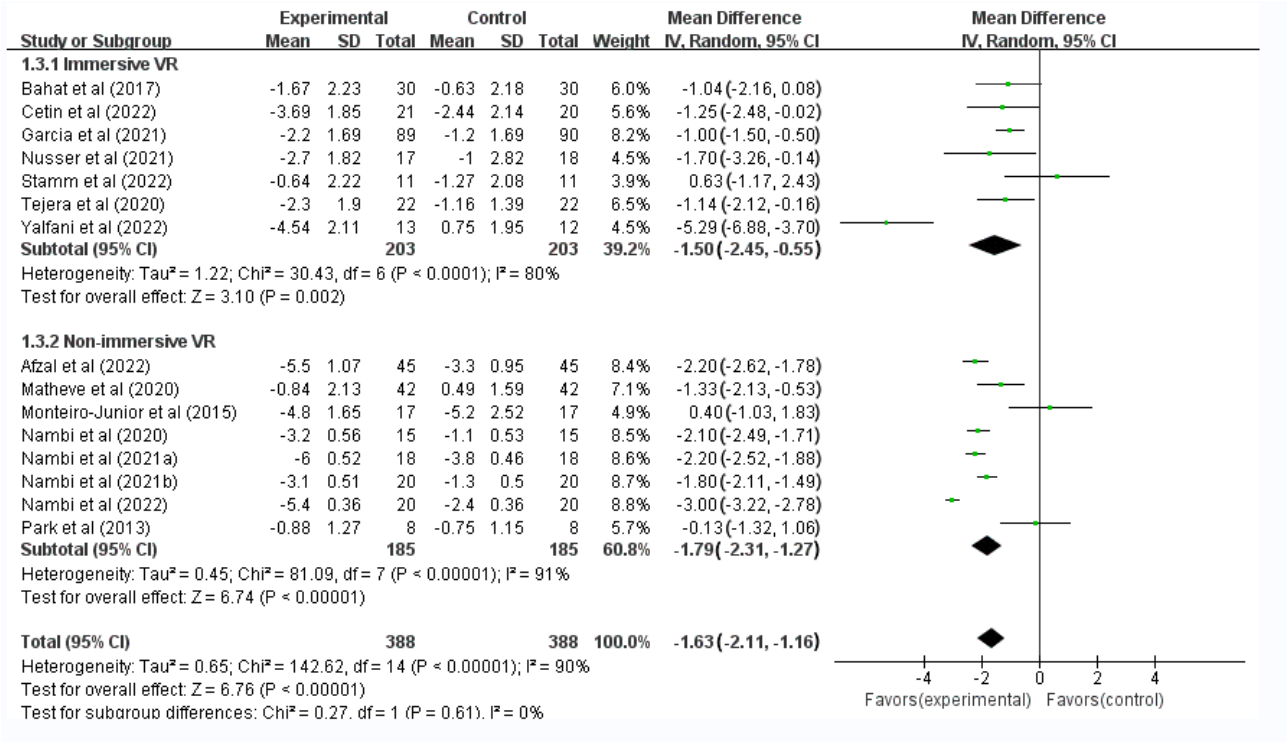


Figure 4. Forest plots of the effect of VR compared with other treatments on pain intensity in patients with CSP: subgroup analysis of posttreatment effectiveness for the VR intervention type. CSP: chronic spinal pain; VR: virtual reality.



Secondary Outcomes

Inflammatory Markers

Patients with CSP develop a systemic inflammatory response and have elevated levels of inflammatory markers in the blood [51]. Two studies (62 patients) focused on the levels of inflammatory markers (eg, CRP, TNF-α, IL-2, IL-4, and IL-6) by collecting 10 mL of venous blood [38,39]. The results showed that VR therapy significantly improved the level of CRP (WMD=–0.89, 95% CI –1.07 to –0.70, P<.001, I^2=0%),

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TNF-α (WMD=–6.60, 95% CI –8.56 to –4.64, P<.001, I^2=98%), and IL-6 (WMD=–2.76, 95% CI 2.98 to –2.53, P<.001, I^2=0%). No significant differences were found between the IL-2 and IL-4 subgroups (Figure S1 in Multimedia Appendix 5).

Fear of Movement

Four studies (162 patients) reported fear of movement according to the 11-item or 17-item Tampa Scale of Kinesiophobia (TSK-11 or TSK-17, respectively) [42,47]. No significant differences were found in either the TSK-11 (WMD=–0.81, 95% CI –4.48 to 2.86, P=.66, I^2=0%; Figure S2 in Multimedia Appendix 5) or TSK-17 (WMD=–9.66, 95% CI –22.01 to 2.68, P=.13, I^2=97%; Figure S3 in Multimedia Appendix 5).

Spinal Range of Motion

Three studies reported changes in the ROM of the neck in 4 directions before and after the intervention [45-47]. No significant differences were found between the groups in terms of flexion (WMD=2.67, 95% CI –2.31 to 7.64, P=.29, I^2=61%), extension (WMD=3.92, 95% CI –2.17 to 10.0, P=.21, I^2=48%), right rotation (WMD=–0.22, 95% CI –4.38 to 3.95, P=.92, I^2=0%), or left rotation (WMD=0.08, 95% CI –3.90 to 4.05, P=.97, I^2=42%); see Figure S4 in Multimedia Appendix 5.

Disability Level

Three studies (139 patients) reported disability levels in patients with CNP by using the Neck Disability Index (NDI) [45-47], a 10-item questionnaire that assesses self-reported disability related to CNP. Higher scores on the NDI indicate higher levels of disability. No significant differences were found in the pooled analysis of 3 (19%) studies (WMD=–2.66, 95% CI –5.47 to 0.15, P=.06, I^2=48%); see Figure S5 in Multimedia Appendix 5.

Adverse Events

One study reported that after 1 month of intervention, patients experienced nausea and motion sickness [32], two studies reported that there were no adverse events [33,37], and the remaining studies did not mention adverse events. The overall dropout rate was 4.25% (17/400) in the intervention group and 3.75% (15/400) in the control group.

Publication Bias and Sensitivity Analysis

The Egger test indicated significant publication bias in the results for pain intensity (P=.03; Figure 5). The sensitivity analysis for pain intensity revealed that removing each study separately did not significantly affect the pooled results, thus indicating that the results are robust (Figure 6). The trim-and-fill method was performed, and it was estimated that there were 4 missing studies. The pooled estimates (95% CIs) calculated for the fixed effects model and the random effects model were –2.30 (–2.42 to –2.18) and –2.06 (–2.50 to –1.61), respectively (Figure 7). No significant changes in the results were observed before or after pruning or filling, indicating that our results are robust and plausible.

Figure 5. Funnel plot of pain intensity in the VR group compared with the control group. VR: virtual reality; WMD: weighted mean difference.

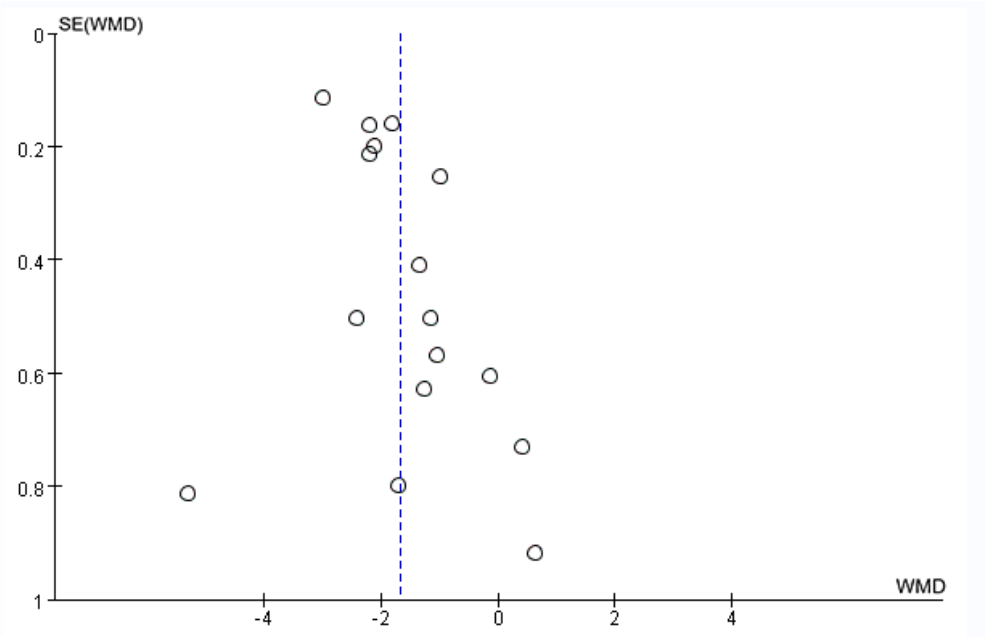

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Figure 6. Sensitivity analysis of the included studies.

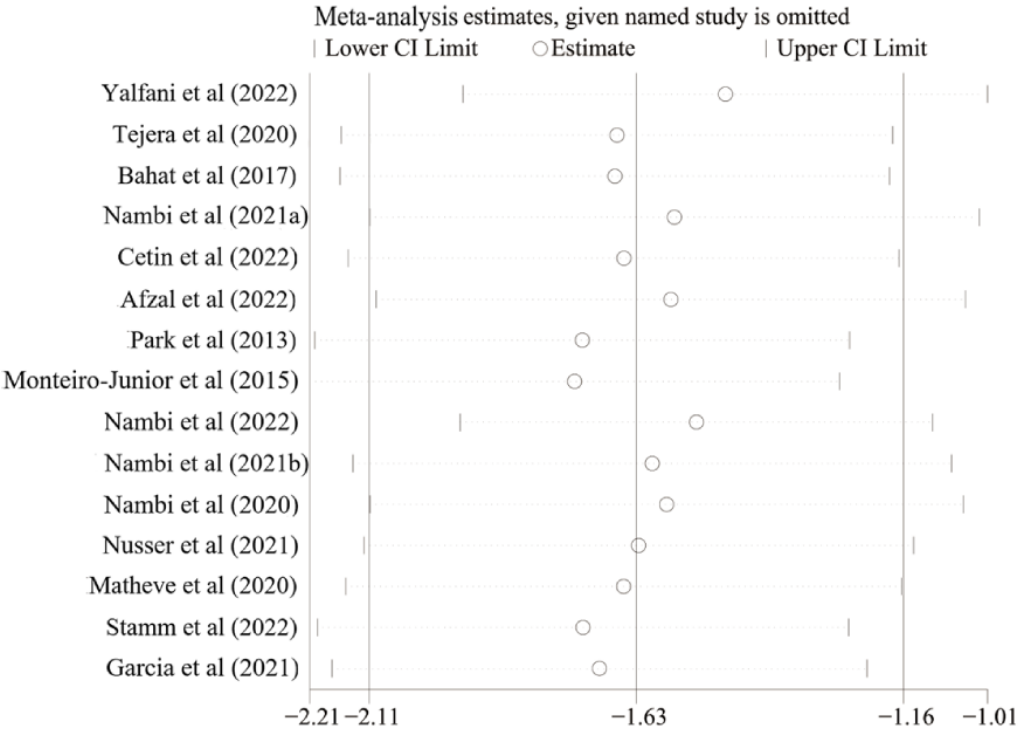
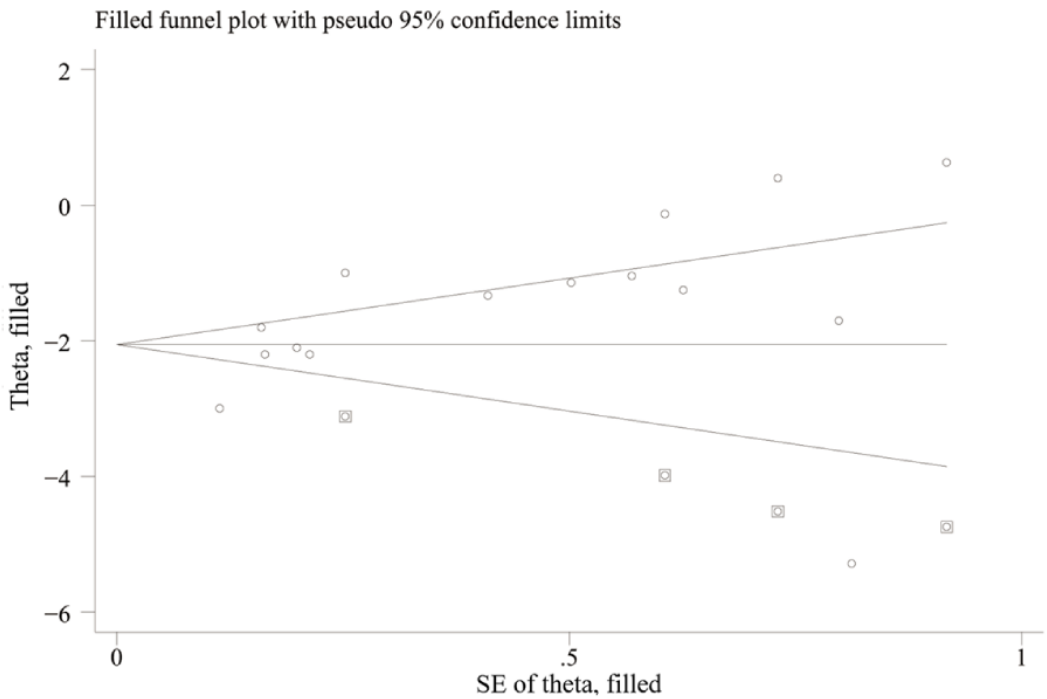


Figure 7. Trim-and-fill analysis to estimate the number of potentially missing studies about the effect of VR on CSP. Circles represent real studies, and squares represent studies estimated by this method. Circles represent real studies, and squares represent studies estimated by this method. CSP: chronic spinal pain; VR: virtual reality.



Discussion

Principal Findings

The primary purpose of this meta-analysis was to compare the relative efficacy of VR therapy and other therapies (eg, conventional therapy, sham stimulation, and standard care) for treating CSP. The results indicated that VR therapy can effectively relieve CSP. The results of subgroup analyses showed that VR is a beneficial pain management strategy for patients with CNP and CLBP. For different types of VR, subgroup analyses showed that compared to the control group, IVR and NIVR both significantly improved CSP. No statistically

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significant differences were found between patients who underwent VR treatments for a duration of <4 weeks and a duration of ≥4 weeks. VR was associated with a significant improvement in inflammatory marker levels but not in the fear of movement, spinal ROM, or disability level. VR was found to be well tolerated among these patients.

Discussion of the Results

The primary result suggested that VR reduces self-reported pain intensity, which might be explained by several implicating mechanisms [52,53]. A previous study reported that abdominal muscle strength is significantly lower in people with LBP [54], and a lack of strength in the core trunk muscles can lead to a decrease in intra-abdominal pressure, affecting spinal stability [55]. VR, as a novel human-computer interaction approach, can stimulate and mobilize the sensory system during training and results in changes in neuroplasticity and enhanced performance of relevant muscle groups, promoting a new motor learning process and leading to increased spinal stability [37,56], which would benefit pain relief. Furthermore, previous studies have reported that an intervertebral disc undergoes aging or pathological changes in the adjacent region in patients with CSP, exposing cells within the nucleus pulposus to macrophages, resulting in an inflammatory response that might trigger pain [7,8]. VR therapy may enhance the activity of disc fibroblasts and increase the thickness of the multifidus muscle [39,57], which is beneficial for relieving pain intensity. Furthermore, pain is an unpleasant subjective sensation associated with actual or potential tissue damage and is correlated with the degree of patient attention given to the pain area [58-61]. The various virtual game environments and real-time feedback methods are the most eye-catching features in the VR training process; these methods can be used to attract the patient's visual and auditory attention to achieve motor performance, while relatively less attention has been given to the effects of VR on pain [62,63].

Although the high heterogeneity of the primary outcome and the results of the subsequent subgroup analyses suggest that the region of CSP, VR type, and treatment duration may play a role in the heterogeneity, the results of the sensitivity analysis indicate that these differences are more likely to be caused by 6 studies [33-35,37,38,40], which included participants of different ages.

VR therapy significantly improved the levels of inflammatory markers, including CRP, TNF-α, and IL-6. Numerous studies have previously reported an association between CSP and changes in inflammatory cytokines, such as IL-1 and TNF-α, which are thought to be closely related to the pathogenesis of disc herniation and degeneration [64,65]. Similarly, Nambi et al [66] reported that 4 weeks of VR training could significantly decrease pain intensity, increase functional impairment, and improve CRP, TNF-α, IL-2, IL-4, and IL-6 levels. However, the limited number and low quality of the included studies need to be noted, and further RCTs with large samples and rigorous study designs are needed to elucidate these results.

Patients with CSP may engage in fear/avoidance behaviors to avoid pain and protect themselves by limiting spinal motion, which ultimately affects spinal mobility and the speed of movement [67,68], with the degree of pain catastrophizing being proportional to the degree of disability [69,70]. However, we found no statistically significant differences in fear avoidance beliefs after the VR intervention but at the 3-month follow-up [47]. A systematic review and meta-analysis reported that VR therapy enhances spinal ROM and physical functioning in patients with CNP [26]. We failed to observe significant differences in the spinal ROM or disability level after VR intervention compared to those in the control group, which may be attributed to the relatively short duration (0-8 weeks) of the VR intervention (the reported mean duration was 4.81 weeks).

Limitations

Several limitations need to be addressed in this meta-analysis. First, the pooled analysis of the studies may be imprecise due to the large heterogeneity and the low quality of evidence from most of the included studies, and the results should be interpreted with caution. Second, the optimal duration of treatment for CSP could not be determined. Third, the effectiveness of VR therapy in patients with CSP and its analgesic effects in long-term follow-up must be further explored in high-quality studies. Fourth, indicators related to quality of life, such as depression and anxiety, should be emphasized and investigated in depth in future studies of patients with CSP.

Conclusion

VR therapy is an innovative and effective analgesic method that has beneficial effects on inflammatory markers in patients with CSP compared to other therapies (sham stimulation, usual care, conventional treatment). However, this approach may not have significant effects on the fear of movement, spinal ROM, or disability level. Notably, the quality of the evidence from the RCTs included in this study ranged from moderate to low. Therefore, we recommend that readers interpret the results of this study with caution. Future trials with large sample sizes, rigorous designs, and long-term follow-up periods are needed to explore the clinical significance of these differences and key issues in patients with CSP and to elucidate the underlying mechanisms of VR.

Acknowledgments

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Data Availability

All data generated or analyzed during this study are included in this published paper and its supplementary information files.

Authors' Contributions

All authors contributed to the writing and redrafting of the manuscript. QD and XZ had the original idea. TZ and FW performed the literature search, XL and ZH assessed the risk of bias; YS, YF, and LZ rated the certainty of the evidence for each outcome; and XL and FW undertook data collection. The results were analyzed, interpreted, and discussed by XZ and QD. All authors contributed to the conception and design of the study, the analysis and interpretation of data, and the drafting and revising of the manuscript and have approved the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The PRISMA checklist. PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analysis.
[DOCX File , 29 KB - games_v12i1e50089_app1.docx]

Multimedia Appendix 2
Search strategy for all electronic databases.
[DOCX File , 24 KB - games_v12i1e50089_app2.docx]

Multimedia Appendix 3
The GRADE criteria. GRADE: Grading of Recommendations, Assessment, Development and Evaluation.
[DOCX File , 22 KB - games_v12i1e50089_app3.docx]

Multimedia Appendix 4
Forest plots of the effect of VR compared with other treatments for pain intensity in patients with CSP: subgroup analysis of posttreatment effectiveness for treatment duration. CSP: chronic spinal pain; VR: virtual reality.
[DOCX File , 37 KB - games_v12i1e50089_app4.docx]

Multimedia Appendix 5
Forest plots of the effect of VR compared with other treatments for inflammatory marker level, fear of movement, spinal ROM, and disability level in patients with CSP. CSP: chronic spinal pain; ROM: range of motion; VR: virtual reality.
[DOCX File , 130 KB - games_v12i1e50089_app5.docx]

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Abbreviations

CLBP: chronic low back pain
CNP: chronic neck pain
CRP: C-reactive protein
CSP: chronic spinal pain
DVPRS: Defense and Veterans Pain Rating Scale
GRADE: Grading of Recommendations, Assessment, Development and Evaluation
IL: interleukin
IVR: immersive virtual reality
LBP: low back pain
NDI: Neck Disability Index
NIVR: nonimmersive virtual reality
NPRS: Numerical Pain Rating Scale
NRS: Numeric Rating Scale
NSAID: nonsteroidal anti-inflammatory drug
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analysis
RCT: randomized controlled trial
ROM: range of motion
TNF-α: tumor necrosis factor-alpha
TSK: Tampa Scale of Kinesiophobia
VAS: Visual Analogue Scale
VR: virtual reality
VRE: virtual reality exercise
WMD: weighted mean difference

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Review

Extended Reality–Based Mobile App Solutions for the Therapy of Children With Autism Spectrum Disorders: Systematic Literature Review

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Abstract

Background: The increasing prevalence of autism spectrum disorder (ASD) has driven research interest on the therapy of individuals with autism, especially children, as early diagnosis and appropriate treatment can lead to improvement in the condition. With the widespread availability of virtual reality, augmented reality (AR), and mixed reality technologies to the public and the increasing popularity of mobile devices, the interest in the use of applications and technologies to provide support for the therapy of children with autism is growing.

Objective: This study aims to describe the literature on the potential of virtual reality, AR, and mixed reality technologies in the context of therapy for children with ASD. We propose to investigate and analyze the temporal distribution of relevant papers, identify the target audience for studies related to extended reality apps in ASD therapy, examine the technologies used in the development of these apps, assess the skills targeted for improvement in primary studies, explore the purposes of the proposed solutions, and summarize the results obtained from their application.

Methods: For the systematic literature review, 6 research questions were defined in the first phase, after which 5 international databases (Web of Science, Scopus, ScienceDirect, IEEE Xplore Digital Library, and ACM Digital Library) were searched using specific search strings. Results were centralized, filtered, and processed applying eligibility criteria and using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The results were refined using a technical and IT-oriented approach. The quality criteria assessed whether the research addressed ASDs, focused on children's therapy, involved targeted technologies, deployed solutions on mobile devices, and produced results relevant to our study.

Results: In the first step, 179 publications were identified in Zotero reference manager software (Corporation for Digital Scholarship). After excluding articles that did not meet the eligibility or quality assessment criteria, 28 publications were finalized. The analysis revealed an increase in publications related to apps for children with autism starting in 2015 and peaking in 2019. Most studies (22/28, 79%) focused on mobile AR solutions for Android devices, which were developed using the Unity 3D platform and the Vuforia engine. Although 68% (19/28) of these apps were tested with children, 32% (9/28) were tested exclusively by developers. More than half (15/28, 54%) of the studies used interviews as an evaluation method, yielding mostly favorable although preliminary results, indicating the need for more extensive testing.

Conclusions: The findings reported in the studies highlight the fact that these technologies are appropriate for the therapy of children with ASD. Several studies showed a distinct trend toward the use of AR technology as an educational tool for people with ASD. This trend entails multidisciplinary cooperation and an integrated research approach, with an emphasis on comprehensive empirical evaluations and technology ethics.

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(JMIR Serious Games 2024;12:e49906) doi:10.2196/49906

KEYWORDS

autism; autistic; autism spectrum disorder; ASD; virtual reality; augmented reality; extended reality; mixed reality; mobile app; children; preschool; mobile phone

Introduction

Background

In recent years, there has been increased interest in using technology to address the unique challenges faced by individuals with autism spectrum disorder (ASD). Among the various technological approaches, extended reality (XR), which includes augmented reality (AR) and virtual reality (VR), has emerged as a promising solution for intervention and therapy in children with ASD. XR offers the potential to create immersive and engaging environments that can address the specific needs of individuals on the autism spectrum, assisting them with communication, social interaction, and skill development. As a result, researchers and practitioners have explored the development of XR-based mobile apps tailored to the therapy of children with ASD.

However, the rapid growth in this field has spawned a multitude of XR-based mobile app solutions, each claiming unique benefits and features. With this proliferation of interventions, it is important to comprehensively assess the current landscape of XR-based mobile apps for the therapy of children with ASD, not only to strengthen existing knowledge in the field but also to provide critical insights into the research field.

In light of these considerations, this systematic literature review aimed to explore and assess the current status of XR-based mobile app solutions for the therapy of children with ASD. By synthesizing evidence from existing studies, this review aimed to provide an updated overview of the field, identify research gaps, and provide valuable insights. In this endeavor, this review aimed to contribute to the advancement of knowledge and practice in the field of XR-based interventions for ASD therapy, ultimately aiming to improve the quality of life of children on the autism spectrum and their caregivers.

ASD is a neurological condition that has a significant negative impact on a person's social, verbal, and physical abilities. Researchers claim that ASD is typically discovered around the third year of life [1], but it can be identified and diagnosed as early as the age of 18 months [2]. According to a study from 2022, a total of 1% of infants have ASD [3]. On the basis of studies conducted over the past 50 years, the World Health Organization predicts a global increase in the prevalence of ASD [3].

Researchers consider 3 techniques that could be used to facilitate the evaluation of this condition's prevalence: providing diagnostic tools, enhancing diagnostic standards, and increasing public awareness of ASDs [4].

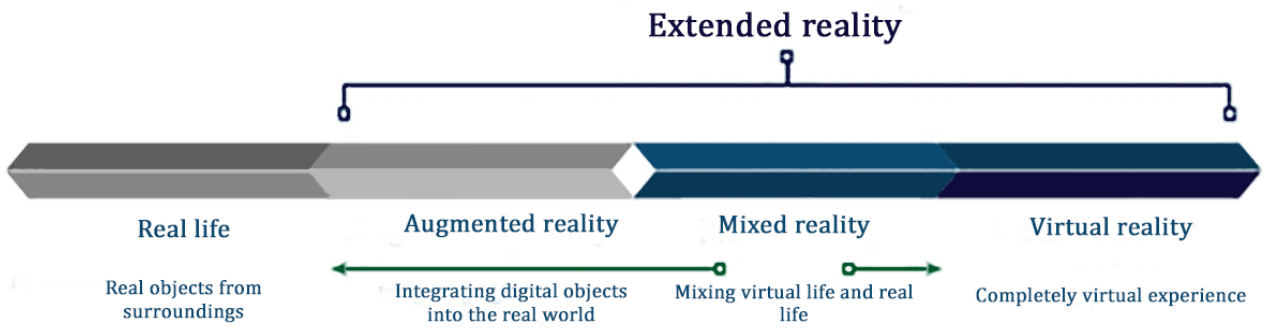
On the basis of each individual's verbal IQ and level of language delay, the diagnosis assesses the severity of the disorder (mild, moderate, or severe) [5], which can estimate the extent to which daily life is affected. Many people with ASD are timid, have difficulty communicating, or experience anxiety when engaging in casual conversation. Despite their communication and social skill deficits, individuals with ASD have demonstrated a preference for technology [6]. Furthermore, the use of technology in behavioral therapy for people with ASD has the additional advantage of being cost-effective in terms of both caregiver and treatment facility expenses [7]. In addition, various studies have shown that individuals with ASD respond better to visual stimuli than to other sensory stimuli [8]. The findings of these studies have led to various applications of technology in digital behavioral treatment.

XR, AR, VR, and Mixed Reality

As evidenced, the evolution of IT has accelerated in recent years. According to the study by Abad-Segura et al [9], rapid technological advancements have caused a significant and positive shift in how people view modern living.

The relatively new term XR refers to the entire spectrum from AR to VR, including mixed reality (MR; Figure 1 [10]).

Figure 1. The extended reality concept [10].



AR is a technology that enables real-time interaction and integration of 3D virtual models into the physical world [11]. Although the first portable AR system was developed in 2003 [12], AR did not acquire widespread acceptance and public

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awareness until the release of the mobile game Pokémon GO [13] in 2016. Despite the various implementation challenges, AR has many potential applications. In addition to applications in specific domains such as industry, construction, or medicine, as well as in advertising and commerce, education, and gaming [14], AR can be used by a broader audience for everyday tasks such as finding information about nearby points of interest, navigation, and assistance while following a route [14]. Most of these apps are now accessible owing to advances in mobile device technology and the spread of smart mobile phones. AR facilitates behavioral therapy by enhancing the experiences and abilities of people with ASD and establishing an integrated learning environment that enables the visualization of educational materials in 3D and engaging manipulation of real-world objects [15]. By generating "physical" structures to improve specific skills, AR fosters the imagination of patients with ASD without impairing it [16,17]. Moreover, AR can be used to create more engaging and appealing user interfaces, thereby eliminating the need for conventional input devices such as a keyboard and mouse [18]. AR technology is typically accessed using various devices and platforms. Among the widely used platforms and tools for developing AR apps are Unity, Unreal Engine, ARCore, and HP Reveal.

As described in the study by Azuma [11], VR is a computer-generated environment that simulates real-life scenarios, creating an immersive and interactive experience. This means that the users are placed in a completely virtual world, which can be similar to or different from the real one. This technology requires specialized equipment, such as VR headsets or glasses to enable users to see and interact with the virtual environment.

As seen in the studies by Bursali and Yilmaz [19] and El-Jarn and Southern [10], MR is situated between AR and VR, integrating the 2 technologies to provide the user with a unique and captivating experience in real time. It can be difficult to precisely define the limits of MR as they depend on the devices and equipment used as well as the extent to which VR or AR is incorporated into the final product. A model describing the integration of digital objects from the physical world into the virtual world is shown in the study by Milgram and Kishino [20], which also presented a taxonomy for MR, stating that it can be defined as a part of the human-computer interface field, which integrates VR and AR elements to create an environment in which virtual and real objects coexist and interact.

To be used, technologies from the XR spectrum require specific hardware with an optical sensor [19]. In addition, well-known technology companies such as Google, Facebook, Apple, Amazon, and Microsoft have significantly contributed to the development of AR tools and services [21,22], including handheld devices; holographic screens (Microsoft HoloLens); and heads-up displays, which are mainly designed for MR, tablets, and mobile devices (smartphones).

The development of collaborative XR, which enables simultaneous communication and collaboration among multiple users, is one of the research trends in the field of XR [23].

Given the benefits that AR, VR, and MR can offer as a new mode of human-computer interaction and the fact that these technologies are becoming ubiquitous and part of our daily lives, this systematic review aimed to describe how these technologies can be used in the therapy of children with ASDs.

Methods

Overview

According to Kitchenham [24], a systematic literature review is a method for identifying, evaluating, and interpreting all available research relevant to a field of study as well as answering specific research questions (RQs). We conducted this research following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [25] and the recommendations suggested by Kitchenham [24].

To conduct this literature review, several well-known scientific databases were queried, and publications containing relevant information for our analysis were filtered. We defined RQs and provided answers to each of them, thus achieving our proposed objective.

Search Strategy

According to the considered methodology, the following 7 RQs were formulated. These questions consider aspects relevant to the understanding of concepts important to this study:

1. What is the papers' distribution over time? (RQ 1)
2. What category of people are the studies aimed at? (RQ 2)
3. Which technologies are used with XR or any of its subdivisions to develop apps for ASD therapy? (RQ 3)
4. What skills were targeted for improvement in primary studies? (RQ 4)
5. What are the purposes for which the proposed solutions were used? (RQ 5)
6. What are the results obtained using the proposed solutions? (RQ 6)

To study the literature and answer the aforementioned questions, we searched for scientific publications using various academic research databases. Our study primarily focused on the technical aspects of mobile app solutions using XR for autism therapy. To comprehensively cover our research domain, we chose to use multidisciplinary scientific databases—Scopus, ScienceDirect, and Web of Science—along with 2 databases particularly relevant to computer science, namely, IEEE Xplore Digital Library and ACM Digital Library. From these sources, we only considered publications that were relevant in computer science–related categories, such as technology, engineering, and computer science, excluding categories related to medicine, chemistry, or neurosciences considering that the RQs were focused not only on the available apps but also on their technical details. The functionalities, the technologies used, and the entire process of their development also constituted an objective. Thus, the approach from a technical point of view and the development of these apps were followed. This was done using the results refinement interface available in the aforementioned databases. Initially, to view and analyze the results of queries conducted using the considered search strings, the search was not limited to a particular time.

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Given the topic of this study, we aimed to query scientific databases so that the resulting list of publications would meet the following criteria:

1. Reference to ASDs
2. Consideration of one of the technologies that are part of the concept of XR (VR, AR, or MR)
3. Addressing mobile apps
4. Aim to develop solutions for the therapy of children

The literature was searched using keywords relevant to achieving the proposed objectives: *autism*, *autistic*, *ASD*, *virtual reality*, *augmented reality*, *extended reality*, *mixed reality*, *mobile application*, and *children*.

Following the analysis of these keywords, the query process was extended by including the following terms: *Autis**, *VR*, *AR*, *MR*, *XR*, *Mobile app**, *Smartphone app**, *Child**, *Infan**, *Toddler**, *Preschool**, *Kid**, and *Juvenile*. In the aforementioned list, an asterisk stands for any number of characters at the end of the current string (eg, *Preschool** refers to *Preschool*, *Preschooler*, and *Preschoolers*).

Information Sources

Depending on the search options available in each database considered, specific search strings were defined for querying the databases (Table 1). These query strings were defined using advanced search functions and appropriate operators. The search of Web of Science and Scopus publications was performed by title, abstract, and keywords, and IEEE Xplore Digital Library, ScienceDirect, and ACM Digital Library were searched using a general search. The queries were executed on December 18, 2022.

Table 1. The search strings used for querying the databases (N=219).

Item	Database	Search string	Returned results, n (%)
1	Web of Science	(TS=(Autis*) OR TS=(ASD)) AND (TS=(virtual reality OR VR) OR TS=(augmented reality OR AR) OR TS=(mixed reality OR MR) OR TS=(extended reality OR XR)) AND (TS=(mobile app* OR smartphone app*)) AND (TS=(child* OR infan* OR toddler* OR preschool* OR kid* OR juvenile))	45 (20.5)
2	Scopus	(TITLE-ABS-KEY (autis*) OR TITLE-ABS-KEY (asd)) AND (TITLE-ABS-KEY (“virtual reality” OR vr) OR TITLE-ABS-KEY (“augmented reality” OR ar) OR TITLE-ABS-KEY (“mixed reality” OR mr) OR TITLE-ABS-KEY (“extended reality” OR xr)) AND (TITLE-ABS-KEY (“mobile app*” OR “smartphone app*”)) AND (TITLE-ABS-KEY (child* OR infan* OR toddler* OR preschool* OR kid* OR juvenile))	32 (14.6)
3	IEEE Xplore Digital Library	(Autis* OR ASD) AND (Augmented reality OR AR OR Mixed reality OR MR OR Extended Reality OR XR OR Virtual Reality OR VR) AND (Mobile OR Tablet OR Smartphone OR Phone OR Smartglass) AND (App* OR Solution*) AND (child* OR kid* OR infan* OR preschool* OR juvenile OR toddler*)	26 (11.9)
4	ScienceDirect	(“Autism Spectrum Disorder” OR “ASD”) AND (“Augmented reality” OR “Mixed reality” OR “Extended reality”) AND (“App OR Application”) AND (“kids OR children”)	48 (21.9)
5	ACM Digital Library	[[All: “autis*”] OR [All: “asd”]] AND [[All: “augmented reality”] OR [All: “mixed reality”] OR [All: “virtual reality”] OR [All: “extended reality”]] AND [All: “mobile”] AND [[All: “app”] OR [All: application]]	68 (31.1)

Eligibility Criteria

The papers obtained by querying scientific databases had an interdisciplinary nature. However, our study took a technical and IT-focused approach to mobile app solutions using XR for autism therapy. Therefore, we needed to refine the results by considering inclusion and exclusion criteria. As previously stated, no constraints were imposed on the publication dates of the articles during the search conducted in the scientific databases. Nevertheless, considering the significant progress in mobile device capabilities and their widespread use over the last decade, which have facilitated the development and growth of the global use of XR-based mobile apps for therapeutic purposes, we focused our investigation on the period following 2012 [26,27]. In line with our technical focus on mobile app solutions using XR for the therapy of children with ASD, we refined the search results across the 5 considered databases, prioritizing computer science–related domains. We deliberately excluded categories related to medicine, chemistry, or neurosciences as our RQs focused on both the available apps and their technical details.

Before centralizing the results for analysis, they were refined according to the inclusion and exclusion criteria. The inclusion criteria were as follows:

1. Articles published in English
2. Articles published after 2012

The exclusion criteria were as follows:

1. Book chapters
2. Paper tables of contents
3. Articles published in languages other than English
4. Results on the topics of medicine, chemistry, or neurosciences

After initial processing, the database searches returned the number of results presented in Table 2.

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Table 2. Results obtained after initial data processing (N=179).

Database	Results, n (%)
Web of Science	43 (24)
Scopus	22 (12.3)
IEEE Xplore Digital Library	25 (14)
ScienceDirect	41 (22.9)
ACM Digital Library	48 (26.8)

Selection Process

During the selection process, the PRISMA guidelines were considered [25]. These guidelines outline 3 steps: identification (centralizing the results and excluding duplicate publications), screening (review of titles and abstracts and testing eligibility), and inclusion (the publications identified as answering the proposed RQs). The PRISMA 2020 checklist is available in Multimedia Appendix 1. The Zotero reference manager software (Corporation for Digital Scholarship) was used to perform the specified steps. In the first step, 179 publications resulting from the search of the 5 considered databases were imported, after which duplicate publications (n=20, 11.2%) and some conference papers (n=4, 2.2%) were removed. For the next step, 86.6% (155/179) of the publications were considered. To enable author collaboration, the data were imported into Google Sheets. In total, 2 reviewers (M-VT and CET) conducted an independent screening of publications for inclusion based on title and abstract analysis. Studies meeting the eligibility criteria according to both reviewers were then considered for full-text screening. Any disagreements were discussed face-to-face between the reviewers, and a third party was involved to help reach unanimity where necessary. The same process was implemented for the full-text review with the assistance of a third reviewer (SV).

After reviewing the titles and abstracts, a total of 41.9% (65/155) of the publications were excluded as they did not address the proposed topic, focusing either on another condition or on other technologies.

Despite the high quality of the publications, as evidenced by their indexing in prestigious international databases, the analysis included a full text review (where available) of the remaining 58.1% (90/155) of the publications, and the following quality assessment criteria were applied to ensure their relevance to the RQs considered. Articles with no full text accessible were excluded. The following quality criteria (QCs) were applied to 78 publications:

1. Does the research topic address ASDs? (QC 1)
2. Does the study address children's therapy? (QC 2)
3. Does the study include one of the technologies targeted in this review? (QC 3)
4. Is the solution deployed on a mobile device? (QC 4)
5. Are the results relevant to this review? (QC 5)

Given the nature of the research and its objectives, the 5 QCs that were developed specifically to achieve the goals of the research were used to evaluate the studies' quality by 2 authors. Each publication was carefully reviewed and assigned a score from 0 to 2 measuring the extent to which it corresponded to the quality assessment criteria and to the subject of this study (0=no; 1=partially; 2=yes). Thus, the maximum score for a paper could be 10. After that, the data were combined for further analysis using Microsoft Excel (Microsoft Corp). After consolidation, a score with a decimal part (eg, 1.5) was rounded up to the nearest integer for better inclusion.

After reviewing the full texts, 3 publications were found to be not written in English, and in other publications, ASD was not addressed (only mentioned), other technologies were addressed, or the proposed solution was not clearly described and the results were inconclusive (see the sample in Figure 2; the entire table is available in Multimedia Appendix 2 [28-104]).

Following this, only publications with a score of ≥7 were evaluated as they adequately addressed the RQs. The type of publication, whether it was a review or aimed at developing an app, was also noted. Systematic literature review publications were investigated to identify any references that could be added to this study, but they were removed from the list after being reviewed. The entire publication selection process is illustrated in Figure 3.

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Figure 2. Screenshot of the quality assessment of the papers.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	No.	Item Type	Contribution or review	Publication Year	Author	Title	Publication Title	Abstract Note	QC1	QC2	QC3	QC4	QC5	Total
2	1	journalArticle	review	2021	Lian, Xiaojie; Sunar, M	Mobile Augment	APPLIED SCIEN	Over the past decade, e	2	2	2	2	2	10
3	2	journalArticle	contribution	2022	Lopez-Belmonte, Jesu	The Impact of Ge	EDUCATION IN	Today's education is in t	2	2	0	0	1	5
4	3	conferencePaper	contribution	2016	Gea, M.; Alaman, X.;	TOWARDS SMAR	EDULEARN16:	Smart city is a promising	1	1	1	0	1	4
5	4	conferencePaper	contribution	2013	Vullamparthi, Annie J	Assistive Learning	2013 IEEE FIFT	Innovative computer aid	2	2	2	2	2	10
6	5	journalArticle	review	2020	Baragash, Reem Sula	Augmented reali	EUROPEAN JOU	There is a growing inter	1	1	1	1	1	5
7	6	journalArticle	contribution		Glaser, Noah; Newbu	Video-Based Virt	TECHNOLOGY	Research suggests that	2	0	2	1	1	6
8	7	conferencePaper	contribution	2020	Bouaziz, Rahma; Alhe	Using Marker Ba	2020 IEEE INTE	Autistic children suffer f	2	2	2	2	2	10
9	8	conferencePaper	contribution	2017	Pradibta, Hendra; Wi	Designing AR Dai	2017 INTERNA	An Individual with Autis	2	2	2	2	1	9
10	9	journalArticle	contribution	2019	Abou El-Seoud, M. Sa	Assisting Individu	INTERNATIONA	Individuals with autism	2	2	2	2	2	10
11	10	journalArticle	contribution	2022	Hashim, Haida Umier	`AReal-Vocab': A	SUSTAINABILIT	The American Psychiatr	2	2	2	2	2	10
12	11	conferencePaper	contribution	2018	Pradibta, Hendra; Wi	The evaluation o	3RD ANNUAL A	ARdoa is Mobile Augme	0	0	0	0	0	0
13	12	journalArticle	contribution	2022	Wan, Guobin; Deng, F	FECTS: A Facial E	COMPUTATION	Traditional training met	2	2	0	1	2	7
14	13	conferencePaper	contribution	2015	Nubia, Rincon M.; Fal	Development of a	2015 WORKSH	An augmented reality m	2	2	2	2	2	10
15	14	conferencePaper	contribution	2020	Wang, Katherine; Zha	Using Mobile Aug	CHI'20: EXTEN	Adults on the autism spe	2	0	2	2	2	8
16	15	conferencePaper	contribution	2019	Tang, Tiffany Y.; Xu, J	Automatic Object	3RD INTERNAT	A number of previous co	2	2	2	2	2	10
17	16	journalArticle	contribution	2021	Hashim, Haida Umier	Augmented Reali	ARAB WORLD	American Psychiatric As	0	0	0	0	0	0
18	17	conferencePaper	contribution	2021	Kavitha, V; Mohan, A	Immersive Learn	ICSPC'21: 2021	Autism Spectrum Disord	2	2	2	2	2	10
19	18	journalArticle	review	2018	Johnston, Daniel; Ege	Innovative comp	COGENT PSYCH	Individuals with autism	2	2	0	0	1	5
20	19	journalArticle	review	2019	Putnam, Cynthia; Har	Interactive Techr	ACM TRANSAC	Autism spectrum disord	2	2	0	1	1	6
21	20	journalArticle	review		Mukherjee, Debarati	Digital tools for d	AUTISM	Current challenges in ea	2	0	1	1	0	4
22	21	journalArticle	review	2020	Valentine, Althea Z.;	A systematic revi	CLINICAL PSYC	Technology-based inter	1	2	2	2	1	8
23	22	conferencePaper	contribution	2022	T, Nithya Shree; Selva	An Interactive Nu	2022 Internati	Autism in children is cha	2	2	2	2	2	10
24	23	conferencePaper	review	2019	Khowaja, Kamran; Al-	Use of augmente	2019 IEEE 6th	The purpose of this revie	2	2	2	1	2	9
25	24	conferencePaper	review	2020	Almurashi, Hanin A.;	Augmented Reali	2020 IEEE Inte	Currently, augmented r	2	1	1	1	1	6
26	25	conferencePaper	contribution	2020	Xia, Mengting; Chen,	ParaShop: A Mob	2020 IEEE MIT	Approximately 1 in 160	2	2	2	2	2	10
27	26	conferencePaper	contribution	2017	Silva, Salatiel Dantas;	Knowledgemon H	2017 19th Sym	Autism Spectrum Disord	2	2	2	2	1	9
28	27	journalArticle	review	2021	Farzana, Walia; Sarke	Technological Ev	IEEE Access	Augmentative and Alter	2	2	1	2	2	9
29	28	conferencePaper	contribution	2021	Gulati, Rishi; Handa,	Towards Develop	2021 Third Inte	Children suffering from	2	2	2	0	1	7
30	29	journalArticle	contribution	2014	Escobedo, Lizbeth; Te	Using Augmente	IEEE Pervasive	Children with autism ha	2	2	2	2	2	10
31	30	conferencePaper	contribution	2022	Romadlon Junaidi, Ah	Usability Testing	2022 2nd Inter	The development of con	2	2	2	0	0	6
32	31	conferencePaper	contribution	2019	Machado, Eduardo; C	An Assistive Augn	2019 IEEE Intl	Acquiring daily living skil	2	2	2	2	2	10

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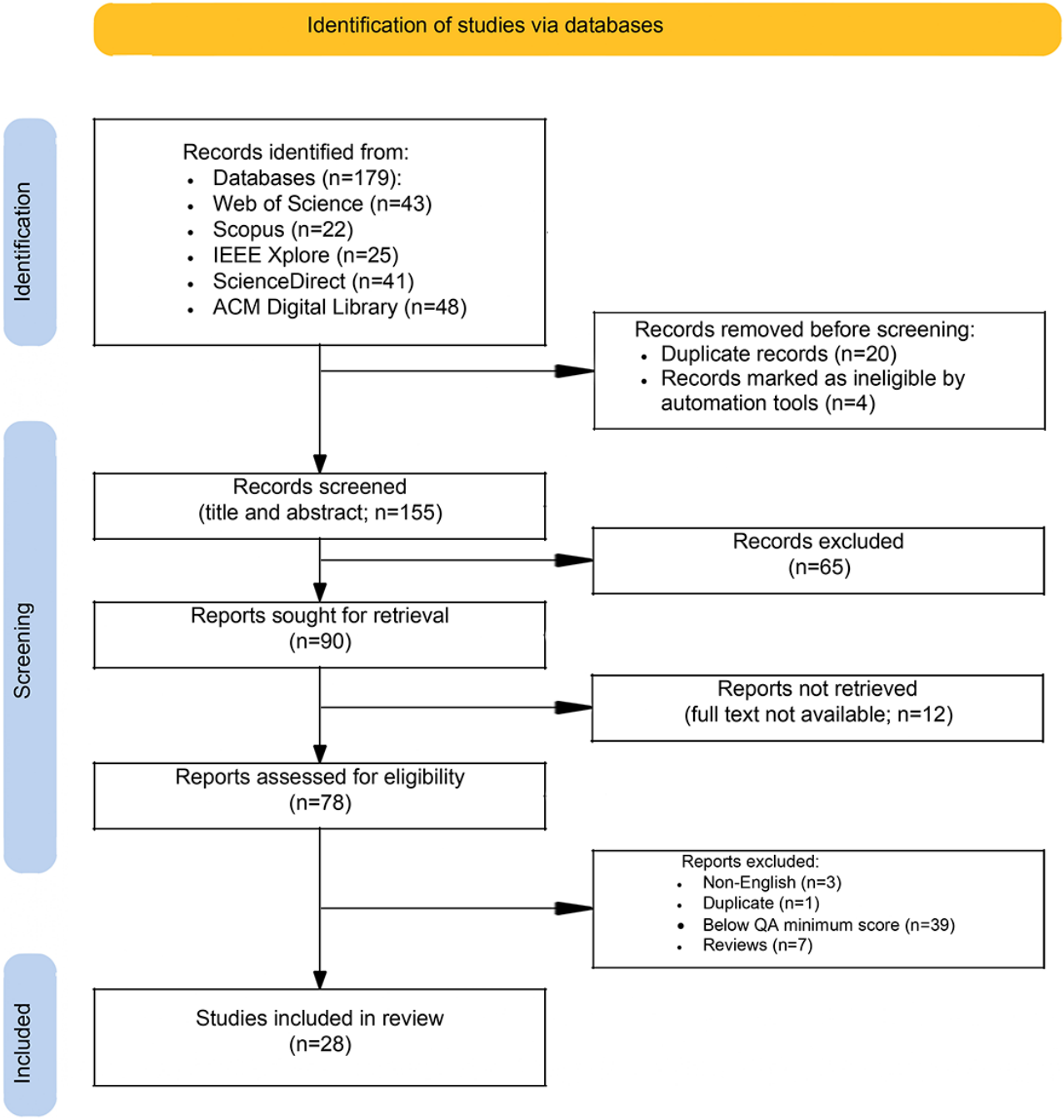
Figure 3. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram. QA: quality assessment.



Synthesis Methods

The data extraction process was carried out to methodically address the stated RQs. Initially, a single reviewer handled the task of data extraction, leveraging the analytical capabilities of Microsoft Excel to facilitate a structured and organized approach to data collection and analysis. The same tool was used for data organization and representation. Within this app, a comprehensive table was constructed in which the rows were designated to the considered references and data corresponding to individual RQs were entered into separate columns, fostering a systematic representation of the data obtained. Subsequently, to enhance the reliability and validity of the data integration process, a second reviewer performed a verification of the initially extracted data. This encompassing procedure ensured a high degree of accuracy and reduced potential discrepancies, thus guaranteeing the integrity of the data.

Results

As a result of applying the PRISMA guidelines, a total of 28 publications were considered in this study to address the RQs.

RQ 1: What Is the Papers' Distribution Over Time?

Considering the time range for paper analysis, Figure 4 depicts the time distribution of publications over the period of 2012 to 2022.

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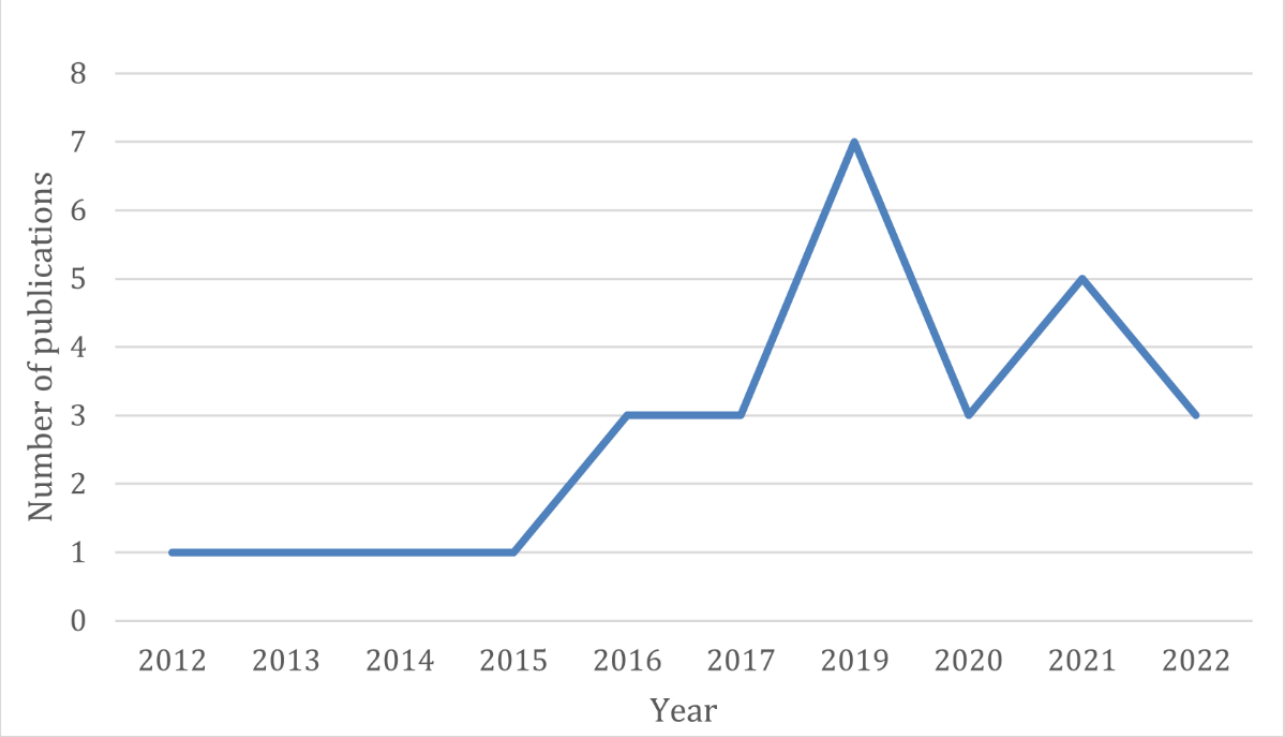
Figure 4. Time distribution of the reviewed publications.



Analyzing Figure 4, we can see an increasing trend in the number of publications starting in 2015, with the maximum value being reached in 2019. This denotes an increasingly high interest in these technologies. The number of publications decreased again in 2020, probably because of the pandemic, which limited human interaction and prevented the development and testing of apps dedicated to children with autism.

Regarding the types of publications, more than half (17/28, 61%) were presented at conferences, and 39% (11/28) were articles published in specialized scientific journals.

RQ 2: What Category of People Are the Studies Aimed at?

The analysis of the considered publications revealed that 43% (12/28) [29,31-33,36,39,43,44,47,50,51,53] stated that they were about children without mentioning the number of participants or their ages. Textbox 1 summarizes the data obtained.

The paper by Xia et al [47] addressed people with autism without mentioning whether they were children or adults, and the study by Wang et al [54] only involved adults but was of interest because the proposed solution can be applied to children as well.

In addition, the studies by Zheng et al [38], Escobedo et al [46], and Voss et al [49] included children both with and without ASD to compare the results and the process recorded in both cases.

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Textbox 1. Number and age of the children involved in the studies.

- Hashim et al [28]: 6 children aged between 5 and 12 y
- Machado et al [29]: children—age not stated
- Tang et al [30]: children aged <4 y and between 4 and 8 y; number not mentioned
- Selvarani et al [31]: children—age not stated
- Abou El-Seoud et al [32]: children—age not stated
- Vullamparthi et al [33]: children—age not stated
- Singh et al [34]: children aged between 9 and 12 y
- Chen et al [35]: 6 teenagers aged between 11 and 13 y
- Tang et al [36]: children—age not mentioned
- Giraud et al [37]: 12 children aged between 5 and 9 y
- Zheng et al [38]: 12 children, 6 with autism spectrum disorder (ASD) and 6 with typical development
- Pradibta and Wijaya [39]: children—age not stated
- Nubia et al [40]: 6 children (5 boys and 1 girl) aged between 3 and 9 y
- Sait et al [41]: 9 children aged between 4 and 12 y
- Wan et al [42]: 10 children aged between 3 and 8 y
- Kavitha et al [43]: children—age not stated
- Silva et al [44]: children—age not stated
- Kalantarian et al [45]: 8 children aged between 6 and 12 y
- Escobedo et al [46]: unknown number of children aged between 8 and 11 y, including 3 children with autism
- Xia et al [47]: mainly people with autism
- Amado et al [48]: children aged between 7 and 9 y; number not indicated
- Voss et al [49]: 20 children with ASD and 20 children without ASD
- Washington et al [50]: 14 families
- Gulati and Handa [51]: children—age not stated
- Escobedo et al [52]: 12 children and 7 teachers
- Bouaziz et al [53]: children—age not stated
- Wang et al [54]: 4 adults, but the system was suitable for children as well
- Gelsomini et al [55]: 5 children (2 with mild ASD, 2 with medium ASD, and 1 with psychomotor retardation)

RQ 3: What Technologies Are Used With XR or Any of Its Subdivisions to Develop Apps for ASD Therapy?

AR mobile apps for therapy for children with ASD typically used a combination of the following technologies:

1. Mobile devices such as smartphones and tablets equipped with cameras; displays; and sensors such as accelerometers, gyroscopes, and GPS
2. AR software development kits such as ARKit, ARCore, and Vuforia, which provide the tools and framework needed for developing AR apps
3. Graphical and game engines such as Unity and Unreal Engine for 3D model development and creating animations and interactive environments
4. Natural language processing and speech recognition technologies for creating voice-activated AR experiences
5. Computer vision and image-processing techniques for real-time object tracking and recognition of objects, faces, and gestures
6. Machine learning algorithms for customizing the AR experience based on the child's performance and preferences
7. Cloud computing infrastructure for data storage, management, and analysis of therapy progress

Of the 28 analyzed publications, 22 (79%) addressed a solution from the spectrum of AR implemented on mobile devices such as smartphones owing to their processing power and integrated sensors that make them suitable tools for implementing apps without the need for additional and sophisticated equipment. In addition, the papers by Giraud et al [37], Sait et al [41], Gulati and Handa [51], and Gelsomini et al [55] presented solutions based on VR. Although the articles by Wan et al [42] and Kalantarian et al [45] did not present an AR or VR solution, the methodology addressed and the results obtained show the

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potential for research in this area. Textbox 2 summarizes information about the technologies and platforms used for app development.

Unity 3D and Vuforia were among the most common platforms used in the development of AR apps for mobile devices, with the Android operating system often mentioned. Several studies (6/28, 21%) [29,38,41,49,51,55] used wearable devices such as Google Glass, Oculus Go, Google Cardboard, Leap motion sensors, and E4 wearable sensors along with the mentioned technologies. Interactive cards were also used as markers to overlay virtual content.

Textbox 2. Technologies and platforms used.

- Hashim et al [28]: interactive cards, augmented reality, and smartphones
- Machado et al [29]: augmented reality based on smart glasses and Android, web platform, Node.js, eye tracker, sensors, and Amazon Alexa
- Tang et al [30]: augmented reality and Google TensorFlow
- Selvarani et al [31]: interactive cards, augmented reality based on markers, Vuforia, Android smartphone, and Unity 3D
- Abou El-Seoud et al [32]: augmented reality based on markers, smartphones, and the Aurasma framework
- Vullamparthi et al [33]: smartphone, Android, augmented reality, and QR codes
- Singh et al [34]: desktop app and augmented reality
- Chen et al [35]: Vuforia and smartphone or tablet PC
- Tang et al [36]: Google TensorFlow, augmented reality, and smartphone or PC
- Giraud et al [37]: virtual reality (VR) and Unity 3D
- Zheng et al [38]: augmented reality, Microsoft Kinect, and portable E4 sensor
- Pradibta and Wijaya [39]: interactive cards, augmented reality, Android smartphone, and Adobe for animation and graphic illustration
- Nubia et al [40]: augmented reality, Android tablet PC, Unity 3D, Vuforia, and Blender
- Sait et al [41]: VR, Unity 3D, and VR glasses (Oculus Go)
- Wan et al [42]: system that can be implemented on a PC, smartphones or robots; no use of augmented reality or VR
- Kavitha et al [43]: augmented reality, Android smartphone, Vuforia, and ARCore
- Silva et al [44]: augmented reality, smartphone or tablet PC, and Vuforia
- Kalantarian et al [45]: Android smartphone; no VR or augmented reality
- Escobedo et al [46]: augmented reality and Android smartphone
- Xia et al [47]: augmented reality, Android or iOS smartphone, React, Node.js, and Python for object recognition
- Amado et al [48]: augmented reality, Vuforia, Unity 3D, Android smartphone, Balsamiq Mockups 3, and Tinkercad
- Voss et al [49]: augmented reality, Android smartphone, and Google Glass
- Washington et al [50]: Google Glass and Android smartphone
- Gulati and Handa [51]: VR, Leap motion sensors, and VR camera
- Escobedo et al [52]: augmented reality, smartphone or tablet PC, PC server, MySQL database, and HTTP
- Bouaziz et al [53]: interactive cards, augmented reality, smartphone, and Vuforia
- Wang et al [54]: augmented reality, tablet PC or smartphone, Unity 3D, and Vuforia
- Gelsomini et al [55]: VR, Google Cardboard, smartphone, and Unity 3D

RQ 4: What Skills Were Targeted for Improvement in Primary Studies?

Owing to the deficiencies of children with ASD, the aim was to improve some basic skills such as the following:

1. Communication and language development
2. Social interaction and play skills
3. Fine and gross motor skills
4. Emotional regulation and collaborative strategies
5. Cognitive and problem-solving abilities
6. Attention and ability to follow instructions
7. Independence and self-help capabilities

Table 3 presents the number of publications aimed at improving basic skills.

A total of 25% (7/28) of the publications [28,30,33,36,40,49,52] focused on improving communication skills such as English vocabulary learning [28]; word learning using automatic object recognition through an app based on the TensorFlow library that can be used either when connected to the internet or offline [29]; speaking, reading, and associating images using an app that allows for customization of lessons by parents or therapists [33]; and communication and socialization by delivering certain cues through smart glasses [49]. Textbox 3 details the skills targeted in the studies.

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Table 3. Targeted learning skills (n=28).

Skill	Studies, n (%)
Religious skills	1 (3)
Daily activities, meal preparation, toothbrushing, and eating	3 (11)
Cognitive or attention	2 (7)
Expressing emotions or social skills	5 (18)
Environment adaptation	1 (3)
Motor skills	2 (7)
Task training	1 (3)
General skills	3 (11)
Number learning	1 (3)
Object recognition	2 (7)
Communication or vocabulary	7 (25)

Textbox 3. Skills aimed to be improved.

- Hashim et al [28]: communication skills; learning English vocabulary, pronunciation, and articulation skills
- Machado et al [29]: daily routine activities (preparing meals)
- Tang et al [30]: word learning and object recognition
- Selvarani et al [31]: number learning
- Abou El-Seoud et al [32]: general skills; the user can choose the augmented reality (AR) content to be displayed
- Vullamparthi et al [33]: speaking abilities, reading, image associations, and activity scheduling
- Singh et al [34]: procedural task fulfillment
- Chen et al [35]: expressing emotions and social abilities
- Tang et al [36]: object recognition and vocabulary learning skills
- Giraud et al [37]: motor and social skills
- Zheng et al [38]: toothbrushing abilities
- Pradibta and Wijaya [39]: religious abilities—prayers
- Nubia et al [40]: communication abilities
- Sait et al [41]: adaptation to a new or unfamiliar environment
- Wan et al [42]: cognitive skills and practicing facial emotions
- Kavitha et al [43]: general skills; the user can choose the AR content to be displayed
- Silva et al [44]: social and general skills
- Kalantarian et al [45]: expressing emotions and social abilities
- Escobedo et al [46]: social skills in real-life situations, building and maintaining social relationships, improving conversational ability, and managing behavior and emotions
- Xia et al [47]: social and self-help abilities (shopping)
- Amado et al [48]: cognitive skills
- Voss et al [49]: social and communication abilities
- Washington et al [50]: expressing emotions
- Gulati and Handa [51]: motor, focusing, and general skills
- Escobedo et al [52]: object recognition
- Bouaziz et al [53]: self-help skills (feeding)
- Wang et al [54]: attention skills
- Gelsomini et al [55]: general skills (attention, concentration, and understanding) and narration

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Some studies (3/28, 11%) focused on the development of self-help skills such as preparing meals with the help of smart glasses, receiving real-time information about the steps to follow [29], brushing teeth [38], or eating [53]. By improving the skills aimed at in the studies considered in this review and developing skills that can improve the deficiencies present in children with ASD, the social inclusion of children with ASD was pursued.

RQ 5: What Are the Purposes for Which the Proposed Solutions Were Used?

Using at least one of the technologies targeted in this review, the solutions presented in these publications were used to assist children with ASD. Developed for use by both therapists and parents at home or in specialized medical centers, these solutions aimed to improve certain fundamental aspects of the lives of children with autism. Textbox 4 presents information related to the reasons for which the apps were developed.

Hashim et al [28] created an app for the development of children's English vocabulary, which could potentially be used with other languages as well. The solution proposed in the paper by Machado et al [29] used multiple technologies to allow the therapist to model activities using a web platform and provide hints to users via smart glasses. It also works as an attention-monitoring tool via an eye tracker so that activities can be evaluated and improved. The study by Tang et al [30] addressed the problem of communication through automatic object recognition using a smartphone and display of virtual content (object names) on the screen. This app works either when connected to the internet or offline. A similar approach was observed in the study by Selvarani et al [31], in which children could learn numbers by scanning notebooks using their mobile devices, after which the relevant content was displayed on the screen.

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Textbox 4. The purpose of the developed apps.

- Hashim et al [28]: the Areal-Vocab app was developed to help children with autism improve their English vocabulary.
- Machado et al [29]: the aim was to develop an assistive app using augmented reality (AR) based on smart glasses and a visual attention analysis tool to help people with autism in daily tasks by providing complementary information (eg, to pick up the knife and then cut the strawberries). The therapist can model the activity.
- Tang et al [30]: the researchers intended to develop a mobile app for children with autism that could run either connected to the internet or offline that would improve word learning skills by using object recognition.
- Selvarani et al [31]: the aim was to help children with autism learn numbers by scanning an interactive card using the app so that complementary video and audio content is displayed on the screen.
- Abou El-Seoud et al [32]: the aim was to develop a framework to help parents or educators use AR in a personalized way by choosing what type of AR educational content to display over a printed marker representing a familiar cartoon character.
- Vullamparthi et al [33]: a tool was developed that included an interface for parents or educators to scan a QR code and create various lessons and an interface for children. It used the smartphone camera, an Android apk (Android application package), a web page, a database, and Jakarta server pages.
- Singh et al [34]: the paper was a comparative study that aimed to explore the effectiveness of AR in the execution of tasks among less privileged children (who have had minimal interaction with technology), healthy but younger children, and children with autism.
- Chen et al [35]: the researchers developed a Vuforia-based AR app that can be deployed on Android or iOS devices (smartphones or tablets). This app can scan storybooks (with images captured from videos) and overlay relevant content to assist children with autism in expressing and understanding emotions and developing social skills.
- Tang et al [36]: the aim was to develop a tool for children with autism that can recognize objects and display their names.
- Giraud et al [37]: the study aimed to involve children with autism in common actions (moving furniture) by interacting with a virtual character projected on a tactile magnetized surface.
- Zheng et al [38]: the goal was to develop an AR system (Cheerbrush) that could teach children with autism how to brush their teeth considering how important this is to stay healthy and avoid dental procedures. It uses Kinect to capture the user's movement, a 3D-printed toothbrush to assess brushing skills, a monitor to view the surroundings, and an avatar. It also uses a wristband to assess children's stress while using the app.
- Pradibta and Wijaya [39]: the aim was to help children with autism learn daily prayers. The goal was to develop an app that contains animated learning materials in the form of daily prayers from the Islamic religion.
- Nubia et al [40]: the aim was to help children with autism communicate better using an app that can identify human-recognizable objects such as animals, fruits, or other common objects and match them with specific sounds.
- Sait et al [41]: the goal was to develop a virtual reality (VR) framework in which the teacher can enter information about the child and prepare scenes that can be watched by a child wearing VR glasses. The main objective was to familiarize children with autism with places such as school, the schoolyard, and the classroom by previously visualizing the environment.
- Wan et al [42]: the aim was to help children with autism recognize, practice, and express emotions such as happiness, sadness, fear, or anger.
- Kavitha et al [43]: the aim was to help children with autism recognize objects or animals by rendering 3D content over certain images.
- Silva et al [44]: the aim was to help reduce the isolation of children with autism by encouraging them to explore the world with the help of an app based on geolocation and AR.
- Kalantarian et al [45]: the goal was to help children with autism learn to express their emotions. Guess what? is an Android mobile app similar to Heads up!, a game in which a parent holds the smartphone with the screen facing the child, the child imitates what they see, and the parent tries to guess the simulated emotion.
- Escobedo et al [46]: the paper describes the design and development of the MOSOCO app, which is a mobile app that provides real-time support and guidance to children with autism in practicing social skills. The app uses AR technology to overlay social hints directly into the child's real environment, allowing them to practice social skills in real-life situations.
- Xia et al [47]: the app provided step-by-step guidance for people with autism to go shopping by augmenting real shopping scenes using object recognition, barcode reading, and automatic classification.
- Amado et al [48]: the main objective was to develop an AR mobile app to be used by parents of children with autism for their therapy during the pandemic, when human interaction was limited.
- Voss et al [49]: the system described in the paper aimed to help people with autism spectrum disorder improve their social skills by providing discrete real-time social cues via wearable technology. Social cues are provided directly in the wearer's field of vision using AR technology and are intended to help the wearer navigate social situations and improve their social interactions and communication skills.
- Washington et al [50]: the goal was to develop an app that runs on an Android smartphone (used by a parent) that is connected to a Google Glass device worn by the child. Social cues are delivered to the glasses based on emotions recognized by the mobile app, which also records the session (video only for privacy reasons). The activities are gamelike—catch the smile, guess the emotions, and unstructured activities.
- Gulati and Handa [51]: the aim was to develop a VR game to improve reading, basic math, and spelling. Motor skills are improved by reading gestures and helping coordinate them with the eyes using the Leap motion sensor.

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- Escobedo et al [52]: the aim was to create an app that can identify objects that are tagged and display relevant content over them, such as text, 3D models, vibrations, video, or audio, and the user can receive a reward. The main architecture is composed of a module called therapy manager, an ambient notification system, and a tag manager.
- Bouaziz et al [53]: the aim was to develop an app dedicated to children with autism that teaches them how to eat by scanning an interactive card and displaying on top of it a 3D character depicting the targeted skill.
- Wang et al [54]: the aim was to help adults with autism be more focused by performing certain tasks, such as rearranging objects in a scene.
- Gelsomini et al [55]: the aim was to develop a VR mobile app for smartphones that can be used with Google Cardboard, helping children with autism understand activities through storytelling and allowing caregivers to customize the content using a web app, monitor children's attention, and analyze statistics.

The apps developed in the studies by Abou El-Seoud et al [32] and Vullamparthi et al [33] aimed to go through some lessons that parents and educators could customize by accessing a web platform so that they could choose which type of content to display when the app detected an object in the visual area. The study carried out by Singh et al [34] compared the effects of apps that use AR to perform certain tasks in both children with ASD and children with typical development. Religious activities were also included in one study [39], which presented an app containing animated materials that helped children learn prayers.

Given the fact that children with autism typically experience difficulties adapting to a new environment, Sait et al [41] aimed to develop an app that uses VR, VR glasses, and a web platform in which therapists can enter information about each child and set up custom scenes, such as a classroom, to be viewed virtually and get used to. In addition to the goal of conducting basic activities, Xia et al [47] developed an app to guide individuals with autism with grocery shopping step by step.

RQ 6: What Are the Results Obtained Using the Proposed Solutions?

Depending on the proposed solution and the objectives of the studies, the results were different, but in general, where the app was tested, encouraging results were obtained, with the remark that these were to be improved and tested more thoroughly. In cases in which the app was not tested with the intended audience but was proven to function, it was deemed to have potential. Textbox 5 summarizes the results obtained in each study.

Upon analyzing the results of the studies included in this review, it was found that only 68% (19/28) of the apps were tested with children with autism, whereas 32% (9/28) were tested only by the developers for functionality purposes. Regarding the methods used to quantify the results, 54% (15/28) of the studies used interviews, and only 14% (4/28) of the studies used an assessment method based on assigning a score according to the degree of skill improvement after using the apps.

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Textbox 5. Summary of the results.

- Hashim et al [28]: children and their parents or educators in the study used the app and reported positive results based on interviews: "Helps listen and understand instructions, helps maintain attention longer, helps with pronunciation and enunciation, helps keep them engaged and interested to learn the vocabulary in depth."
- Machado et al [29]: the app has great potential considering the fact that smart glasses can very easily transpose the user into the world of augmented reality (AR) and help them by displaying complementary information, as well as giving feedback to the therapist. It has been tested by developers but has not been tested with children with autism, so it does not show quantifiable results.
- Tang et al [30]: the first pilot study was conducted on a university campus with neurotypical children and adults, who provided positive feedback and showed a lot of interest. The second study was conducted in a special education unit involving 2 groups: one with children aged <5 y and one with children aged between 6 and 8 y. It was noticed that the younger children had difficulty using the app, but it was well received by the older children. Positive feedback was also provided by parents and teachers, pointing out that the offline module required improvement.
- Selvarani et al [31]: the app (NUM09) is functional but has not been tested on children with autism with quantifiable results.
- Abou El-Seoud et al [32]: a total of 3 patients with autism, together with their instructors, performed a usability test. According to responses to a questionnaire, the system can improve communication, concentration, and attention and is easy to use.
- Vullamparthi et al [33]: this study developed an Android smartphone app that helps children with autism and their parents or therapists create personalized lessons to improve basic skills such as reading, writing, or picture recognition. A workshop was held, and positive feedback from parents was reported. There are no quantifiable results.
- Singh et al [34]: the main task was to complete a tangram puzzle. In the first stage, the involved children did not solve the puzzle without clues involving AR, but it was reported that solving took longer in the AR training mode. In the first study, children aged 9 to 12 y rated the desktop-based instruction mode as the least preferable, whereas the performance using the AR mode was superior. In the second study, 4 children with autism followed the same procedure but had difficulty using the AR-based solution, resulting in poorer performance on the task.
- Chen et al [35]: the app was tested in a dedicated room equipped with a computer, a 52-inch monitor, and 8 tablets. The therapist showed the children the app and asked them to look at the pictures, answer some questions, and use the tablet to access the AR content by pointing it at the picture with the app running in the background. Positive feedback was reported from the children, who were curious and eager to discover new visual cues, showing interest in the facial expressions, gestures, and related activities of the characters. The children had low scores on the initial assessment, but all 6 scores increased significantly after the app intervention. The most dramatic improvement was in one child, from 30% to 89.5%.
- Tang et al [36]: the app works, but it has not been tested on children with autism with quantifiable results.
- Giraud et al [37]: 12 children with autism spectrum disorder (ASD; including 2 girls) aged between 5 and 9 y participated in the study for a period of 3 mo. In total, 7 of the children showed little conversational language. A 3-stage experiment was conducted (familiarization, moving an object with an agent following the child, and training with an agent that the child follows). Preliminary results were encouraging: one-third of the children completed the training, another third needed device adjustments, and some had difficulty using the system.
- Zheng et al [38]: to evaluate the system, 6 children aged between 3 and 6 y (3 with ASD and 3 without ASD) were involved in an experiment comparing the results. It was noted that all the children were able to complete the training sessions, but the children with ASD were clearly more engaged and interested. After training, the most notable improvements were observed in children with autism. During an interview, both children and parents said that they liked the app and that it helped them improve their toothbrushing skills.
- Pradibta and Wijaya [39]: no proof of testing with children with autism and no quantifiable results.
- Nubia et al [40]: by playing relevant sounds in line with images, the app helped children improve their learning skills compared with traditional methods. A 14% increase in attention and a 9% increase in verbal language were reported.
- Sait et al [41]: the system was used by 9 children with autism who benefited from the help of therapists who guided them in adjusting the Oculus Go headset and using the app (AutiVE). One of the issues was the virtual reality (VR) headset itself and the VR environment, but the website provided had a video explaining them. In total, 8 of the children eventually accepted the device. There were some improvements in learning skills, but no detailed statistics were mentioned.
- Wan et al [42]: the children completed a 20-min training session each day for 4 consecutive days. A total of 6 participants showed improvement in proficiency in operating the system, 5 of 6 completed all tasks, and 4 of 6 showed improvements in expressing emotions. Children aged <5 y found the app difficult and did not perform in a satisfactory manner.
- Kavitha et al [43]: the app works, but it has not been tested with quantifiable results.
- Silva et al [44]: an app similar to Pokémon GO was developed in which users can find "monsters" in certain areas and, by clicking on them, find relevant information. The concept of gamification was used, but the system was not validated with real users with autism.
- Kalantarian et al [45]: the solution was tested with 8 children, all boys, playing up to 5 games in 1 session. In total, 94%, 81%, 92%, and 56% of the emotions were labeled correctly as disgust, neutrality, surprise, and fear, respectively.
- Escobedo et al [46]: the app was evaluated over 7 wk. Interview results revealed that the app was well received by children with autism and their therapists and that it was effective in helping children practice and improve their social skills in real-world situations. The authors reported that users were able to use the app easily and that the AR technology was effective at providing children with real-time support and feedback. The study also showed that the app was well accepted by therapists, who found it a useful tool for their patients' therapy.
- Xia et al [47]: the app, called ParaShop, was tested by a nonprofit organization that helps people with disabilities. Staff said that the app helped people with autism buy their groceries, but the number of participants or other details were not mentioned.

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- Amado et al [48]: a case study was conducted using Google Forms asking parents to answer questions related to their children (eg, age, gender, and whether the parents lived together). Several studies with parents were conducted, and then the app was developed based on their responses and requirements. In the last stage of the case study, 5 questions were posed about the final prototype of the app. The survey revealed that 46.2% of parents were satisfied and 23.1% were very satisfied. Overall, the mobile app received positive feedback from respondents.
- Voss et al [49]: the research entailed a study involving 20 participants with ASD and 20 participants without ASD who used a system called Superpower Glass over a 4-mo period. The results showed that the participants found the social cues useful in situations and improved their social interactions and communication skills. The study also assessed the acceptability and usability of the system, and the results suggest that it was well received by participants and easy to use.
- Washington et al [50]: the app was tested by families, and they reported that it was useful, with some of them recording the sessions and then showing them to the children to see how they behaved for further improvement. Overall, based on interviews, parents reported positive outcomes.
- Gulati and Handa [51]: the concept of gamification was used; it has potential, but it has not been tested in children with autism. To play the game, a dedicated gaming room and specific equipment are required.
- Escobedo et al [52]: the app (Mobis) was tested with 7 teachers caring for 12 children with autism aged between 3 and 8 y. The researchers conducted weekly interviews with the teachers, keeping in mind that only 3 out of 12 children were able to properly pronounce words. The duration of the observation was 54 h. Participants were reported to find Mobis "exciting, useful, and easy to use." Students improved their motor skills by focusing the camera on the target. Mobis increased the time that students stayed on task by 20% and motivated them to use the app as they were excited to discover new objects in their environment. Selective attention improved by 62%, and sustained attention improved by 45%. Mobis also induced positive emotions and taught behavioral skills such as tolerance.
- Bouaziz et al [53]: no proof of testing with children with autism and no quantifiable results.
- Wang et al [54]: the app was developed for demonstrative purposes only; it has not been tested with quantifiable results.
- Gelsomini et al [55]: the solution (Wildcard) was tested in a special unit with 5 children with autism during 8 individual therapy sessions. Therapists reported improvements in children's attention and cognitive skills, but the paper only reported qualitative data. Therapists were excited to be able to customize each VR session and noted that patients embraced the app and found it engaging.

Discussion

Principal Findings

The analysis revealed an increasing trend in publications starting from 2015, reaching its highest point in 2019 and followed by a decline in 2020, potentially because of the pandemic. Most of the papers (17/28, 61%) were presented at conferences and largely focused on AR solutions (22/28, 79%) for mobile devices to assist children with ASD in enhancing basic skills and fundamental life aspects. Notably, Unity 3D and Vuforia emerged as popular development platforms. Although a substantial percentage of publications (13/28, 47%) did not provide details on participating children, most of the identified participants were aged between 3 and 13 years. Developed for use by both therapists and parents at home or in specialized medical centers, these solutions showed encouraging preliminary results but underscore the necessity for further, more extensive testing, particularly as a significant portion (9/28, 32%) were only developer tested.

Main Directions of Research

Upon examining the scientific publications included in our study, several main directions for the use of XR to support children with autism can be identified.

One notable topic is the use of AR in the area of language skills and vocabulary learning in children with autism. Researchers in some studies (3/28, 11%) [28,30,43] focused on the development of AR-based mobile apps that facilitate word learning and object recognition through techniques such as deep learning and automatic object recognition.

Another topic addressed in some studies (3/28, 11%) [29,39,53] was the use of smart glasses or wearable devices to support children with autism in social interactions. These devices provide real-time visual cues and information to enhance communication and social interaction skills.

The use of AR occupational therapy and the development of cognitive skills in children with autism were explored in some studies (3/28, 11%) [31,38,46], which proposed AR-based apps to aid children in learning numbers, teeth-brushing skills, or environmental adaptation skills.

Furthermore, it was stated that the apps specifically designed for children with ASD should be tested with a target group of children, and the results should be quantified in a pertinent manner given that a large part of the findings were obtained through interviews.

Personalization and adaptability are other key aspects of developing mobile apps, as shown in the studies by Wan et al [42], Kalantarian et al [45], and Washington et al [50]. These publications addressed the development of personalized systems and apps to maximize the therapeutic and educational benefits for children with autism.

Some studies (3/28, 11%) [32,34,52] also examined the use of AR to provide individual support for people with autism and cognitive impairment. These studies proposed AR-based frameworks and approaches to assist individuals with autism in various activities and tasks, such as training in procedural tasks, perception and recognition of facial emotions, or assistance in real-life situations.

In addition, some studies (3/28, 11%) [35,37,55] investigated the use of AR in the context of education and social skill development. These studies focused on the use of interactive books, serious games, or training apps to support children with

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autism in understanding and interpreting facial expressions, social cues, and social interactions.

The use of AR in the context of learning in a geographical environment or learning environmental coping skills was addressed in some studies (3/28, 11%) [40,41,47]. These studies proposed AR-based apps to assist children with autism in exploring and learning in a geographical environment or in developing adaptive skills applicable to different situations and contexts.

A relatively small number of studies (6/28, 21%) [34,38,46-48,52] focused on VR-based approaches for apps, indicating a shift toward the adoption of AR owing to its lower cost and greater usability. Using VR, the study by Abou El-Seoud et al [32] evaluated joint action (moving furniture) abilities using a virtual character, and the preliminary results were encouraging, with one-third of the children completing the training despite 7 of them having limited conversational language. Another issue addressed in the study by Tang et al [36] was adaptation to unfamiliar surroundings. Researchers reported improvements in learning abilities but stated that the equipment and VR environment posed the greatest challenges. The concept of gamification was integrated with VR in the study by Escobedo et al [46] to enhance reading, basic mathematics, and spelling. This app required a special room to run. Although this app has great potential, it has not yet been tested in children with ASD. In addition, an app using Google Cardboard and VR was developed to enhance the cognitive and attentional skills of children. Therapists expressed satisfaction with the outcomes as they were able to personalize each session using unique teaching methods.

User Interaction Perspectives

Overview

The interaction of children with ASD with XR devices, such as AR and VR platforms, brings forth a distinct set of considerations. The manner in which children with ASD use these devices can be influenced by their sensory sensitivities, motor skills, cognitive abilities, and preferences. Although the experiences can vary widely, the following are some ways in which children use XR devices and the challenges they may face.

Physical Interaction

Children use XR devices by interacting with touch screens, controllers, or wearable components. They may tap, swipe, or perform gestures to navigate through XR environments. However, children with fine motor difficulties may struggle with precise interactions, leading to accidental inputs or difficulties in selecting desired options.

Visual Engagement

Children engage visually with the XR content displayed on screens or through headsets. Visual stimuli can capture their attention and spark interest. Nonetheless, those with sensory sensitivities may experience sensory overload or visual discomfort if the content is excessively bright, flashy, or overwhelming.

Spatial Awareness

XR experiences often involve spatial interactions such as moving through virtual environments or manipulating virtual objects. Children's spatial awareness skills can influence their ability to navigate these environments. Some children may find it challenging to grasp the concept of a virtual space, leading to disorientation.

Auditory Response

Many XR apps incorporate auditory cues, sound effects, or voice instructions. Children may respond to auditory prompts by vocalizing or reacting physically. However, children who are sensitive to loud or sudden sounds may experience distress in XR environments with intense auditory stimuli.

Attention and Engagement

Children's level of attention and engagement with XR content can vary. Some may become deeply immersed and engaged, whereas others may have difficulty sustaining their attention because of the novelty of the experience or sensory distractions.

Preferences and Comfort

Children's preferences for certain types of interactions or content can influence their engagement. Some children may appreciate exploring virtual worlds, whereas others may prefer more structured or repetitive activities. Ensuring a variety of XR experiences allows for accommodating different preferences.

Transition Challenges

Transitioning between the real world and the XR environment can be challenging for some children. They may have trouble understanding that the virtual elements are not physically present or struggle with transitioning back to reality after prolonged XR use.

Response Variability

Children with ASD may respond to XR experiences differently across sessions. Factors such as mood, sensory sensitivities, and cognitive states can influence their interactions. Some days, children may be more receptive to XR, whereas on other days, they may be less engaged or overwhelmed.

Calibration and Setup

XR devices require proper calibration and setup for optimal interaction. Children may need assistance in adjusting headsets, ensuring proper alignment, or calibrating controllers. Technical difficulties can lead to frustration or disengagement.

Challenges

The identified challenges are as follows:

1. Individualized learning needs: a prevalent challenge across the studies in this review was catering to the diverse learning preferences and abilities of children with ASD. For instance, Hashim et al [28] faced the task of addressing the specific needs of children with mild ASD. Similarly, the studies by Abou El-Seoud et al [32] and Singh et al [34] addressed the challenge of tailoring their AR experiences to suit varying preferences and capabilities.

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2. Transferability and generalization: a common limitation is the transfer of learned skills to real-world scenarios. As seen in the studies by Tang et al [36] and Giraud et al [37], researchers have encountered challenges in translating acquired skills into practical applications. In addition, studies such as those by Chen et al [35] and Kavitha et al [43] noted limitations in transferring learned skills beyond the AR context, possibly owing to the variations in real-world stimuli.
3. Technical feasibility and personalized support: technical feasibility and ongoing support emerged as challenges in some studies [29,38]. Maintaining the functionality of AR-based smart glasses and ensuring accurate real-time feedback for toothbrushing techniques required continuous technical support.
4. Sensory overload and individualization: sensory sensitivities and the need for individualized solutions were prominent challenges. Sait et al [41] encountered the challenge of designing virtual environments that cater to sensory sensitivities, whereas studies such as the one by Voss et al [49] highlighted the importance of unobtrusive cue presentation in wearables for children with ASD.
5. Cognitive adaptation and user adoption: cognitive adaptation and user adoption challenges were evident in some studies [48,52]. Designing tasks that effectively target cognitive skills and maintaining user engagement over time were key considerations.
6. Ethical implications of data handling: as AR interventions involve interactions and data collection, ethical considerations are paramount. The study by Wan et al [42] delved into recognizing facial expressions, which raises ethical concerns related to data privacy and security. Ensuring that data-handling protocols adhere to ethical standards becomes crucial, underscoring the need to protect sensitive user information while deriving meaningful insights from the interactions.
7. Cross-cultural adaptation and applicability: given the diversity of cultures and languages, ensuring the cross-cultural adaptation and applicability of AR interventions becomes a notable challenge. The study by Wang et al [54], which explored mobile AR for attention improvement in adults with ASD, highlights the importance of adapting interventions to diverse cultural contexts. This challenge emphasizes the need for cultural sensitivity and the localization of content to ensure that interventions are universally accessible and effective.
8. Long-term impact measurement: measuring the long-term impact of AR interventions and tracking the progress of children over time poses significant challenges, as pointed out in the study by Escobedo et al [46], which emphasized the importance of assessing the sustained effects of interventions beyond short-term interactions. This challenge underscores the necessity of devising reliable methodologies for gauging the lasting benefits of AR interventions and understanding how these interventions contribute to the developmental trajectory of children with ASD.

In the realm of AR apps for children with ASD, studies have striven to engage children through various interaction modes while tackling shared challenges. The diverse engagement strategies and the collective endeavor to overcome common limitations underscore the continuous efforts to create meaningful and effective AR-based interventions for this unique demographic.

Research in this area demonstrates an interdisciplinary approach involving collaboration among specialists in education, IT, and mental health. This is illustrated by the diversity of authors and publications included in this review, suggesting that integrating AR, VR, and MR into ASD pedagogy requires a comprehensive approach that considers multiple aspects—from technology design to educational and mental health psychology. It was also specified that the apps aimed at children with ASD should be tested with a target group of children and that the results should be quantified in a more relevant manner given that a large part of the reported results was obtained only through interviews. The analysis of the studies indicates a trend in research toward the use of diverse and innovative study methods, such as using both quantitative and qualitative methods to investigate the impact of AR, VR, and MR on people with ASD.

Furthermore, the analyzed publications suggest that the development and implementation of AR-, VR-, and MR-based technologies extend beyond academia or research, involving partnerships with the private sector and local communities. This demonstrates the awareness of the need to transfer research findings into practice to have a direct impact on people with autism.

Limitations

Considering the publications reviewed in this study, several limitations were identified regarding the development and testing of AR-, VR-, and MR-based mobile apps:

1. Sample size: some studies involved small samples of participants, which may have limited the generalizability of their results to a larger population of children with autism. The involvement of a limited number of participants in many studies can be attributed to the unique characteristics of the target population—children with ASD. The diversity in ASD manifestation, severity, and individualized needs necessitates careful participant selection. Moreover, recruitment challenges, ethical considerations, and the resource-intensive nature of working with children with ASD contribute to the small sample sizes. However, this limitation was often acknowledged in the papers, along with the understanding that the findings may not be easily generalizable to the broader population with ASD.
2. Study duration: the duration of the studies included in this review varied from short testing sessions to several weeks or months. The short duration of many studies was due to practical constraints and the inherent complexities of conducting research involving children with ASD. Longitudinal studies involving children with ASD can present challenges in terms of participant retention, compliance, and data collection consistency over extended periods. In addition, the rapid pace of technological advancements may affect the relevance of the findings if studies are conducted over prolonged durations. However, the researchers did recognize the limitations imposed by

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short study durations and provided justifications for the chosen time frames.

3. Diversity of diagnosis and level of functioning: autism is a disorder with a wide variety of symptoms and levels of functioning, which adds complexity and variability to the research.
4. Standardized outcome assessment: some studies did not use standardized outcome assessment tools, which may have affected the comparability and validity of the obtained results.
5. Availability and accessibility of technology: although the presented studies demonstrate the potential of AR technology to support children with autism, it is important to consider the availability and accessibility of this technology in real-world settings. The cost, infrastructure, and availability of AR devices and apps may be limiting factors in the widespread adoption of this technology.

The relatively small sample sizes and short durations commonly observed in many studies involving children with ASD and XR interventions are notable aspects of the research landscape. Although solutions to these issues were not always addressed in the papers, they remain ongoing areas of consideration for researchers in the field. In the selected papers, although some discussions and considerations regarding the challenges of small sample sizes and short study durations were present, comprehensive solutions were not elaborated on. The researchers often acknowledged these limitations and offered potential insights or recommendations, but definitive solutions were not always a primary focus of the papers, the primary focus being on the technical details and potential outcomes of their approach.

In addition, this study itself has several limitations, which should be considered for further research:

1. Limited number of databases queried: despite using comprehensive search strategies, it is possible that some relevant studies were omitted because they were published in nonindexed or less accessible sources.
2. Field evolution: this field of study is rapidly evolving, and new research may have been published since the literature search was conducted. Consequently, this review may not capture the most recent evidence and emerging trends in the field.
3. No distribution of publication authors: this review did not present information on the regional distribution of authors or the origin of the apps and systems, disregarding the influence of cultural differences on the development of these types of apps.
4. Lack of security analysis: this study did not analyze the security issues associated with the proposed solutions.
5. Absence of cost information: no information regarding the cost of the presented solutions could be identified.

Conclusions

This study aimed to conduct a systematic review of the specialized scientific literature in terms of applications, devices, and technologies relevant to the development of AR-, VR-, and MR-based mobile apps dedicated to the therapy of children with ASDs, an objective that was successfully achieved. At the beginning of this paper, the general concept of ASD was presented, after which the RQs and inclusion and exclusion criteria were defined and the results of applying the PRISMA guidelines for the selection of publications to be reviewed were reported. The answers to the RQs were discussed. At the end of the paper, the limitations of the research were presented.

Although the concepts of AR, VR, and MR are not entirely new, their use in the development of therapeutic apps for children with autism has only recently gained popularity. The findings documented in various publications indexed in 5 scientific databases emphasize the suitability of these technologies for such therapy, thereby warranting further in-depth research and the future development of apps based on these technologies. The studies indicated a clear trend toward the use of AR, VR, and MR technologies as a pedagogical tool for people with ASD. This trend involves multidisciplinary collaborations and an integrated approach to research, with a focus on empirical evaluations and ethics regarding the use of technologies. As the field advances, it is essential that research and practice continue to be guided by a balanced and integrated approach that considers both the technological possibilities and the needs and rights of individuals with ASD. However, there are still many issues that require further exploration and research.

Moreover, the publications studied illustrate a wide range of research areas related to the use of AR, VR, and MR in the context of ASD, as well as a variety of methodological and theoretical approaches adopted by the researchers. This suggests that the field is in a phase of rapid growth and diversification, with a wealth of opportunities for future research and development.

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Data Availability

All data generated or analyzed during this study are included in this published article (and its multimedia appendices).

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Authors' Contributions

M-VT and CET were involved in the concept and design of this review. All authors made substantial contributions to the analysis, preparation, interpretation, and organization of the data. The final manuscript was read, revised, and approved by all the authors.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 checklist.
[PDF File (Adobe PDF File), 108 KB - games_v12i1e49906_app1.pdf]

Multimedia Appendix 2
Quality assessment of the papers.
[XLS File (Microsoft Excel File), 201 KB - games_v12i1e49906_app2.xls]

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Abbreviations

AR: augmented reality
ASD: autism spectrum disorder
MR: mixed reality
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QC: quality criterion
RQ: research question
VR: virtual reality
XR: extended reality

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Review

Immersive Virtual Reality–Based Methods for Assessing Executive Functioning: Systematic Review

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Abstract

Background: Neuropsychological assessments traditionally include tests of executive functioning (EF) because of its critical role in daily activities and link to mental disorders. Established traditional EF assessments, although robust, lack ecological validity and are limited to single cognitive processes. These methods, which are suitable for clinical populations, are less informative regarding EF in healthy individuals. With these limitations in mind, immersive virtual reality (VR)–based assessments of EF have garnered interest because of their potential to increase test sensitivity, ecological validity, and neuropsychological assessment accessibility.

Objective: This systematic review aims to explore the literature on immersive VR assessments of EF focusing on (1) EF components being assessed, (2) how these assessments are validated, and (3) strategies for monitoring potential adverse (cybersickness) and beneficial (immersion) effects.

Methods: EBSCOhost, Scopus, and Web of Science were searched in July 2022 using keywords that reflected the main themes of VR, neuropsychological tests, and EF. Articles had to be peer-reviewed manuscripts written in English and published after 2013 that detailed empirical, clinical, or proof-of-concept studies in which a virtual environment using a head-mounted display was used to assess EF in an adult population. A tabular synthesis method was used in which validation details from each study, including comparative assessments and scores, were systematically organized in a table. The results were summed and qualitatively analyzed to provide a comprehensive overview of the findings.

Results: The search retrieved 555 unique articles, of which 19 (3.4%) met the inclusion criteria. The reviewed studies encompassed EF and associated higher-order cognitive functions such as inhibitory control, cognitive flexibility, working memory, planning, and attention. VR assessments commonly underwent validation against gold-standard traditional tasks. However, discrepancies were observed, with some studies lacking reported a priori planned correlations, omitting detailed descriptions of the EF constructs evaluated using the VR paradigms, and frequently reporting incomplete results. Notably, only 4 of the 19 (21%) studies evaluated cybersickness, and 5 of the 19 (26%) studies included user experience assessments.

Conclusions: Although it acknowledges the potential of VR paradigms for assessing EF, the evidence has limitations. The methodological and psychometric properties of the included studies were inconsistently addressed, raising concerns about their validity and reliability. Infrequent monitoring of adverse effects such as cybersickness and considerable variability in sample

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sizes may limit interpretation and hinder psychometric evaluation. Several recommendations are proposed to improve the theory and practice of immersive VR assessments of EF. Future studies should explore the integration of biosensors with VR systems and the capabilities of VR in the context of spatial navigation assessments. Despite considerable promise, the systematic and validated implementation of VR assessments is essential for ensuring their practical utility in real-world applications.

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KEYWORDS

virtual reality; executive functioning; neuropsychological assessment; systematic review; psychometric properties; cybersickness; immersion; cognition

Introduction

Background

Executive functioning (EF) has long been a focus of neuropsychological assessment because of the significant role it plays in everyday functioning. EF is an umbrella term for higher-order cognitive skills used to control and coordinate a wide range of mental processes and everyday behaviors [1-5], including "...mentally playing with ideas; taking the time to think before acting; meeting novel, unanticipated challenges; resisting temptations; and staying focused" [6]. Although a universally accepted definition of EF does not exist [5], there is agreement on the attributes of 3 core executive functions: inhibition, cognitive flexibility, and working memory [2,4,6]. These core executive functions support other higher-order executive functions such as reasoning, planning, and problem-solving [6-8]. As EF impairment has been linked to a variety of mental disorders [9], it is often considered a transdiagnostic risk factor [10].

Although traditional methods used to assess EF are popular [11,12] and well validated [13], they have been criticized for their lack of ecological validity [14,15]. Ecological validity, within the scope of this study, is defined as the "functional and predictive relationship between the person's performance on a set of neuropsychological tests and the person's behavior in a variety of real world settings" [16]. Specifically, we interpret ecological validity as comprising 2 principal components: representativeness—the degree to which a neuropsychological test mirrors the demands of a person's daily living activities that it aims to evaluate [17], sometimes referred to as *verisimilitude* [18]—and generalizability—the extent to which test performance predicts an individual's functioning in their daily living activities [17], also known as veridicality [18].

Traditional assessments tend to take a "construct-led" approach, with each test intended to isolate a single cognitive process in an abstract measure. This process of abstraction may limit the ecological validity of the measure by resulting in poor alignment between the test outcomes and real-world functioning. In turn, this produces a large amount of variance in EF that is unaccounted for by traditional tasks. For example, Chaytor et al [19] noted that traditional EF tests accounted for only 18% to 20% of the variance in the everyday executive ability of participants. This lack of explained variance may be attributed to the nature of the testing environment, the constructs assessed in isolation, the participant's affective state, and the compensatory strategies available to the participant [19]. A related methodological issue, known as the "task impurity problem" [4,20], indicates that the score on an EF task usually reflects not only the systematic variance attributable to the specific aspect of EF targeted by that task but also the (1) systematic variance across multiple types of EF tasks, (2) systematic variance attributable to non-EF aspects of the task, and (3) nonsystematic (error) variance (see the study by Snyder et al [10] for a detailed review). Outside the testing environment, the process of making a decision or planning and eliciting goal-directed behavior in everyday life is often highly dynamic and influenced by numerous internal and external factors [13,14]. Therefore, an ecologically valid assessment tool will need to include relevant contextual, dynamic, and multidimensional features such as affect and physiological state, which traditional assessments cannot include.

Furthermore, although traditional EF assessment tools may be appropriate for clinical populations, they generate less information about functioning in relatively healthy individuals. For example, the Trail-Making Test (TMT) has routinely been administered as a neuropsychological assessment of driving performance. Although some studies have demonstrated a relationship between the two [21,22], others have shown no relationship [23], particularly in nonclinical populations [24,25]. Thus, although traditional tools are adequate for detecting more severe EF impairments, they are less effective in detecting subtle changes in EF and early decline. Increased test sensitivity to detect subtle intraindividual changes may enable better detection of the prodromal stages of cognitive decline. Early detection is important as it enables early intervention, which may in turn improve prognosis. For example, sensitive detection can identify the prodromal stages of Alzheimer disease in seemingly healthy individuals [26] and mild cognitive decline up to 12 years before clinical diagnosis [27]. Similarly, in a situation in which an individual requires a capacity assessment for an activity, traditional assessments may have limited utility for nonclinical populations. The triangulation of multiple data sources such as biosensors may increase sensitivity to better identify subtle changes in capacity.

To address the shortcomings of poor ecological validity and test sensitivity, research on psychological assessment has begun to investigate virtual reality (VR) technology as a means of providing a more naturalistic environment for evaluating EF in clinical neuropsychological assessments. VR enables the development of custom-designed simulated environments that can replicate real-life environments, potentially increasing its ecological validity through representativeness. In addition, VR could increase engagement [28,29], reduce test time, and better integrate data from biosensors with in-task events that facilitate

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assessment. The following sections will expand on these points and consider the importance of validating and assessing the reliability of VR for EF assessment.

Ecological Validity and Representative Tests

There is an increasing emphasis on conducting EF assessments using tasks that resemble situations experienced in everyday life [30]. For example, the Multiple Errands Test (MET) [31] requires individuals to run errands in a real environment (eg, a shopping center). Empirical assessment of the MET has demonstrated its generalizability to daily functioning [32] and carer reports of daily functioning [33]. However, given that the MET is designed to be performed in real-life locations, it is impractical for routine administration by clinicians [34,35] and susceptible to the variable features of real-world environments that are outside experimental control. VR can mitigate these difficulties by maintaining the real-world environment without requiring travel while enabling fine-tuned control and uniform presentation of environmental characteristics [36]. Several studies [37-39] have investigated and developed platforms for this purpose, commonly known as the virtual MET.

Engagement

VR has the potential to enhance individual engagement more effectively than traditional pencil-and-paper or computerized tasks by offering a fully immersive experience [40]. Recognized as a crucial aspect of cognitive assessment, engagement can be improved through gamification, thereby improving task performance [41]. “Serious games,” defined as games intended for a variety of serious purposes, such as training, learning, stimulation, or cognitive assessment [42], have been shown to be more engaging than nongamified tasks [43-45]. The unique immersive environment of VR captures increased attention, leading to reduced average response times and response time variability [46]. Notably, recent studies using electroencephalography (EEG)-based metrics have shown greater attention elicited in immersive VR paradigms than in 2D computerized assessments [46]. This heightened immersion and engagement in VR may enhance the reliability of the measures by capturing a more accurate representation of an individual’s best effort.

Cybersickness

Despite their increased engagement, VR paradigms have the potential to induce cybersickness, which can threaten the validity of the paradigm. Cybersickness (ie, dizziness and vertigo) is akin to motion sickness but occurs in response to exposure to VR [47]. Previous research suggests that there is a negative relationship between cybersickness and cognitive abilities. For example, Nalivaiko et al [47] found that reaction times were moderately correlated (r=0.5; P=.006) with subjective ratings of nausea. Similarly, Sepich et al [48] found that participants’ accuracy on n-back task performance was weakly to moderately negatively correlated (r=−0.32; P=.002) with subjective cybersickness ratings. Therefore, there is reasonable concern that the potential benefits of engagement and ecological validity may be compromised if participants experience cybersickness.

Validity, Reliability, and Sensitivity

Arguably, the biggest threat to the utility of VR platforms is that many studies do not document their validity and reliability. A meta-analysis showed that VR assessment tools are moderately sensitive to cognitive impairment across neurodevelopmental, mental health, and neurological disorders [49], demonstrating their promising application in clinical settings. Borgnis et al [50] reviewed the VR-based tools for EF assessment that are currently available, illustrating the plethora of platforms developing in this field. The works by Negu et al [49] and Borgnis et al [50] highlight the utility of VR assessment tools to detect dysfunction and present the various tools in the literature created to investigate EF. Kim et al [51] provided an overview of the research trends using VR for neuropsychological tests and documented the cognitive functions assessed in each study. However, to the best of our knowledge, there is no overview or examination of the psychometric properties of these VR tools or how they are being evaluated.

Typically, novel measures and assessments are validated against current gold-standard tasks for concurrent validity [52]. Concurrent validity can be a reliable means of determining whether two assessments measure the same construct. However, concurrent validity can also occur when two tests contain the same problems, such as inaccurately measuring a particular construct in the same way. Sequentially, many VR tasks are being created from a “function-led” perspective but validated against “construct-led” tasks [53,54]. Given their different approaches, function-led and construct-led assessments should be validated in different ways or at least using several validation approaches. If function-led VR assessments improve upon the validity of current assessment methods, validation techniques may also need to go beyond comparisons with traditional assessments. For example, function-led VR assessments may be better validated against additional alternative methods, such as carer reports, real-life performance (eg, self-care, residence, transportation, and employment), and diagnostic trajectory [49] as opposed to validation through traditional (construct-led) assessment. Without incorporating tests of ecological validity, the potential advantages of VR may go unrecognized. Given the increasingly rapid development of VR neuropsychological assessments, it will be imperative to maintain high validation standards for these tools [55].

Establishing the reliability of novel VR EF assessments is also critical to the integrity of the outcomes. Reliability ensures that the measure yields consistent and repeatable results, a foundational element for test validity. Consequently, both reliability and validity ought to be evaluated for each measurement tool. Test-retest reliability, confirming consistency over time, should be accompanied by the interval between assessments and the correlation of the results. Internal consistency, typically measured using the Cronbach α, should also be reported for each target construct or domain of assessment. Importantly, for immersive VR EF assessments that evaluate multiple EF constructs, it is essential to report the α for each distinct construct rather than a collective coefficient. This is because the coefficient is intended to evaluate item consistency within a scale measuring a single construct; applying

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it across disparate constructs could be confusing and potentially misleading.

Consistency of Terminology

Finally, to ensure psychometric precision and build on previous research, EF assessment paradigms must adopt consistent terminology for their target assessment constructs. The field of EF, although of significant interest to both researchers and clinicians, is marked by varied terminology for identical constructs. This issue, longstanding in EF research (see the study by Suchy [5]; for a review, see the study by Baggetta and Alexander [56]), presents challenges to VR in the EF assessment field. For instance, inconsistent terminology hinders the synthesis of research findings. Diverse labels such as "impulsivity" and "impulse control" might, upon examination, refer to the same underlying construct. Consequently, researchers aiming to extend the literature on "impulsivity" might overlook pertinent studies or exclude valuable references because of terminological discrepancies.

This literature review sought to examine and discuss the development of the VR tools used to assess EF with a specific focus on evaluating their psychometric properties. The studies selected for inclusion in this review were those that developed assessment tools for EF either holistically or in part. The aims of this review were to (1) determine the components of EF assessed using VR paradigms, (2) investigate the methods used to validate VR assessments, and (3) explore the frequency and efficacy of reporting participants' immersion in and engagement with VR for EF assessment.

Methods

Our review methodology followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement [57]. In line with the literature, EF was defined as a set of executive functions, including inhibition, cognitive flexibility, and working memory [2,4,6], that support other higher-order executive functions, such as reasoning, planning, and problem-solving [6,8].

Inclusion Criteria

Before conducting the literature search, the inclusion criteria were established. First, only peer-reviewed articles and conference proceedings (complete manuscripts) written in English would be included. Second, articles that detailed an empirical, clinical, or proof-of-concept study in which an immersive virtual environment (ie, using a head-mounted display, not a 2D computer screen) was reported to broadly investigate EF or higher-order cognition or that examined EF via a selection of one or more subconstructs (eg, inhibitory control and working memory) would be included. Finally, only articles with an adult participant population published after 2013 would be included. This temporal limit was based on the release date of the Oculus Rift Development Kit 1 as it was one of the first accessible products for public use of VR. Articles were identified through the EBSCOhost, Scopus, and Web of Science (WoS) citation databases. Scopus and WoS were chosen because of their prominence as citation databases [58]. To compensate for the bias toward engineering and natural science articles found through Scopus and WoS [59], EBSCOhost was searched for articles published in fields such as (clinical) psychology and medicine.

Search Strategy

Keywords were developed by identifying 3 main components that the relevant literature should include. The 3 components were based on "Virtual Reality," "Neuropsychological Tests," and "Executive Function." It was decided not to search for specific components of EF because of the lack of consensus in the field regarding its components. Rather, it was assumed that, if an article addressed EF or a component of EF, it would include "executive functioning" as a keyword in the title, abstract, or keywords. Other reviews looking broadly at VR paradigms have used similar search strategies [49].

In this study, key terms were developed by identifying synonyms for key components and concatenating them using the "AND" Boolean operator. The final keywords used for the search were as follows: (["virtual" OR "artificial" OR "simulated"] AND ["realit*" OR "world" OR "environment"]) AND ([neuropsych* OR function* OR cognit*] AND [(executive AND function*) OR (high* AND order AND cognit*)] AND [assessment]).

Literature queries made through EBSCOhost were limited to the following databases: Academic Search Complete, AgeLine, AMED, Applied Science and Technology Source, CINAHL, E-Journals, Health Source Consumer and Nursing/Academic Edition, MEDLINE, Mental Measurements Yearbook, Psychology and Behavioral Sciences Collection, and all variations of the American Psychological Association databases. Furthermore, for the search, 3 topic fields (ie, title, abstract, and subject terms) were used to paste the keywords. The 3 topic fields were concatenated using the "OR" Boolean operator. Using the Scopus database, we implemented a basic search in the article title, abstract, or keywords using the keywords. No additional limitations were applied. Our search in WoS included all databases, and the advanced search method was used wherein keyword searches in the article title, abstract, and keyword topic fields were concatenated using the "OR" Boolean operator (ie, Title=(keywords) OR Abstract=(keywords) OR Keywords=(keywords)).

The results for each database were exported to Covidence systematic review software (Veritas Health Information) [60], which removed duplicates. All abstracts were screened independently by the first author and the senior author to determine whether the contents met the inclusion criteria. Full-text screening was also performed by the same authors. Any disagreement was discussed by the first (RK), second (LK), and senior (KR) authors.

Data Extraction

The first and second authors completed the data extraction process by manually reviewing each manuscript; data items (see the following section) were recorded in a tabular format using Microsoft Excel (Microsoft Corp).

Data Items and Synthesis

Demographic details, qualitative descriptions of the VR paradigm, user experience, cybersickness, immersion and

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engagement details, and comparative measures for validation purposes were extracted (Multimedia Appendix 1 [53-55,61-76]).

A qualitative evaluation of the studies included in the review was performed, meaning that the content of each manuscript was assessed based on the reported target constructs or constructs relevant to EF and the extent to which the reported VR task was related to the assessment of the target construct or constructs. To do this, studies were categorized based on the construct they targeted through their VR paradigm as reported by the authors of the respective articles. If multiple constructs were assessed in a single study, the study was included for each construct. No inferences were made about which cognitive construct or constructs was assessed based on the tasks that were reported in the manuscripts. For example, if an article indicated only that they used a VR version of the Stroop test (ST) but did not disclose which construct it assessed using this test, the study was not categorized under inhibitory control or cognitive flexibility but under the general factor "executive functioning."

Next, it was indicated whether the articles explicitly or implicitly disclosed the way in which the comparative measures (such as particular metrics) were used to validate the VR paradigm. For instance, if the article directly stated a priori that they hypothesized a correlation between a VR task measuring inhibition and a validation task such as the ST, this was recognized as providing explicit validation for inhibition. Conversely, if an article indicated that participants completed the ST, which assessed inhibition and processing speed, and mentioned that the VR paradigm evaluated inhibition, it was considered to provide implicit validation for inhibition. Furthermore, traditional construct- and function-led assessments were identified from the text.

The (quantitative) results of the studies were screened to identify (1) the direction and strength of the relationship between traditional and VR assessments and (2) whether the results from all possible and a priori–defined comparisons were reported.

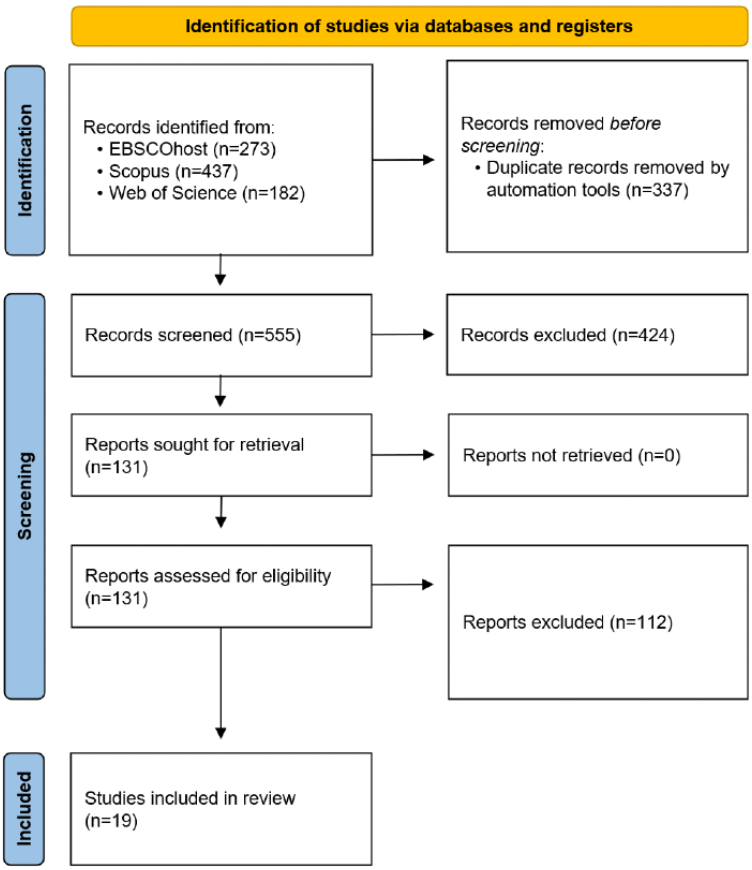
Finally, qualitative and quantitative tools used to evaluate beneficial and adverse effects of VR immersion were identified from the manuscripts and categorized in a tabulated format. The results of the studies were screened to identify whether they assessed the influence of the beneficial and adverse effects of VR immersion on task performance.

Results

Overview

Through WoS, EBSCOhost, and Scopus, 892 items were identified, from which the Covidence systematic review management platform [60] filtered 337 (37.8%) duplicates. A total of 555 unique articles remained, of which 424 (76.4%) were deemed irrelevant through abstract screening. The final 131 articles had their full texts screened, and 19 (14.5%) met the inclusion criteria. The systematic literature search process is shown in Figure 1.

Figure 1. Systematic review process and results from literature searches in EBSCOhost, Scopus, and Web of Science databases.



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General EF

In total, 7 of the 19 (37%) of the reviewed studies assessed EF in general, meaning that the authors of these articles did not explicitly state which subconstruct of EF was targeted using the VR task. Table 1 shows which validation tasks were used in each study to measure EF.

Table 1. The validation tasks, authors, and total number of studies examining general executive functioning.

VR[a] target construct and validation task	Validation	Authors	Studies examining the construct, n (%)
Executive functioning: general			7 (37)
• D-KEFS[b] [77] • TMT-A[c] and TMT-B[d] • ST[e] • Modified version of the SET[f] • HTT[g] • ZMT[h]	Implicit	Banville et al [61][i]	
• ST • TMT-A • TMT-B	Implicit	Davison et al [62][j]	
• TMT-B • OTS[k] CANTAB[l] • VFT[m]	Explicit	Miskowiak et al [63]	
• TMT-A • TMT-B	Explicit	Pallavicini et al [64]	
• Groton Maze Learning Test (Cogstate)	Implicit	Porffy et al [65]	
• None specifically reported	N/A[n]	Tan et al [66]	
• None specifically reported	N/A	Tsai et al [67]	

[a]VR: virtual reality.

[b]D-KEFS: Delis-Kaplan Executive Function System.

[c]TMT-A: Trail-Making Test version A.

[d]TMT-B: Trail-Making Test version B.

[e]ST: Stroop test.

[f]SET: Six Elements Test.

[g]HTT: Tower of Hanoi test.

[h]ZMT: Zoo Map Test.

[i]The VR task was predominantly a sorting task for executive functioning assessment. The comparative assessments that validated this assessment were detailed under “executive function” broadly as the paper did not specify which components of the VR task the comparative tasks aimed to validate.

[j]The VR task was reported to assess executive functioning. The comparative assessments that validated this assessment were detailed under “executive function” broadly as the paper did not specify which components of the VR task the comparative tasks aimed to validate.

[k]OTS: One Touch Stockings of Cambridge.

[l]CANTAB: Cambridge Neuropsychological Test Automated Battery.

[m]VFT: verbal fluency test.

[n]N/A: not applicable.

Banville et al [61] immersed participants in a Virtual Multitasking Test (VMT), which was in principle designed to measure prospective memory and executive functions by having participants perform multiple tasks in a virtual apartment. However, this paper reported specifically on the task in which participants had to store groceries as fast as possible while also being attentive to other tasks, such as answering the phone or closing a window. Although the authors hypothesized that VMT scores would be correlated with neuropsychological assessments, such as mental flexibility, planning, and inhibition, it was not explicitly stated which metric of the VMT would be correlated with which neuropsychological assessment. Nonetheless, the authors identified that grocery storing time was correlated with the rule-break score on the Six Elements Test (r_{19}=−0.49; P=.04; P value as reported in the manuscript). Furthermore, the number of errors in storing fruits and vegetables was found to correlate with the perseveration score on the Zoo Map Test (r_{20}=0.53; P=.02; P value as reported in the manuscript) and reading speed

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during the second condition of the ST (r_{20}=0.44; *P*=.05; *P* value as reported in the manuscript).

Davison et al [62] immersed participants in a parking simulator and a chemistry laboratory where they had to park a vehicle, sort chairs, or locate items. Before immersion, participants completed the ST and the TMT versions A (TMT-A) and B (TMT-B). The authors identified that the completion time of the second level (Kendall τ=−0.32; *P*=.01; *P* value as reported in manuscript) and the number of levels completed in the parking simulator (τ=0.43; *P*<.01; *P* value as reported in manuscript) were correlated with participants' performance on the ST. In addition, the ST was correlated with seating arrangement metrics, such as time to place the first stool (τ=−0.33; *P*=.01; *P* value as reported in manuscript) and number of stools placed (τ=0.33; *P*=.02; *P* value as reported in manuscript), as well as with time to locate the first item in the chemistry laboratory (τ=−0.37; *P*=.01; *P* value as reported in manuscript). Correlations between the TMT-A or TMT-B and, for example, the number of completed parking levels (τ=−0.49; *P*<.01; *P* value as reported in the manuscript) or the number of items placed in the seating arrangement task in the chemistry laboratory (τ=−0.35; *P*=.01; *P* value as reported in the manuscript) were reported. However, reporting was limited to significant correlations only, and no a priori expectation of how performances on the VR and validation tasks were correlated was indicated in the study.

Miskowiak et al [63] assessed executive functions by letting participants complete the TMT-B, One Touch Stockings of Cambridge mean choices to correct, and verbal fluency test versions S and D. The performance on these tests was compared with participants' performance on a cooking task in VR. The authors hypothesized that the number of cooking tasks that were correctly placed on a to-do list and the latency to solve the task would be VR-equivalent measures of EF. The authors found that VR performance was correlated (r_{121}=0.26; *P*=.004) with EF, which consisted of a correlation between the average performance on the VR subtasks and the average performance on the validation tasks. The correlations between the individual performances on the VR and validation tasks were not reported in the manuscript.

Pallavicini et al [64] had participants play the Audioshield dance game, which the authors hypothesized could be closely related to EF constructs such as inhibition and working memory. However, the authors correlated participants' performance on the Audioshield game with their performance on the TMT-A and TMT-B, which measure psychomotor speed (TMT-A) and mental flexibility (TMT-B). Nonetheless, the results showed that TMT performance was negatively correlated with Audioshield performance metrics.

Porffy et al [65] had participants complete VStore, where the 2 tasks measured EF, namely the "Find" task and the "Coffee" task. Specifically, participants had to find 12 items from a list they had previously memorized. In addition, participants had to order a hot drink from the coffee shop after finding, bagging, and paying for the 12 remembered items they had found in the store. Notably, the authors indicated that the 2 VR tasks also tapped into navigation (ie, "Find" task) and processing speed (ie, "Coffee" task). Furthermore, the Groton Maze Learning Test from Cogstate, which the participants completed before the VR task, was used to evaluate general EF. Nonetheless, through their regression analysis, the authors identified that the Groton Maze Learning Test was not a predictor for the "Find" task (*B*=0.024; SE 0.029; *P*=.11; *P* value as reported in the manuscript) or the "Coffee" task (*B*=−0.003; SE 0.051; *P*=.96; *P* value as reported in the manuscript).

Tan et al [66] had 100 participants complete 13 tasks in a virtual environment that were designed to measure 6 cognitive domains, such as EF and complex attention. Although differences in performance on VR tasks related to EF between age groups were found, no comparison was made with a traditional neuropsychological assessment of EF or any subconstructs of EF.

Tsai et al [67] immersed 2 participant groups in a virtual shopping environment: one group with mild cognitive impairment (MCI) and one control group. The VR tasks assessed participants' memory, EF, and calculation by having them memorize a shopping list, search for the listed items in the shop, and subsequently pay for them. The authors trained machine learning models on features extracted from the VR tasks to predict whether participants had MCI or were healthy controls, which was achieved with high accuracy. Nonetheless, no neuropsychological assessment of EF was reported as a validation for the VR tasks.

Targeted Constructs

The following subsections elaborate on the EF constructs and subconstructs addressed in the studies under review. A range of correlation coefficients were reported in these papers; however, because of the lack of uniformity in results reporting, these coefficients were omitted from the current synthesis. Typically, the papers reported only significant correlations between metrics without presenting all potential correlations. Furthermore, only 16% (3/19) of the studies specified an α level (ie, .05), with another 16% (3/19) of the studies indicating statistical significance at a *P* value of ≤.05. A total of 21% (4/19) of the studies did not indicate an α level but mentioned applying corrections for multiple comparisons, yet they did not detail the adjusted α level. In total, 5% (1/19) of the studies adopted Bayesian statistics using a Bayesian factor of >10 for statistical inference. Nonetheless, in the reviewed studies, it was not consistently clarified which VR tasks were validated against traditional tasks, hindering the construct validity of the various EF components. Consequently, drawing consistent conclusions on how EF constructs of subconstructs were evaluated was not feasible without inferring the nature of the tests and assessment paradigms.

Core Executive Functions

Inhibition

Of the 3 "core" executive functions, 37% (7/19) of the studies included in our review investigated inhibitory control, interference control, or impulsivity either singly or combined. Table 2 details the respective validation tasks and target constructs of each of these studies. For example, Chicchi Giglioli et al [68] presented participants with 6 standardized tasks, 3 of

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which assessed inhibition (Table 2), before administering a serious game in which participants were required to perform tasks in outer space. In total, 10 of the 36 possible correlations between measures for the standardized tasks and the serious game tasks were reported as statistically significant and ranged from weak ($0.20<r<0.39$; relative P values indicated in the manuscript, eg, $P<.05$) to strong ($0.60<r<0.79$; relative P values indicated in the manuscript). For example, the latency metric of the dot-probe task (DPT) correlated positively ($0.35<r<0.54$; relative P values indicated) with the latency metric of the 3 VR tasks aimed at measuring inhibition, whereas no correlations were reported between the correct answer metric of the DPT and the correct answer metric of the 3 VR tasks aimed at measuring inhibition. None of the metrics from the ST correlated with those of the VR task (requiring participants to fight aliens); however, the correct answer and latency metrics of the ST correlated with those of the VR task (requiring participants to repair a valve).

Table 2. The validation tasks, authors, and total number of studies examining each construct.

VR[a] target construct and validation task	Validation	Authors	Studies, n (%)
Inhibition or Inhibitory control			6 (32)
• DPT[b] • GNG[c] • ST[d]	Implicit	Chicchi Giglioli et al [69]	
• DPT • GNG • ST	Explicit	Chicchi Giglioli et al [68]	
• GNG	Implicit	Marín-Morales et al [70]	
• CPT[e]	Implicit	Voinescu et al [71][f]	
• None specifically reported	N/A[g]	Parsons and Carlew [72]	
• ST	Implicit	Parsons and Barnett [73]	
Interference control			3 (16)
• ST	Implicit	Marín-Morales et al [70][h]	
• The CW-IT[i] from the D-KEFS[j] • Automated neuropsychological assessment metrics • ST	Implicit	Parsons and Carlew [72]	
• CW-IT from the D-KEFS	Implicit	Parsons and Barnett [73]	
Impulsivity			1 (5)
• None specifically reported	N/A	Chicchi Giglioli et al [68]	

[a]VR: virtual reality.

[b]DPT: dot-probe task.

[c]GNG: Go/No-Go.

[d]ST: Stroop test.

[e]CPT: continuous performance test.

[f]Some traditional tasks listed were included for divergent validity and, therefore, have been omitted from this table.

[g]N/A: not applicable.

[h]The VR task involved 42 VR mini-games that assessed various cognitive constructs. A total of 4 mini-games and their target constructs were documented and included in this table; however, the comparative assessments were not provided, and an extensive list of all 42 mini-games was not provided.

[i]CW-IT: Color-Word Interference Test.

[j]D-KEFS: Delis-Kaplan Executive Function System.

Similarly, Chicchi Giglioli et al [69] immersed participants in a virtual kitchen in which they had to cook different types of food. The activities were grouped into 4 subtasks of incremental difficulty where, in the third level, inhibition was assessed by determining whether the right dressing was added using a Go/No-Go (GNG)–type paradigm. The authors stated that the DPT, GNG, and ST were used as standard tasks to assess inhibition. The unspecified metric of "correct dressing" was shown to correlate well ($r=0.527$; $P<.01$; relative P value indicated in the manuscript) with the correct answer metric of

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the ST in one group, whereas in the second group, a moderate negative correlation (r=−0.486; P≤.05; relative P value indicated in the manuscript) was found between the execution time of the Tower of London task and the correct dressing metric. However, no other correlations between the VR task metric and those of the traditional assessments of inhibition were reported.

Marín-Morales et al [70] had participants complete neuropsychological assessments, including the GNG task, as well as 42 mini-games in VR. An undisclosed set of variables from the mini-games was used as predictors for measures of neuropsychological batteries. The mini-game predictor variables were fed into different machine learning algorithms. The authors highlighted that games related to inhibition produced worse results compared with other games but did not report any results on inhibition. The authors did find that mini-game features of planning and attention could predict GNG hit proportions and mean time with 80% and 94% accuracy, respectively.

Parsons and Carlew [72] had participants perform the ST in a virtual classroom as well as complete a computerized and paper-and-pencil version of the task. The authors found that participants' performance was lower for color naming and word reading in the VR paradigm than in the paper-and-pencil version but interference performance was better in the VR paradigm than in the paper-and-pencil version. Similarly, Parsons and Barnett [73] had participants perform the ST in a virtual apartment as well as complete a computerized and paper-and-pencil version of the task. Here, the authors found that participants were more accurate in the ST in the paper-and-pencil version than in the VR paradigm.

Voinescu et al [71] immersed participants in a virtual aquarium where they had to perform a variety of tasks. For example, participants had to respond when they saw a fish that was different from a clown fish or heard a fish name different from surgeonfish. After the VR aquarium, participants completed a variety of computerized tasks, among them a continuous performance test (CPT), which was hypothesized to measure sustained attention and inhibition. The authors found weak to moderate (0.22<r<0.49; relative P values indicated, eg, P<.05) correlations between CPT measures and VR measures.

Working Memory

Working memory was investigated in 21% (4/19) of the studies [63,65,70,74]. Table 3 details the respective validation tasks and target constructs of each of these studies. The working memory component from the study by Marín-Morales et al [70] included a mini-game wherein participants had to recall the ingredients of a recipe seen before the mini-game and collect from a range of options only those ingredients found in the recipe. However, no correlations with neuropsychological tasks were presented. Miskowiak et al [63] compared their VR paradigm with a traditional task that assessed working memory. In this study, participants were instructed to plan and cook a meal in a virtual kitchen. Performance metrics, such as the number of drawers opened and the latency until the task was completed, were used to assess working memory and were correlated with metrics from traditional tasks such as the Wechsler Adult Intelligence Scale Letter-Number Sequencing. The authors reported a significant positive correlation (r_{121}=0.31; P=.001) between the VR task metrics and the traditional task metrics that evaluated working memory.

Table 3. The validation tasks, authors, and total number of studies targeting working memory.

VR[a] target construct and validation task	Validation	Authors	Studies, n (%)
Working memory			4 (21)
• WAIS-IV[b] • The Working Memory Index (Digit Span and Arithmetic)	Implicit	Marín-Morales et al [70][c]	
• WAIS-III[d] LNS[e] • SWM[f] CANTAB[g] (error and strategy)	Explicit	Miskowiak et al [63]	
• 1-back and 2-back test (Cogstate)	Implicit	Porffy et al [65]	
• None specifically reported	N/A[h]	Robitaille et al [74][i]	

[a]VR: virtual reality.

[b]WAIS-IV: Wechsler Adult Intelligence Scale–IV.

[c]The VR task involved 42 VR mini-games that assessed various cognitive constructs. In total, 4 mini-games and their target constructs were documented and included in this table; however, the comparative assessments were not provided, and an extensive list of all 42 mini-games was not provided.

[d]WAIS-III: Wechsler Adult Intelligence Scale–III.

[e]LNS: Letter-Number Sequencing.

[f]SWM: Spatial Working Memory.

[g]CANTAB: Cambridge Neuropsychological Test Automated Battery.

[h]N/A: not applicable.

[i]Robitaille et al [74] used a VR paradigm with avatars to trial a dual-task walking protocol.

Porffy et al [65] asked participants to operate a virtual store in which the working memory component was assessed at the "Pay" step, where participants had to select and pay for their items at a self-checkout machine providing the exact amount.

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The authors specified that the reaction time on the 1-back task and the accuracy of performance on the 2-back task were metrics from traditional tasks used to assess working memory. Using linear regression, the authors found that performance on the 2-back task was negatively associated (B=−0.085; SE 0.042; P=.047) with participants' performance on the "Pay" step.

Robitaille et al [74] assessed working memory during their simultaneous cognitive tasks, in which participants had to both recognize faces in windows that had been previously declared as "hostile" or "nonhostile" and complete a navigation task. However, no correlations between the traditional and VR tasks were reported.

Cognitive Flexibility

One study by Chicchi Giglioli et al [68] investigated cognitive flexibility (termed "cognitive shifting" in the paper) through 3 VR tasks. The authors specified that the TMT was used as a traditional task to assess cognitive flexibility as a comparator for the first VR task (CF1, cultivating food) and the Wisconsin Card Sorting Test was used as a traditional task to evaluate cognitive flexibility as a comparator for the other 2 VR tasks (CF2, growing plants, and CF3, fueling a turbine). The total time metric of the first VR task correlated positively with the total time of the TMT-B (r=0.396; P<.01; P value as reported in the manuscript), and multiple metrics of VR tasks 2 and 3 correlated with the performance metrics of the Wisconsin Card Sorting Test.

Higher-Order Executive Functions: Planning

In total, 26% (5/19) of the studies [62,68,69,75,76] identified planning as a target construct in their VR paradigms. Table 4 details the respective validation tasks and target constructs of each of these studies. The VR environment created by Chicchi Giglioli et al [69] used a cooking task with 4 levels of difficulty. In the 3 more difficult levels, planning was required to complete the tasks as 2 burners were used. There was no clearly specified metric for the VR task that was used to evaluate planning, but the authors specified that the Tower of London task was used as a traditional assessment to evaluate planning. A variety of VR task metrics, such as total time to complete a difficulty level, were shown to correlate with various Tower of London task metrics.

Table 4. The validation tasks, authors, and total number of studies targeting planning.

VR[a] target construct and validation task	Validation	Authors	Studies, n (%)
Planning			5 (26)
TOL-DX[b]	Implicit	Chicchi Giglioli et al [69]	
TOL[c]	Explicit	Chicchi Giglioli et al [68]	
None specifically reported	N/A[d]	Davison et al [62][e]	
The Key Search task from BADS[f] [78]	Explicit	Kourtesis et al [76]	
None specifically reported	N/A	Kourtesis and MacPherson [75]	

[a]VR: virtual reality.

[b]TOL-DX: Tower of London–Drexel test.

[c]TOL: Tower of London test.

[d]N/A: not applicable.

[e]The VR task was used to assess executive function. The comparative assessments that validated this assessment were detailed under "executive function" broadly as the paper did not specify which components of the VR task the comparative tasks aimed to validate.

[f]BADS: Behavioral Assessment of the Dysexecutive Syndrome.

In another study, Chicchi Giglioli et al [68] used a VR paradigm based on an outer-space environment. The paradigm contained 8 tasks, one of which assessed planning ability (task 7). The authors stated that the Tower of London task was the traditional assessment tool used to evaluate planning and explained that the total score, initial time, and execution time of the VR task were the outcome metrics. Moderate positive correlations were found between the execution time of the VR task and of the Tower of London task (r=0.463; P<.01; P value as reported in the manuscript) and between the initial time of the VR task and the total time of the Tower of London task (r=0.372; P<.05). Furthermore, the VR task correlated with some metrics of other traditional assessments used to assess planning ability, although these were not specified a priori.

Both the studies by Kourtesis et al [76] and Kourtesis and MacPherson [75] used the same VR environment based on a variety of everyday tasks. One task assessing planning ability required participants to draw their route around the city (eg, visiting the bakery, supermarket, and library and returning home) on a 3D board. Kourtesis et al [76] explained that the Key Search Test from the Behavioral Assessment of the Dysexecutive Syndrome was used as a traditional measure to assess planning and found a strong positive correlation between the traditional and VR tasks (r=0.80; Bayes factor=4.65×10^8). Furthermore, Kourtesis and MacPherson [75] noted in their results that planning explained a substantial 12% (P=.03) of the variance in time-based prospective memory, which was required in 10 of 17 tasks.

Davison et al [62] assessed planning ability using a task involving the arrangement of a table and a chair. However, they did not explicitly mention the traditional task that was used to evaluate planning. Various correlations between the performance metrics of the VR task and the traditional task were reported.

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For example, the performance on the Stroop Color and Word Test was negatively correlated with the time participants took to place a blue chair in the seating arrangement task (Kendall $\tau=-0.39$; $P=.01$; P value as reported in the manuscript).

Other Domains

Several studies (14/19, 74%) examined domains of functioning that did not align with the EF definition used in this review. Broadly, these domains fell under the categories of memory, attention, processing, task performance, and a variety of other uncategorized subconstructs. As the literature [1,2,4,6] does not relate these broad domains to EF, they are not discussed further but are presented in Tables 5-6.

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Table 5. The validation tasks, authors, and total number of studies targeting constructs classified as uncategorized.

VR[a] target construct and validation task	Validation	Authors	Studies, n (%)
Memory			11 (58)
Memory (general)			1 (5)
• None specifically reported	N/A[b]	Tsai et al [67]	
Verbal memory and verbal learning			2 (11)
• RAVLT[c] subtests: total, immediate recall, delayed recall, and recognition	Explicit	Miskowiak et al [63]	
• International Shopping List Test (Cogstate; verbal learning)	Implicit	Porffy et al [65]	
Prospective memory			4 (21)
• None specifically reported	N/A	Banville et al [61][d]	
• CAMPROMPT[e] [79]	Explicit	Kourtesis et al [76][f]	
• None specifically reported	N/A	Kourtesis and MacPherson [75]	
• CVLT-II[g] [80]	Implicit	Parsons and McMahan [53]	
Episodic memory			3 (16)
• RBMT-III[h] [81]	Explicit	Kourtesis et al [76][f]	
• CVLT-II	Implicit	Parsons and McMahan [53]	
Immediate recognition			2 (11)
• RBMT-III [81]	Explicit	Kourtesis et al [76]	
• None specifically reported	N/A	Kourtesis and MacPherson [75]	
Delayed recognition			2 (11)
• RBMT-III [81]	Explicit	Kourtesis et al [76][f]	
• None specifically reported	N/A	Kourtesis and MacPherson [75]	
Attention			13 (68)
General attention			4 (21)
• DPT[i] • GNG[j] • ST[k]	Implicit	Chicchi Giglioli et al [69]	
• DPT • GNG • ST • TMT-A[l] • TMT-B[m]	Explicit	Chicchi Giglioli et al [68]	
• DPT—selective attention • GNG—sustained attention • ST—selective attention • TMT[n]—visual attention	Implicit	Marín-Morales et al [70][o]	
• RVP[p] CANTAB[q] (accuracy and latency) • RBANS-DS[r]	Explicit	Miskowiak et al [63]	
Divided attention			2 (11)

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VR[a] target construct and validation task	Validation	Authors	Studies, n (%)
• None specifically reported	N/A	Robitaille et al [74][s]	
• CTT-B[t] [75,82]	Explicit	Wilf et al [54]	
Complex attention			1 (5)
• None specifically reported	N/A	Tan et al [66]	
Selective visual attention			2 (11)
• The map task from the Test of Everyday Attention	Explicit	Kourtesis et al [76][f]	
• None specifically reported	N/A	Kourtesis and MacPherson [75]	
Selective auditory attention			2 (11)
• The Elevator Counting With Distraction task of the Test of Everyday Attention	Explicit	Kourtesis et al [76][f]	
• None specifically reported	N/A	Kourtesis and MacPherson [75]	
Sustained visual attention			1 (5)
• CTT-A[u] [82]	Explicit	Wilf et al [54]	
Visuospatial attention			2 (11)
• The Ruff 2 and 7 Selective Attention Test	Explicit	Kourtesis et al [76][f]	
• None specifically reported	N/A	Kourtesis and MacPherson [75]	
Sustained attention			1 (5)
• CPT[v] [83]	Implicit	Voinescu et al [71]	
Processing			3 (16)
Processing speed			3 (16)
• WAIS-IV[w] Processing Speed Index (symbol search and coding)	Implicit	Marín-Morales et al [70][o]	
• RBANS-CT[x] • TMT-A	Explicit	Miskowiak et al [63]	
• Detection task (Cogstate)	Implicit	Porffy et al [65]	
Task performance			4 (21)
Dual task			1 (5)
• TMT-A • TMT-B	Implicit	Chicchi Giglioli et al [69]	
Multitask			3 (16)

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VR[a] target construct and validation task	Validation	Authors	Studies, n (%)
• Modified version of the SET[y]	Implicit	Banville et al [61][d]	
• CTT[z] [82]	Explicit	Kourtesis et al [76][f]	
• None specifically reported	N/A	Kourtesis and MacPherson [75]	

[a]VR: virtual reality.

[b]N/A: not applicable.

[c]RAVLT: Rey Auditory Verbal Learning Test.

[d]The VR task was predominantly a sorting task for executive function assessment. The comparative assessments that validated this assessment were detailed under “executive function” broadly as the paper did not specify which components of the VR task the comparative tasks aimed to validate.

[e]CAMPROMPT: Cambridge Prospective Memory Test.

[f]Kourtesis et al [76] explicitly broke episodic memory down into immediate and delayed recognition. However, we gathered these two constructs under episodic memory.

[g]CVLT-II: California Verbal Learning Test–Second Edition.

[h]RBMT-III: Rivermead Behavioral Memory Test–Third Edition.

[i]DPT: dot-probe task.

[j]GNG: Go/No-Go.

[k]ST: Stroop test.

[l]TMT-A: Trail-Making Test version A.

[m]TMT-B: Trail-Making Test version B.

[n]TMT: Trail-Making Test.

[o]The VR task involved 42 VR mini-games that assessed various cognitive constructs. In total, 4 mini-games and their target constructs were documented and included in this table; however, the comparative assessments were not provided, and an extensive list of all 42 mini-games was not provided.

[p]RVP: Rapid Visual Information Processing.

[q]CANTAB: Cambridge Neuropsychological Test Automated Battery.

[r]RBANS-DS: Repeatable Battery for the Assessment of Neuropsychological Status–Digit Span.

[s]Robitaille et al [74] used a VR paradigm with avatars to trial a dual-task walking protocol.

[t]CTT-B: Color Trails Test B.

[u]CTT-A: Color Trails Test A.

[v]CPT: continuous performance test.

[w]WAIS-IV: Wechsler Adult Intelligence Scale–IV.

[x]RBANS-CT: Repeatable Battery for the Assessment of Neuropsychological Status–Coding Test.

[y]SET: Six Elements Test.

[z]CTT: Color Trails Test.

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Table 6. The validation tasks, authors, and total number of studies targeting constructs classified as uncategorized.

VR[a] target construct and validation task	Validation	Authors	Studies, n (%)
Uncategorized[b]			12 (63)
Visual perception			1 (5)
• None specifically reported	N/A[c]	Marín-Morales et al [70][d]	
Verbal learning			2 (11)
• RAVLT[e] subtests: total, immediate recall, delayed recall, and recognition	Explicit	Miskowiak et al [63]	
• International Shopping List Test (Cogstate)	Implicit	Porffy et al [65]	
Navigation			2 (11)
• None specifically reported	N/A	Porffy et al [65]	
• None specifically reported	N/A	Robitaille et al [74]	
Associate learning			1 (5)
• Continuous Paired Associate Learning Test (Cogstate)	Implicit	Porffy et al [65]	
Pattern recognition			1 (5)
• Continuous Paired Associate Learning Test (Cogstate)	Implicit	Porffy et al [65]	
Perceptual motor			1 (5)
• None specifically reported	N/A	Tan et al [66]	
Social cognition			1 (5)
• None specifically reported	N/A	Tan et al [66]	
Learning and memory			1 (5)
• None specifically reported	N/A	Tan et al [66]	
Language			1 (5)
• None specifically reported	N/A	Tan et al [66]	
Calculation			1 (5)
• None specifically reported	N/A	Tsai et al [67]	

[a]VR: virtual reality.

[b]Williams et al [55] replicated the Wisconsin Card Sorting Test and multitasking task but did not explicitly state the cognitive constructs that the VR task was assessing. For this reason, the paper has not been assigned a target construct.

[c]N/A: not applicable.

[d]The VR task involved 42 VR mini-games that assessed various cognitive constructs. In total, 4 mini-games and their target constructs were documented and included in this table; however, the comparative assessments were not provided, and an extensive list of all 42 mini-games was not provided.

[e]RAVLT: Rey Auditory Verbal Learning Test.

Validity and Reliability

Tables 1-6 show details of the current validated comparator tasks against the novel VR tasks if they were explicitly provided by the authors. Where "None specifically reported" is stated, the authors of each paper did not identify or indicate a direct comparator. All but 2 studies (17/19, 89%) [72,73] set out to assess multiple constructs. In some cases, the subconstructs that were assessed were individually validated against existing validated tasks. In other cases, a suite of existing validated tasks was included in the analysis for correlation against a variety of subconstructs being assessed using the VR battery. In these cases, there was no validation at the construct level identified a priori. In 16% (3/19) of the studies, there was no reported validation of the VR paradigm.

Notably, only one study used real-life validation criteria in addition to construct-driven tests to present a validation of their VR paradigm. Specifically, Miskowiak et al [63] functionally assessed participants using the Functioning Assessment Short Test (FAST) and the brief University of California, San Diego, Performance-Based Skills Assessment (UPSA-B). Participants'

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scores on these assessments were correlated with their performance on the test domains of the VR paradigm, called cognition assessment in VR (CAVIR). The authors identified that participants' performance on the FAST was negatively associated ($-0.17<r<-0.30$; no exact or relative P values reported) with CAVIR test domains such as processing speed and working memory, whereas participants' performance on the UPSA-B was positively associated with the CAVIR test working memory (r=0.40; P value not exactly or relatively reported) and cognition composite (r_{68}=0.44; P<.001) domains. Moreover, the authors noted that lower global scores on traditional (ie, construct-led) neuropsychological tests were negatively associated with FAST scores (r_{121}=−0.45; P<.001) and positively associated with UPSA-B scores (r_{68}=0.52; P<.001), highlighting that lower CAVIR scores were associated with more functional disability, as indicated by the functional and traditional assessment tools.

The reliability of the VR paradigm was only assessed in 5% (1/19) of the studies. This was done by Kourtesis et al [76], who reported good internal reliability (Cronbach =.79) of their VR Everyday Assessment Lab (EAL) paradigm. However, this global internal consistency report did not provide a reliability estimate of the unique cognitive functions targeted by their VR EAL paradigm. Nonetheless, none of the reviewed studies included a test-retest analysis to highlight the reliability of their VR paradigm.

Evaluation of User Experience, Cybersickness, Immersion, and Engagement

An overview of the measures used to evaluate participants' experiences and well-being can be found in Multimedia Appendix 1 [53-55,61-76]. Of the 19 studies, 5 (26%) included user experience assessments. To measure participants' virtual presence, experience, and well-being, the studies administered the Igroup Presence Questionnaire [61], Presence Questionnaire [63,71,74], or Slater-Usoh-Steed questionnaire [74]. To measure participants' discomfort, the studies used the Simulator Sickness Questionnaire [61,71,74] or an adaption of it, the Virtual Reality Sickness Questionnaire [63]. To evaluate the usability of the virtual environment, the studies used the System Usability Scale [71]. To measure participants' virtual experience and comfort, 11% (2/19) of the studies used the Virtual Reality Neuroscience Questionnaire [76].

Two studies (2/19, 11%) investigated whether system usability, virtual presence, or cybersickness affected participants' task performance. For example, Porffy et al [65] measured participants' technical familiarity and found that it explained between 10% and 42% of the variability in participants' performance on the VStore outcomes "Recall", "Find", and "Select". Conversely, participants' technical familiarity appeared to influence their performance on VStore. Kourtesis et al [76] used questionnaires to evaluate the quality of the VR paradigm, participants' gaming experience, and the realism (verisimilitude) and pleasantness of the VR paradigm. The authors identified no relationship between VR experience, gaming experience, and performance on the VR EAL tasks.

Some papers (4/19, 21%) reported on cybersickness, presence, or usability scores but did not report an analysis of the relationship between task performance and measures evaluating the VR paradigm. For example, Banville et al [61] recorded participants' sickness and virtual presence but did not report any test evaluating whether sickness or presence affected task performance. Similarly, Voinescu et al [71] obtained system usability ratings from participants; however, no test was reported wherein the effect of usability on task performance was assessed. Finally, Chicchi Giglioli et al [68] recorded participants' use of technology but did not report an analysis between technology use and task performance.

Finally, some studies (2/19, 10%) evaluated participants' experiences post hoc, although it was not disclosed whether any validated scales were used. For example, Davison et al [62] measured participants' enjoyment of the VR tasks and their preference for either the VR tasks or the pencil-and-paper tasks. The authors found that younger participants rather than older ones preferred VR tasks over pencil-and-paper tasks. In addition, 11 out of 40 participants reported having experienced a mild degree of motion sickness. However, 58% (11/19) of the papers did not disclose any information about user experiences.

Discussion

Overview

The purpose of this review was to investigate the development and validation of VR assessment tools for EF. Specifically, we examined the components of EF that were assessed using VR, their validation processes, and whether immersion and cybersickness assessments were used. Although research in this domain is proliferating, the results of this review suggest that the process of development and validation varies considerably between studies.

Components of EF Assessed Using VR Paradigms

Overview

The terminology used in the papers to describe EF constructs was inconsistent. For example, the most popular construct set assessed using VR comprised the inhibition processes. "Inhibitory control" encompasses the inhibition of goal-irrelevant stimuli, cognitions, and behavioral responses [6,84]. In total, two of the key components of inhibitory control are response inhibition and attentional inhibition [85]. Response inhibition was also termed "inhibition control," "prepotent response inhibition," and "motor inhibition," whereas attentional inhibition was also termed "control of interference," "interference control," and "external interference control." Although these terms are used in the literature [85], its readability and synthesis would be improved through agreement on a particular term for the same construct. In the same way, several studies (7/19, 37%) examined "EF" broadly without specifically detailing its components. In these studies, EF was validated using different measurement tools, suggesting that, across studies, EF was defined and used differently in each VR paradigm. As the constructs that these paradigms aimed to assess were not explicitly detailed, this poses a risk of hampering researchers wishing to build upon previous findings.

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Furthermore, there was a broad range of constructs that were not commonly considered as EF domains but were reported as components of EF, making it difficult for future research to replicate the findings of undefined target constructs. For example, several papers (14/19, 74%) reported on verbal learning [63], associate learning pattern recognition [65], perceptual motor, social cognition, language [66], and calculation [67]. Although many of these components rely on EF domains or underpin those domains, they exist at various levels of abstraction. Thus, although the reviewed studies investigated components at different levels and used different languages, it is possible that they overlapped. For example, "organization" may be an umbrella term for a range of EF domains, each of which uses different terminology for the same concept, such as "cognitive flexibility," "flexible updating," and "working memory." Although "organization" is not measured as a higher-order version of the subcomponents, it is difficult for the research that has examined cognitive flexibility and working memory to be extended. Thus, 2 studies assessing the same construct are not able to build on each other's progress.

Recommendation: Establish a Coherent and Consistent Framework for EF Terminology

The Research Domain Criteria (RDoC) framework developed by the National Institute of Mental Health could serve as a framework to address this recommendation. The RDoC was originally created to consolidate the research conducted in various fields of mental health [86]. The framework categorizes cognition into 6 domains and encourages the investigation of these domains via different classes of variables, such as behavioral, physiological, and self-report data. This framework encourages a common language and organizes findings in such a way that researchers can identify gaps or discrepancies in the literature and contribute to the ongoing development of the field. This framework indicates the potential benefits of using a common language for research, although it is not necessarily the only option in this field. Alternatively, researchers could engage in a Delphi study to generate expert-informed consensus on the key constructs of EF that merit investigation using VR paradigms (eg, see the study by Yücel et al [87] for a Delphi study on neuropsychological assessment for addiction). Nonetheless, the emerging area of VR development for neuropsychological assessments would benefit from using the RDoC framework to coordinate the research process.

Validation of VR for EF

Overview

Overall, there was limited reporting on the constructs that were assessed using VR paradigms and the associated validation outcome measures. In some papers, there was inadequate reporting of the constructs that the VR paradigm was intended to assess. In others, the same construct was assessed using a variety of traditional tasks. Furthermore, some VR paradigms were intended to replicate real life yet were validated against traditional tasks, none of which assessed ecological validity. In some studies, the correlations between the VR paradigm and the traditional tasks were incomplete. Finally, sample sizes varied considerably between studies, also affecting the evaluation of their psychometrics. These points are expanded upon in this section.

Several studies (5/19, 26%) examined EF as a broad category and then validated the paradigm against a variety of traditional tasks. However, some studies (3/19, 16%) detailed limited (or no) reporting of which aspect of the VR paradigm each traditional task was intended to validate. That is, no details were provided regarding which traditional task outcome measure corresponded to each component of EF within the VR paradigm. Traditional tasks, which often target one construct, were then correlated against seemingly all outcomes of the VR paradigm. Although this practice may be beneficial during the exploratory phase of VR paradigm development, failure to correct for multiple comparisons may provide misleading results whereby a correlation is found between two constructs incidentally. Conversely, some traditional tasks assessed multiple constructs, which poses a slightly different challenge. For example, if the VR paradigm broadly assessed EF but was validated against the ST, it was then unclear whether the VR paradigm aimed to assess processing speed, attention, inhibitory control, or interference control as the ST could be used to measure all four. Similarly, when these studies used multiple traditional assessments, the reader was expected to presume the target constructs of the VR paradigm as this was not clearly outlined. Poorly defined target constructs and failure to specify which traditional task validates which aspect of the VR task produces a literature that is difficult to interpret. Moreover, this general lack of clarity means that future researchers are more likely to invent a new paradigm rather than adopt or extend existing paradigms, creating inefficiency and hampering progress in the field.

Various standardized tasks were used to validate target constructs in the VR paradigm. For example, the study by Chicchi Giglioli et al [69] examined attention and inhibition control using the DPT, GNG, and ST. However, Voinescu et al [71] examined inhibition using the CPT paradigm. In addition, Marín-Morales et al [70] assessed inhibition using one mini-game of their VR paradigm. However, they neither provided details of a specific comparator task for validation purposes nor reported the statistical outcomes. Furthermore, the DPT, which is typically used to assess selective attention [88], was used to assess inhibition, although its own psychometric properties have been the subject of controversy [89,90]. Although several traditional tasks purport to measure the same construct (ie, there is not one task for one construct), the lack of consistency between studies makes it difficult to compare VR platforms. Furthermore, the traditional comparator task used to validate the VR paradigm needs to have sound psychometric properties in its own right to assess the respective construct; when two tasks are compared with one another, it is unclear which task may be responsible for discrepancies in the outcome [91]. These points are especially pertinent for studies that rely solely on traditional measures to validate tasks in the absence of other validation techniques.

Although it is promising to see that VR paradigms are being used for ecologically valid assessments, their validation remains a challenge. In the case of traditional tasks, we assume that a single construct can be assessed using a behavioral task and

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that the performance on that task is linear with the cognitive construct. In the case of a "function-led" VR task, there is a behavioral task that simulates real-world functioning, which is thought to deteriorate in an EF-declining population. This VR task is not a direct assessment of a target construct—it is a test of a real-world function, such as parking a car. To test convergent validity, the individual would have to park a car in real life and have their performance assessed similarly to that on the VR task and compared. However, when we use traditional measures to validate the "function-led" VR measures, we assume that EF can be reliably measured and the function-led VR task (eg, parking a car) requires the same EF. Thus, those who perform poorly on a traditional EF task are also expected to perform poorly on real-life tasks requiring EF. Critically, if our results do not show this relationship, it could be that the traditional task is a poor test of EF, the function-led assessment is a poor test of EF, or the EF at hand is not related to the functional task (eg, parking a car).

These assumptions place substantial weight on the selection of the traditional task for validating the VR paradigm for predictive validity. Davison et al [62] assessed EF using the ST and TMT. They broadly hypothesized that there would be correlations between the traditional measures and the VR paradigm, which contained tasks that replicated real life, such as car parking, arranging seating, and locating items. In the reported results, the ST and TMT were correlated with all outcome measures of the VR paradigm. For example, performance on the Stroop Color and Word Test was correlated with performance on the second parking simulator task, the number of levels completed on the parking simulator task, and the time taken to place the blue chair in the seating arrangement task. If the ST and TMT are not sufficient validators of the functional task, this may generate misleading results regarding the integrity of the VR paradigm and its ability to sensitively measure EF. Thus, the convergent validity of VR tasks would be better assessed through real-life performance on the same task, such as actually parking in a controlled environment. Although this may seem to be a resource burden to validation, it could provide integral merit to using the paradigm as a proxy for the real-life task thereafter. Alternative options are to assess convergent validity through other forms of real-life functioning (eg, self-care, residence, transportation, and employment) and diagnostic trajectory [49]. Moreover, predictive validators should be carefully chosen to ensure that their target construct aligns with that thought to be required for the function-led assessment.

Nonetheless, for novel task validation, transparent reporting of all results is crucial for advancing future research. Several papers included in this review (4/19, 21%) [61,62,68,69] reported only statistically significant correlations, leaving unanswered questions because of the omission of nonsignificant results. For instance, Chicchi Giglioli et al [69] sought to evaluate inhibition control using the GNG and ST for validation (both are common tasks for assessing inhibition) as well as the DPT yet did not report all correlational data in their results table. Such omissions hinder the comprehensive use or meta-analytic application of these findings. Conversely, Chicchi Giglioli et al [68] provided a detailed comparison between each validation task and its corresponding VR task, including the constructs assessed. However, only significant correlations were reported, some of which were between tasks intended to assess disparate constructs, such as the correlations between the Wisconsin Card Sorting Test (assessing cognitive shifting) and the VR tasks (measuring attention and inhibition control). Although these findings may indicate overlapping constructs in VR tasks, the absence of multiple-comparison correction and a detailed post hoc analysis of these correlations limits the interpretability and applicability of these results.

Finally, it is worth noting that there was significant variation in sample sizes across the studies reviewed. Although it is often accepted that pilot studies or preliminary studies have small sample sizes that often result in underpowered analysis, the utility of the VR paradigms is dependent on sound psychometric properties that require adequate sample sizes and statistical power. As detailed in Multimedia Appendix 1 [53-55,61-76], the sample sizes varied from 12 (6 per group) [74] to 103 (divided into 2 groups) [53]. Although the definition of a "sufficient" sample size may vary between studies and analyses, several of the included VR paradigms would likely require additional validation studies to provide confidence in their psychometric properties.

Recommendations

Our recommendations are as follows:

1. Papers should explicitly detail how their VR paradigms are being validated. If a paradigm has multiple components, it is essential to state how each one is being validated. A good example is the paper by Kourtesis et al [76] in this review.
2. If studies aim to validate a VR paradigm for a specific EF construct, they should identify a priori the precise outcome measures of the VR paradigm that are hypothesized to tap into various EF constructs (eg, time to completion and number of errors) and then validate them against the appropriate traditional tasks that also reliably assess those EF constructs.
3. Where appropriate, the VR paradigm's real-world task should be validated against both traditional task measures and ecologically valid measures. Ecologically valid measures may include carer reports, observation assessments, and activity of daily living assessments.
4. Multiple modes of validation should be used, including measures that provide predictive power [49], and both carer reports of daily functioning and biosensor data should be considered.
5. Papers should report all outcomes of validation data (even those in supplementary materials) to ensure the transparency of the tools' properties. A concerted effort to increase explicit and transparent reporting would greatly benefit this field.
6. To validate the VR paradigm, the psychometric properties of the traditional task must be appropriate.
7. Studies aiming to evaluate the psychometric properties of their VR paradigm should ensure that they have adequate sample sizes for a powered analysis.

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Cybersickness

Overview

Although VR offers several key advantages over traditional tasks, these systems can also produce adverse effects such as cybersickness. In our review, only 21% (4/19) of the studies included an assessment of cybersickness. This is concerning as cybersickness presents a substantial confound for valid VR assessment and has been shown to negatively affect task performance [92,93]. Given that the assessment of EF involves ascertaining a participant's cognitive abilities, the recording of cybersickness is key to ensuring that common side effects such as dizziness and vertigo do not affect the participants' ability to perform at their best on the tasks. Without formal evaluation, the degree to which participants' experiences are altered is unclear. Furthermore, it is unknown at this stage whether cybersickness symptoms affect various client populations differently. For example, it is possible that, although a healthy individual may be able to continue the assessment with minor vertigo, an individual with cognitive impairment may be more affected, resulting in severely affected cognitive outcomes. Thus, caution should be exercised when using VR paradigms to ensure that the potential benefits of engagement and ecological validity are not realized at the cost of the potential negative effects of cybersickness.

Recommendations

Our recommendations are as follows:

1. Future papers should include usability data in the form of cybersickness measurements.
2. Correlations between cybersickness and participants' task performance could be included as supplementary material that should be accessible to readers, enabling them to better understand how the VR battery is performing.
3. Even when a paradigm has already assessed cybersickness, we encourage future researchers to use the same paradigm to conduct their own cybersickness assessments. This is because it is still unclear whether cybersickness will have different effects on various populations.
4. Clinical researchers and engineers should continue to investigate and report on techniques and technologies that reduce the incidence or severity of cybersickness.

Textbox 1 provides an overview of the recommendations of this review.

Textbox 1. Recommendations for future research and practice using virtual reality (VR) head-mounted display–based paradigms for executive functioning (EF) assessment.

Validate against multiple forms

- Examples include carer reports, observation assessments, ecological momentary assessments, activity of daily living assessments, physiological sensors, and in vivo studies.
- Consider longitudinal tracking of participants to establish predictive utility to initially validate the novel paradigm.

Report a priori how each assessment in the VR paradigm is being validated

- If there are multiple components to one paradigm, state how each element is being validated (a good example is the study by Kourtesis et al [76] in this review); for example: "Task 2a aims to assess inhibitory control and is validated against the traditional stop signal task and go/no-go task."

Report all validation data

- Report correlations of all aspects of a task that were identified a priori as validating the VR paradigm. In extending the previous example, show all relevant metrics from task 2a, such as errors, proportion of successful stops, reaction time, and stop signal reaction time against the relevant metrics of both the Stop Signal and Go/No-Go tasks.

Include user experience assessment

- Conduct assessments of immersion, cybersickness, usability, and engagement.

Use a common framework for defining target constructs

- The Research Domain Criteria is one option of a framework that can be applied to ensure that terminology used in the field is consistent.

Consider adding biosensors

- These provide additional objective data that may inform the VR-based EF assessment.

Limitations

We searched for articles that used the terms "executive functioning," "higher order cognition," and "functional assessment" to capture tasks that aimed to broadly assess facets of EF. This search strategy may have missed studies that examined a key construct of EF but did not specifically use the aforementioned terms (eg, used VR to assess inhibitory control alone). In addition, we did not contact the authors of the papers included in this review for further information; however, one of the key outcomes of this review was the amount of information contained in the manuscripts for future studies to extend upon.

Future Directions

The authors posit that the integration of biosensors into a VR system has significant potential. Biosensors such as pupillometry, eye gaze, EEG, and language and grammatical

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characteristic data can be temporally linked to the events occurring in the VR task. For example, pupillometry can offer insights into brain injury prognosis [94] and differentiate between participants with Alzheimer disease and healthy controls [95]. Eye tracking during reading aids Alzheimer disease identification [96], and linguistic attributes (eg, formation and fluency of sentences, syntax, and grammar) distinguish patients with Alzheimer disease from those with MCI [97]. The combination of these biosensor metrics and real-time function-led VR performance could increase the sensitivity of tests, enabling the detection of subtle differences such as between MCI and subjective memory complaints [98]. However, currently, biosignals are rarely evaluated alongside emerging VR paradigms for EF assessment. None of the reviewed studies used biosensors, leaving an untapped potential for VR paradigms to be frontline neuropsychological assessments.

Biosensors could also assist in modulating the cognitive load experienced by participants. Cognitive load is the cumulative working memory resources that an individual requires for a given task [99]. Similar to the gaming industry, VR paradigms could be adaptive and performance driven so that the level of challenge adjusts according to real-time individual responses [100,101]. Modulating the cognitive load adjusts the challenge of a task and enables all participants to encounter similar levels of perceived difficulty for their respective abilities. EEG, pupillometry, and cardiovascular measures are also sensitive to cognitive load capacities [99].

An additional advantage of VR is its ability to facilitate the assessment of spatial navigation. Spatial navigation is a component of cognitive functioning that can be a key factor in detecting early stages of neurodegenerative diseases. However, it cannot be assessed adequately by means of many traditional assessments. Although it is acknowledged that spatial navigation is not a component of EF, the authors of this paper consider it a generally underexamined construct when assessing cognition and general function. For example, spatial navigation is a cognitive marker used to detect early attention deficit [102,103] and offers additional relevant information beyond the traditional neuropsychological tests [103]. The environment could also be systematically manipulated to match the needs of the assessment [104] and tailored to specific populations. However, typically, spatial navigation is assessed using a real-space human analog of the Morris water maze test, which can be difficult to implement under standardized conditions. Computerized versions have been adapted, with findings comparable with those of tests conducted in real space [105], suggesting promise for translating this style of assessment to VR.

Conclusions

VR paradigms assessing EF have great potential to improve upon traditional tests. However, despite their undeniable novelty and potential, their methodological and psychometric properties must be addressed during their development to ensure their validity and reliability. Although there is no shortage of research in this area, the lack of standardized protocols to validate VR-based neuropsychological assessments hinders the progress of this field of research and practice. It is hoped that this study will be the beginning of a larger movement toward systematizing the development and validation of these paradigms.

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Data Availability

All data generated or analyzed during this study are included in this published article (and its supplementary information files).

Authors' Contributions

RK contributed to conceptualization (equal), data curation (equal), formal analysis, investigation, methodology, writing—original draft preparation (lead), and writing—review and editing. LK contributed to conceptualization (equal), formal analysis (lead), investigation, writing—original draft preparation, and writing—review and editing. KR contributed to conceptualization (equal), data curation (equal), writing—original draft preparation, and writing—review and editing. MY contributed to writing—review and editing and funding acquisition. LA and DM contributed to writing—review and editing.

Conflicts of Interest

None declared.

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Multimedia Appendix 1
Article details including participant demographics, virtual reality (VR) paradigm, VR tasks, measures of user experience, and comparative assessments for VR paradigms.
[DOCX File , 34 KB - games_v12i1e50282_app1.docx]

Multimedia Appendix 2
PRISMA checklist.
[DOCX File , 32 KB - games_v12i1e50282_app2.docx]

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Abbreviations

CAVIR: cognition assessment in virtual reality
CPT: continuous performance test
DPT: dot-probe task
EAL: Everyday Assessment Lab
EEG: electroencephalography
EF: executive functioning
FAST: Functioning Assessment Short Test
GNG: Go/No-Go

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MCI: mild cognitive impairment
MET: Multiple Errands Test
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RDoC: Research Domain Criteria
ST: Stroop test
TMT: Trail-Making Test
TMT-A: Trail-Making Test version A
TMT-B: Trail-Making Test version B
UPSA-B: brief University of California, San Diego, Performance-Based Skills Assessment
VMT: Virtual Multitasking Test
VR: virtual reality
WoS: Web of Science

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Review

Digital Gamification Tools to Enhance Vaccine Uptake: Scoping Review

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Abstract

Background: Gamification has been used successfully to promote various desired health behaviors. Previous studies have used gamification to achieve desired health behaviors or facilitate their learning about health.

Objective: In this scoping review, we aimed to describe digital gamified tools that have been implemented or evaluated across various populations to encourage vaccination, as well as any reported effects of identified tools.

Methods: We searched Medline, Embase, CINAHL, the Web of Science Core Collection, the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials, Academic Search Premier, PsycInfo, Global Health, and ERIC for peer-reviewed papers describing digital gamified tools with or without evaluations. We also conducted web searches with Google to identify digital gamified tools lacking associated publications. We consulted 12 experts in the field of gamification and health behavior to identify any papers or tools we might have missed. We extracted data about the target population of the tools, the interventions themselves (eg, type of digital gamified tool platform, type of disease/vaccine, type and design of study), and any effects of evaluated tools, and we synthesized data narratively.

Results: Of 1402 records, we included 28 (2%) peer-reviewed papers and 10 digital gamified tools lacking associated publications. The experts added 1 digital gamified tool that met the inclusion criteria. Our final data set therefore included 28 peer-reviewed papers and 11 digital gamified tools. Of the 28 peer-reviewed papers, 7 (25%) explained the development of the tool, 16 (57%) described evaluation, and 2 (7%) reported both development and evaluation of the tool. The 28 peer-reviewed papers reported on 25 different tools. Of these 25 digital gamified tools, 11 (44%) were web-based tools, 8 (32%) mobile (native mobile or mobile-enabled web) apps, and 6 (24%) virtual reality tools. Overall, tools that were evaluated showed increases in knowledge and intentions to receive vaccines, mixed effects on attitudes, and positive effects on beliefs. We did not observe discernible advantages of one type of digital gamified tool (web based, mobile, virtual reality) over the others. However, a few studies were randomized controlled trials, and publication bias may have led to such positive effects having a higher likelihood of appearing in the peer-reviewed literature.

Conclusions: Digital gamified tools appear to have potential for improving vaccine uptake by fostering positive beliefs and increasing vaccine-related knowledge and intentions. Encouraging comparative studies of different features or different types of digital gamified tools could advance the field by identifying features or types of tools that yield more positive effects across

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populations and contexts. Further work in this area should seek to inform the implementation of gamification for vaccine acceptance and promote effective health communication, thus yielding meaningful health and social impacts.

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KEYWORDS

digital gamified tools; digital game; vaccination; gamification; vaccine uptake; scoping review; review method; vaccine; gamified; COVID-19; COVID; SARS-CoV-2; health behaviour; health behavior; health promotion; behavior change; behaviour change

Introduction

Vaccination is one of the most cost-effective methods of preventing the spread of vaccine-preventable diseases. If vaccination coverage falls below the thresholds that are safe for the prevention of epidemic transmission, the incidence of vaccine-preventable diseases increases [1,2]. For example, measles returned over the past 2 decades, and the incidence of measles in the European Union increased in 2017-2018 [3].

In 2019, prior to the COVID-19 pandemic, the World Health Organization identified vaccine hesitancy (ie, the reluctance or refusal to be vaccinated despite the availability of vaccination services) as 1 of the top 10 threats to worldwide health [4]. Vaccine hesitancy is one of the several reasons some people are un- or undervaccinated [5-9]. Interventions addressing vaccine hesitancy are therefore necessary to promote vaccine acceptance and uptake. As the contributors of vaccine acceptance are diverse, no single intervention will solve this issue [10]. Multicomponent interventions tailored to local barriers to vaccine acceptance and uptake are known to be the most effective [11,12]. Misinformation and conspiracy theories spread online, where extensive antivaccine content is shared [13-15], potentially negatively influencing views about vaccines [16,17]. Efforts have been made to counter vaccine misinformation and mistrust by targeting various groups, such as parents, non–health care workers [18,19], and adolescents [20], and delivering information about the risks and benefits of different types of vaccines, for instance, human papillomavirus (HPV) vaccination [21] and measles, mumps, and rubella vaccines [22,23]. Along with traditional communication strategies, the use of other strategies to inform and educate about immunizations, for example, with digital gamified tools, may help encourage vaccine uptake.

Gamification is defined as the use of game design elements in nongame contexts [24]. It includes several aspects and features, such as fun interfaces, immediate success or feedback, reward systems (levels, point scores, badges), challenges and competitions, team playing, avatars, and quizzes. Previous studies have used gamification to achieve desired health behaviors [25-27] or facilitate their learning about health [28]. Gamification draws on elements from serious games, meaning fully developed digital games used to train and educate players [29,30]. For example, a serious game "Land of Secret Gardens" facilitates conversations about HPV with preteens. In the game, preteens need to protect their bodies with a "potion," which offers a metaphor for the HPV vaccine [31]. However, serious games and digital gamified tools are distinct but related concepts. Serious games use gaming as a central and primary medium [32]. In contrast, digital gamified tools (eg, apps) or gamified interventions are not complete game experiences but have gaming features, such as rewards systems, scoring of points, or engaging users in different challenges [33]. In this study, we defined digital gamified tools as digital apps with the aforementioned gaming features. Our definition includes serious games that meet the criteria, that is, they must include such gaming features. This scoping review provides insight into the reported effects of digital gamified tools to increase vaccine uptake. Our review built upon existing reviews in the field by including a comprehensive search of both published literature and online tools, as well as an examination of both the characteristics and the reported effects of these digital tools. This review was distinct in that it focused specifically on digital gamified tools and their effects, rather than simply the effectiveness of gamification in general. In doing so, this review aimed to fill a gap in the literature by providing evidence-based answers to the question of whether gamification "works" to increase vaccine uptake. Therefore, the objectives of this scoping review [34] were, first, to review digital gamified tools that have been implemented or evaluated across various populations to encourage vaccine uptake and, second, to describe any reported effects of the identified tools in terms of influence on users' knowledge or behavior toward vaccination. Our research questions can therefore be summarized as follows:

- What digital gamified tools intended to encourage vaccination exist and have been described in the literature?
- Do these tools demonstrate any effects on knowledge, attitudes, beliefs, and behaviors about vaccination?

Methods

Search Strategy

For peer-reviewed papers, we searched Medline (Ovid), Embase (Ovid), CINAHL (EBSCO), the Web of Science Core Collection, the Cochrane Database of Systematic Reviews (Ovid), the Cochrane Central Register of Controlled Trials (Ovid), Academic Search Premier (EBSCO), PsycInfo (Ovid), Global Health (Ovid), and ERIC (Ovid) with no language or date restrictions. The proposed search terms were, for example, "vaccine," "vaccination," "immunization," "video games," "gamification," "application," and "virtual reality" (see Multimedia Appendix 1 for the full search strategy). The search was conducted on January 26 and 27, 2022.

We also conducted an online Google search on May 5, 2022, for any digital tools with gamified features that deliver informative or educative messages on vaccination. The search terms we used were "vaccination," "immunization," "electronic game," "computer game," "mobile game," "interactive game," and "digital game" (see Multimedia Appendix 1 for the full

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search strategy). We reviewed the first 30 results for each search, as it is rare for users to click past the third page of 10 search results per page, and therefore, researchers analyzing medical content available on the web often use 30 as a threshold [35-37]. On May 6, 2022, we conducted the same searches in private browsing mode to ascertain whether our results had been affected by a "filter bubble" [38], that is, the way Google search results are adapted to one's previous browsing activity. Our search strategy was constructed and reviewed by 2 librarians. Following the librarians' advice, we expanded our search strategy to include ERIC and Global Health databases.

Study Selection and Screening Process

We used PICO (Population, Intervention, Comparison, and Outcome) to structure study inclusion and exclusion criteria (Table 1). Our population of interest was the general public or any subgroup, including health care professionals and students. We sought studies describing tools with gamification techniques or gamified elements, including gamified web-based quizzes to deliver informative or educative messages on vaccination. Posters, preprints, editorials, conference proceedings, news bulletins, and paper-based or board games were excluded. Our comparator was any control, including offering no education on vaccination or comparing participants before and after an intervention. Our outcomes of interest included common outcomes associated with vaccine uptake, namely knowledge (comprehension, understanding), attitudes (for or against vaccination), beliefs (perceived benefits, perceived risks), and behaviors toward vaccines (vaccination intention [ie, intention to get vaccinated or not get vaccinated] and vaccine uptake [ie, receiving or not receiving a vaccine]). We excluded papers that did not present the description or evaluation of a concrete digital gamified tool.

Table 1. Inclusion and exclusion criteria.

Component	Inclusion criteria	Exclusion criteria	Question related to the criteria
Type of report	• Original paper • Evaluated intervention or digital gamified tool	• Posters, preprints, and conference proceedings • Modeling or simulation study • Brochures • Editorials • Bulletins	Has the study or research described the development of the tool and evaluated it?
Population	• General public (any subgroup) • Professionals • Students	N/A[a]	Who is the audience for whom the key message was intended?
Intervention	• Tools with gamification technique or gamified elements, including gamified web-based quizzes to deliver informative or educative messages on vaccination	• Any study or gamification tools not intended for vaccination/vaccine uptake • Studies or apps to reduce vaccine pain and fears and to report immunization status or record keeping, surveillance or vaccine coverage apps, contact-tracing or early detection apps • Paper games, board games (not digital) • Videos with no gamified element included	Does the study or tool aim to deliver an informative or educative message on vaccination?
Comparator	• Any control, including offering no education or no digital gamified tool	N/A	N/A
Outcome	• Common outcomes that encourage vaccine uptake: knowledge (comprehension, understanding), attitudes (for or against vaccination, beliefs (risk perception, etc), behaviors toward vaccines (vaccination intention [ie, intention to get vaccinated or not get vaccinated] and vaccine uptake [ie, receiving or not receiving a vaccine])	• Outcomes not related to the encouragement of vaccine uptake	Has the study or tool been evaluated for the outcomes that encourage vaccine uptake?

[a]N/A: not applicable.

For Google-searched digital gamified tools, our inclusion and exclusion criteria used the same specifications regarding

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population and intervention. We did not apply comparison and outcome criteria to web-based tools because we did not expect these to report evaluation studies.

We reported this review according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (see the PRISMA checklist in Multimedia Appendix 2) [39]. We registered our protocol on the Open Science Framework [40].

Expert Consultations

After extracting information from peer-reviewed papers and tools identified via a Google search, we contacted experts in the field of digital gamified tools (eg, developers and researchers working on the topic in Canada and worldwide who were already known to the research team) to complement our online searches and ensure completeness. Specifically, we sent emails to 12 experts about the results of our searches and asked them to alert us to any games or papers we might have missed.

Data Charting

We developed a form in Microsoft Excel to guide the charting of data. We pretested and reviewed the form with team members to ensure we were accurately and adequately capturing relevant data. Data charting occurred independently with verification. Specifically, a reviewer (author HH) identified and screened all studies and digital gamified tools for their eligibility. Screening results were verified by a second reviewer (author DG). The data charting was then performed by a reviewer (HH) and again verified by a second reviewer (DG). Any conflicts throughout screening or data charting were resolved by a third reviewer (author ED). From the included papers, we charted data about (1) the type and design of study (developmental or evaluation study, user testing, randomized controlled trial, etc), (2) the vaccine(s) addressed (COVID-19, HPV, etc), (3) the purpose of the study or intervention, (4) the digital gamified tool platform (web based, native mobile app, mobile-enabled web app, virtual reality), and (5) the characteristics of study participants. For the evaluated interventions, we charted data about preselected outcomes that are widely used to predict health-related behaviors and to assess outcomes in studies of interventions about vaccination and immunization [11-14]. Specifically, we extracted data about the tools' effects on knowledge, attitudes, beliefs (perceived benefits, perceived risks), and behavioral intentions. Emotional, cultural, and social factors can also influence a decision about vaccination [29,30]. Therefore, we also extracted data about other outcomes that the studies may have evaluated. Because we sought to understand all possible effects, we did not prespecify any of these as a primary outcome. We organized the extracted data in tables and synthesized them descriptively.

Quality Assessment

To assess the quality of the studies that evaluated their interventions, we used the Mixed Methods Appraisal Tool (MMAT) developed by Pluye et al [41]. Two reviewers independently conducted the quality assessment, resolving disagreements through discussion until reaching a consensus. A third and a fourth reviewer (authors HH and HW) intervened to settle any remaining conflicts.

Data Synthesis

We summarized data using a narrative approach involving framework and content analysis. We classified each digital gamified tool platform using the 4 types of digital gamified tools: web-based tool, native mobile app, mobile-enabled web app, virtual reality tool. For the type of digital gamified tool, we classified web-based tools that explicitly noted their suitability for mobile use (eg, by smartphone or tablet) as mobile-enabled apps. We classified web-based tools without such an explicit statement as web based only, even though they may be functional on mobile devices. For the type and design of study, we grouped randomized designs together, including traditional randomized controlled trials with only 2 study arms and factorial designs with more than 2 study arms. Although these methods are not exactly the same, they all use randomization to minimize potential biases and are therefore functionally equivalent for our purposes of understanding what kinds of evaluations have been undertaken [42]. We summarized the main characteristics of tools, including PICO elements, in a tabular display. We used the PRISMA 2020 flowchart to describe the process of study selection [43].

Results

Papers Identified and Scope of Literature

We identified a total of 2082 records through database searches. After removing duplicates, we screened 1402 (67.3%) database records. Through Google searches, we identified 10 digital gamified tools and 2 papers. In a private browsing mode search, there was no change in search results. Of the 12 experts contacted, 2 (17%) responded and suggested 2 papers and 2 links, of which 1 (50%) digital gamified tool met the inclusion criteria and was included in our review. Through these methods, our final data set included 28 (2%) peer-reviewed papers and 11 digital gamified tools. Figure 1 shows our PRISMA diagram.

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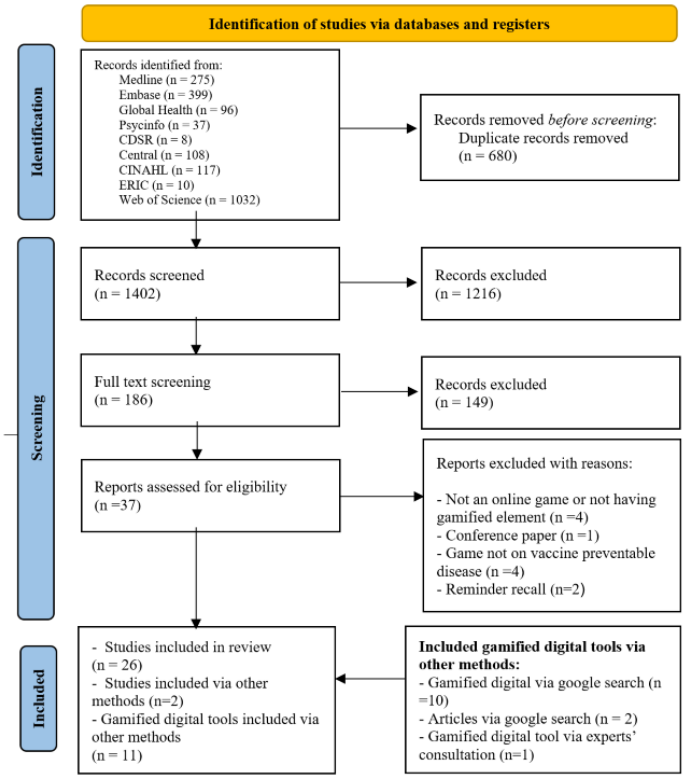
Figure 1. PRISMA flow diagram. PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.



Of the 28 peer-reviewed papers, 7 (25%) explained the development of the tool, 16 (57%) described evaluation, and 2 (7%) reported both development and evaluation of the tool (Table 2). To report our results, we grouped studies together that reported the same tool, meaning 28 peer-reviewed papers reporting on 25 different tools. Of these 25 digital gamified tools, 11 (44%) were web-based tools, 7 (28%) mobile (native mobile or mobile-enabled web) apps, 6 (24%) virtual reality tools, and 1 (4%) offered in both mobile and web-based versions (for details, see Table 2). The most common single vaccines addressed in the tools were influenza (n=6, 24%, tools) and HPV (n=6, 24%, tools). Other tools addressed COVID-19 (n=2, 8%); measles, mumps, influenza, and smallpox (n=2, 8%); a hypothetical disease (n=2, 8%); other vaccine-preventable diseases (n=6, 24%); and the role vaccines play in preventing the spread of disease with no particular vaccine specified (n=1, 4%). Of the 10 digital gamified tools identified via a Google search and 1 suggested by the expert (a total of 11 digital gamified tools; see Table 3), the largest group (n=5, 45%) addressed COVID-19, and the rest were about other vaccine-preventable diseases. The 11 gamified elements identified in the Google search and expert feedback identified 6 types of gamified elements: reward points, serious games, physical trading cards, certificates, role-playing, and quizzes (see Table 3). The most common type was reward points, which appeared in 5 (45%) cases. Two cases used serious games, one case used physical trading cards and reward points, one case used certificates, one case used role-playing, and one case used quizzes. Additional characteristics of the studies included (eg, country of origin, sample size, participant characteristics) are detailed in Multimedia Appendix 3 [31,44-70]. The expanded versions of Table 2 [31,44-70] and Table 3 [71-81] are provided in Multimedia Appendix 4.

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Table 2. General information about the studies.

Type of study and author(s)	Type of digital gamified tool platform	Type of disease/vaccine	Type and design of study (development or evaluation, iterative design, randomized controlled trial, etc)
Evaluation studies			
Betsch and Böhm [44]	Web-based tool	Hypothetical	Evaluation: online experiment
Carolan et al [45]	Web-based tool	Measles, mumps, influenza, and smallpox	Evaluation: pre-post study
Cates et al [31]	Web-based tool	HPV[a]	Evaluation: pilot randomized controlled trial
Dale et al [46]	Native mobile app	Influenza	Evaluation: nonrandomized trial
Darville et al [47]	Web-based tool	HPV	Evaluation: randomized controlled trial
Eley et al [48], McNulty et al [49]	Web-based tool	Bacteria, vaccine-preventable disease	Evaluation: quantitative followed by qualitative research design
Fadda et al [50], Fadda et al [51]	Native mobile app	MMR vaccines	Evaluation: mixed methods research design
Ibuka et al [52]	Web-based tool	Hypothetical disease	Evaluation: experimental design
Kaufman and Flanagan [53]	Web-based tool	Not reported	Evaluation: experimental design
Lee et al [54]	Native mobile app	Influenza	Evaluation: randomized controlled trial
Mitchell et al [55], Laplana [56]	Web-based tool	Influenza	Evaluation: pre-post study
Mottelson et al [57]	Virtual reality tool	COVID-19	Evaluation: randomized controlled trial (2×2 factorial design)
Nowak et al [58]	Virtual reality tool	Influenza	Evaluation: one-way between-subjects design with random assignment
Real et al [59]	Virtual reality tool	Influenza	Evaluation: quasi- randomized controlled trial[b]
Woodall et al [60]	Mobile-enabled web app	HPV	Evaluation: clinic-cluster randomized trial
Vandeweerdt et al [61]	Virtual reality tool	COVID-19	Evaluation: randomized controlled trial
Development studies			
Amresh et al [62]	Web-based tool	HPV	Development: iterative design
Bertozzi et al [63] (data extracted for the game related to vaccines)	Web-based tool	Influenza	Development: iterative design
Carolan et al [64]	Web-based tool	Measles, mumps, influenza, and smallpox	Development: iterative design
de Araujo Lima et al [66]	Native mobile app	Vaccine-preventable diseases	Development: heuristic evaluation by users, content evaluation by experts
Kafai et al [65]	Virtual reality	Dragon swooping cough virus to reflect real-life features of infectious viruses, such as Ebola.	Development: user feedback via surveys (asking users questions) and log files (observing user behaviors)
Real et al [67]	Native mobile app	HPV	Development: usability testing
Streuli et al [68]	Virtual reality	Pediatric vaccines	Development: Community-based participatory research and co-design
Development and evaluation studies			
Davies et al [69]	Mobile or web app (multiple formats available)	Hepatitis B	Development and evaluation: Participatory Action Research
Ruiz-López et al [70]	Native mobile app	HPV	Development and evaluation: Iterative design and evaluation via questionnaire

[a]HPV: human papillomavirus.

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[b]Allocation to a study arm was performed according to work schedules, which are often arbitrary. We therefore considered this quasi-randomization.

Table 3. Tools from Google search and expert suggestions.

Digital gamified tool	Type of disease/vaccine	Type of digital gamified tool platform	Gamification elements (eg, rewards, role-playing, leaderboard, serious game)
Antidote COVID-19 [71]	COVID-19	Native mobile app	Reward points
The Vaccination Game [72]	H11N7 and influenza	Web-based tool	Serious game
Help take down COVID-zilla! [73]	COVID-19	Web-based tool	Role-playing
Just the Vax! [74]	Vaccine-preventable disease	Web-based tool	Reward points
COVID Invaders [75]	COVID-19	Web-based tool	Reward points
Vax Pack Hero [76]	Vaccine-preventable disease	Web-based tool	Reward points and physical trading cards
Flu's Clues [77]	Influenza	Web-based tool	Certificate of completion for solving the influenza mystery
Virus Fighter [78]	COVID-19, influenza, Ebola, measles	Web-based tool	Serious game
Immunization411: for pre-teens and teens' online training [79]	Tdap meningococcal vaccine, varicella, HPV[a], influenza	Web-based tool	Reward points
COVID Chronicles [80]	COVID-19	Web-based tool	Reward points
I Boost[b] [81]	Vaccine-preventable disease	Web-based tool	Quiz

[a]HPV: human papillomavirus.

[b]Suggested by an expert.

The studies were conducted in 26 different countries, with the majority of studies coming from the United States (n=13, 46%, studies) and the United Kingdom (n=5, 18%, studies). Study populations included students at various levels (elementary school to college, specialty programs, eg, nursing and pediatric residency), parents of vaccine-eligible children, adults from the general population, members of particular sociocultural communities (eg, immigrants, Indigenous peoples), and convenience samples, such as players of a game, attendees of a conference, and employees of an organization. Sample sizes ranged from 8 to 50,286. Whenever papers reported study participant characteristics such as age, sex, gender, ethnocultural identity, or socioeconomic levels, we extracted summary data, as shown in Multimedia Appendix 3.

Reported Effects of Evaluated Interventions

In total, 18 (64%) of 28 studies evaluated at least 1 of our outcomes of interest, while 11 (39%) studies reported the effects of the evaluated interventions on more than 1 outcome of interest. Summarized outcomes and their MMAT quality assessments are shown in Table 4. Multimedia Appendix 5 provides full details.

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Table 4. Outcomes of evaluation studies included.

Type of digital gamified tool platform and study	Knowledge (comprehension/understanding, etc)	Attitudes (for/against vaccination, etc)	Beliefs (risk perceptions, etc)	Behavioral intentions (getting vaccinated or not, etc)	Others (eg, emotions)	MMAT[a] quality score
Web-based tool						
Betsch and Böhm [44]	__[b]	Negative vaccine attitudes with compulsory vaccination	—	Decreased vaccine uptake with compulsory vaccination	Increased level of anger with compulsory vaccination	60% quality criteria met
Carolan et al [45]	—	No significant effect on attitudes towards vaccination	—	—	Increased confidence in information needs	80% quality criteria met
Cates et al [31]	Increase in knowledge about immunization	—	—	Positive increase in intentions to vaccinate	Increase in vaccination self-efficacy, decisional balance towards vaccination	100% quality criteria met
Darville et al [47]	—	—	Positive effects on beliefs towards vaccination	Increase in intentions to vaccinate	—	60% quality criteria met
Eley et al [48], McNulty et al [49]	Improvements in knowledge about immunization	—	—	—	—	100% quality criteria met
Ibuka et al [52]	—	—	—	—	Free riding in vaccination decisions decreases vaccine acceptance	80% quality criteria met
Kaufman and Flanagan [53]	The digital version of the game was less effective at facilitating learning	The digital version of the game was less effective at attitude change	—	—	The digital version of the game was perceived to be complicated to use	20% quality criteria met
Mitchell et al [55], Laplana [56]	Increase in knowledge	Positive increase in attitudes for vaccination	—	Increase in vaccine uptake after accessing the game	—	80% quality criteria met (Mitchell et al [55])
Mobile app						
Dale et al [46]	—	—	—	Positive increase in intentions to vaccinate	—	80% quality criteria met
Fadda et al [50], Fadda et al [51]	Improvements in knowledge about immunization	—	—	Increase in intentions to vaccinate	Increase in psychological empowerment and confidence in the decision	80% quality criteria met (Fadda et al [50], Fadda et al [51])
Lee et al [54]	—	—	—	Increase in intentions to vaccinate	—	80% quality criteria met
Woodall et al [60]	—	—	Increase in beliefs towards vaccination	Increase in intentions to vaccinate	Increase in vaccine confidence	40% quality criteria met
Ruiz-López et al [70]	Increase in knowledge after playing the game	—	—	—	—	100% quality criteria met
Virtual reality tool						

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Type of digital gamified tool platform and study	Knowledge (comprehension/understanding, etc)	Attitudes (for/against vaccination, etc)	Beliefs (risk perceptions, etc)	Behavioral intentions (getting vaccinated or not, etc)	Others (eg, emotions)	MMAT[a] quality score
Mottelson et al [57]	—	—	—	Increase in vaccination intention when both the personal and collective benefit of COVID-19 vaccination was communicated	Increase in COVID-19 empathy, vaccination recommendation, and vaccination readiness	80% quality criteria met
Nowak et al [58]	—	—	Positive effects on beliefs towards vaccination	Increase in intentions to vaccinate	—	100% quality criteria met
Real et al [59]	—	Increase in attitudes in favour of vaccination	—	—	—	60% quality criteria met
Vandeweerdt et al [61]	—	—	—	Increase in intentions to vaccinate	Virtual reality intervention increases a sense of collective responsibility	100% quality criteria met
Mobile or web app (multiple formats available)						
Davies et al [69]	Increase in knowledge about immunization	—	—	—	—	80% quality criteria met

[a]MMAT: Mixed Methods Appraisal Tool.

[b]Not reported.

Effects on Knowledge (Includes Comprehension/Understanding, etc)

Overall, the 28 included studies suggested that digital gamified tools may positively influence knowledge. Of 7 (25%) studies that assessed knowledge, 6 (86%) showed an increase in knowledge about immunization in general [31,48,51,55,69,70]. All these 6 (86%) studies were of high quality (≥80%). One study of low quality (≤25%) reported that a digital game is less effective at increasing knowledge compared to its original board game format [53]. When considering only the high-quality (≥80%) studies, we observed that digital gamified tools are associated with increased knowledge.

Effects on Attitudes (for or Against Vaccination)

Overall, digital gamified tools appeared to have mixed effects on attitudes toward vaccination. Of 5 (18%) of 28 studies that assessed attitudes, 2 (40%), one of high quality (≥80%) and the other of medium quality (60%), showed an increase in positive attitudes toward vaccination [55,59]. In addition, 2 (40%) studies, one of high quality (≥80%) and the other of low quality (20%), reported no or less effect on attitudes toward vaccination [45,53], and 1 (20%) study comparing voluntary and compulsory vaccines in a game context showed negative attitudes regarding compulsory vaccination [44]. When considering only the high-quality (≥80%) studies, we observed inconsistent effects on attitudes.

Effects on Beliefs (Perceived Benefits, Perceived Risks)

Overall, digital gamified tools demonstrated positive effects on beliefs toward vaccination. In total, 3 (11%) of 28 studies, 1 (33%) of high quality (100%) and 2 (67%) of medium quality (60% and 40%), evaluated the effects of digital gamified tools on beliefs toward vaccination. All 3 (100%) studies showed positive effects on beliefs toward vaccination [47,58,60]. When considering only the high-quality (≥80%) studies, we observed that digital gamified tools are associated with positive beliefs about vaccines.

Effects on Behavioral Intentions

Overall, the 28 included studies suggested that digital gamified tools may positively influence intentions to receive vaccines. In total, 11 (39%) studies evaluated the effects of digital gamified tools on behavioral intentions with regard to vaccines. Of these 11 studies, 1 (9%) of medium quality (60%) showed a decrease in vaccination intention when compulsory vaccination was introduced within a game context [44], whereas 10 (91%) studies, 3 (30%) of medium quality (60% and 40%) and 7 (70%) of high quality (≥75%), showed increased intentions to vaccinate [31,46,47,51,54,55,57,58,60,61]. When considering only the high-quality (≥80%) studies, digital gamified tools appeared to be consistently associated with increased vaccination intention.

Other Outcomes

In total, 9 (32%) of 28 studies have also evaluated the effects of digital gamified tools on other outcomes. Of these, 4 (44%) studies reported an increase in confidence in vaccines (medium quality=40%) [60], confidence in information needs (high quality=80%) [45], decisional balance in support of vaccination (high quality=100%) [31], and confidence in vaccine decisions (high quality=80%) [50]. In addition, 1 (11%) study of high

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quality (80%) reported an increase in empathy toward those vulnerable to COVID-19 and vaccination recommendations [57], and 2 (22%) studies of high quality (100% and 80%) reported an increase in vaccination self-efficacy and readiness [31,57]. An increase in psychological empowerment (high quality=80%) [51] and in emotions such as anger toward compulsory vaccination (medium quality=60%) [44] was also reported by 2 (22%) studies. One study of high quality (80%) reported that the concept of free riding decreases vaccine acceptance [52], whereas another study of high quality (100%) reported that virtual reality intervention increases collective responsibility [61]. When considering only the high-quality (≥80%) studies, we observed a variety of positive effects associated with digital gamified tools, including confidence in vaccines, confidence in decisions about vaccines, empathy toward vulnerable people, collective responsibility, psychological empowerment, and vaccination self-efficacy and readiness.

Effects of the Platform (Web Based, Mobile, Virtual Reality)

The study designs of the 28 included papers did not permit us to formally compare the effects of different platforms in a robust way. Upon inspection, there did not appear to be a strong effect of the platform. In other words, we did not observe evidence in favor of web-based, mobile, or virtual reality apps over the other 2 types of apps.

Discussion

Principal Findings

The broad objective of this scoping review was to map the state of the science regarding digital gamified tools and their effects. In other words, we wished to answer a common question at the intersection of public health and digital health: does gamification encourage vaccination and influence knowledge, attitudes, beliefs, and behaviors related to vaccination? By mapping both published literature and tools currently available online, we observed 2 principal findings.

First, our results suggest that gamification can increase predictors of vaccine uptake, such as knowledge, attitudes, beliefs, behaviors, and vaccination intention. This finding is similar to the findings of a previous review by Montagni et al [82] suggesting that gamification can contribute to changed behaviors and improved knowledge of vaccination. Similarly, other reviews have suggested the potential benefits of gamification for non–vaccination-related behavior change, such as a systematic review suggesting that gamification interventions could be a feasible way to improve health-related outcomes among cancer survivors [83] and another review suggesting their effectiveness in improving physical activity [84]. Such previous work became even more relevant during the COVID-19 pandemic, as many jurisdictions sought to optimize vaccine uptake in the context of an “infodemic” (ie, overabundance of information, true, false, and misleading, about the pandemic and recommended preventive behaviors) [85]. Half of the digital gamified tools identified in our web search addressed COVID-19, suggesting an active interest in using a gamified approach in the pandemic context. Recent research by Plechatá et al [86] published after our data extraction steps were complete suggested that explaining the concept of herd immunity with gamification has a positive impact on the COVID-19 vaccination intention.

Second, our review suggests that although gamification has the potential to enhance the impact of education strategies, gamified tools alone may not wholly address gaps in vaccine acceptance and uptake. Although some of the identified tools did increase vaccination, the increases did not fully close gaps between previous and desired vaccine uptake. This finding aligns with those of Tozzi et al [87], which suggested that promising results could be achieved by combining gamification with educative and informative tools to improve immunization programs. This finding also aligns with previous reviews suggesting the use of digital gamified interventions as a public health tool of interest in enhancing vaccine uptake [82,88]. Further research published by Real et al [89] after our systematic search similarly observed that integrating gamification, such as virtual reality, in training modules enhances uptake of the HPV vaccine. Integrating gamified features may work because they make digital tools acceptable and more fun to use and may reduce the chances of people feeling pushed toward vaccination. In parallel, gamification may be a promising strategy for increasing knowledge, skills, and confidence among health professionals engaging in discussions about vaccines with their patients [90,91].

In addition to these findings drawn directly from our review of the included tools, we offer a broader observation based on the contents of this scoping review, along with the larger landscape of vaccine acceptance research: context is key. Although an engaging approach may work for some groups or in some situations, it may be less well accepted among other groups and in other situations. For instance, a casual and approachable style of communication will work for the younger audience to convey vaccine information but might be deemed insufficient to health care professionals in a more formal setting, such as hospitals. A good understanding of the factors associated with low vaccine acceptance at the local level is needed prior to developing gamified tools [92]. Future research in this area should consider possible contextual factors, such as local culture, social and demographic characteristics of users, and different influences on vaccine hesitancy and acceptance in different regions. To help better match games to the context(s) in which they will be played, when developing games, developers and researchers may wish to consider involving potential players from different contexts early and often. This aligns with previous work [93,94] suggesting that involving users earlier in developing tools may help in designing interventions suitable for a targeted context. One of the examples in our review was an intervention by Cates et al [31] designed to explain HPV vaccines to teenagers using a “secret garden” theme. Involving potential game players early in the development of the game may have contributed toward its positive effects on vaccination intention.

The implications of this research extend beyond the immediate reported effects of gamified tools and delve into the strategic dimensions of public health policy and communication efforts. Considering the insights gleaned from the findings, this study

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supports a comprehensive and well-informed approach to integrating gamification into strategies for promoting vaccination. As gamification continues to demonstrate its potential in enhancing vaccine uptake, it is crucial to navigate this terrain thoughtfully, considering the various factors that influence its impact. This includes not only the technological and behavioral aspects but also the larger sociocultural context in which vaccination decisions are made. Therefore, our study emphasizes the importance of a comprehensive approach that fosters a mutually beneficial relationship between technological innovation, evidence-based strategies, and an intricate understanding of local contexts. This approach has the potential to make gamification a sustainable and adaptable tool in the arsenal of public health interventions, rather than just a passing trend.

The review does not find a clear advantage for any platform in terms of reported effects. It was challenging to measure the impact of the platforms on behavioral outcomes and calls for more focused research to better understand the specific elements within each platform that drive behavior change. In essence, our study suggests that the reported effects of an app may not be solely determined by its platform but rather by the strategic incorporation of mechanics and elements that facilitate the desired behavior change.

Gamification can influence knowledge, attitudes, and beliefs about vaccines, which can affect vaccine uptake. This is consistent with theories of change proposing that cognitive changes can lead to behavioral outcomes. Although our study mainly examines the immediate effects of gamification on these cognitive aspects, it also offers some implications for using gamification as a potentially viable strategy to improve vaccine acceptance.

Strengths and Limitations

Our study has 5 main limitations. First, because we aimed to capture all relevant evidence and examples, as is typical in a scoping review, we included a broad range of study designs and did not draw conclusions about the relative advantages or disadvantages of different game platforms and features. Given the rapid growth within this field of research, it would be difficult to truly prioritize evidence according to quality criteria at this point. In the future, it may be possible to conduct a systematic review and meta-analysis, restricting included studies to randomized experiments or randomized controlled trials. Such future work may include approaches such as a network meta-analysis to allow for comparison of the effects of different game types or game features. Based on the existing literature, it is difficult to conclude whether certain games are more or less likely to achieve their aims. Second, our results may be influenced by publication bias. It is possible that groups that have developed digital gamified tools that showed disappointing results simply did not publish their studies. This bias could lead to an overestimation of the reported effects of these tools. This highlights the importance of further research to fully understand the real impact of these tools and thus accurately inform policy decisions about the development and use of these tools. Third, and related to the previous 2 points, the rapid growth in this area may mean that we missed more recent evidence in literature published after January 2022 and web searches after May 2022. Fourth, the majority of digital gamified tools on vaccination represented in publications and online were developed in high-income countries. This finding aligns with the findings of previous work by Ohannessian et al [88], who also reported a predominance of high-income countries. This may reflect more widespread internet access and resources for developing digital gamified tools in high-income countries. It may also reflect publication bias in the scientific literature (ie, there may be fewer papers written about digital gamified tools in lower-income countries) and online (ie, tools developed and published in lower-income countries may not be ranked highly by search engines and therefore may not have appeared in our web searches). Tools developed in lower-income countries may also take different forms; for example, they may be text message–based interventions (with or without gamification) rather than web-based tools and therefore would be less likely to be identified in web searches. Analog games from high-income countries were similarly excluded from the scope of our study [95]. Nondigital games, such as board and card games, have demonstrated positive impacts on educational knowledge, cognitive function, and social interactions [96,97]. Such games can support diverse learning across subjects and settings, fostering interactions that develop skills, such as computational thinking and teamwork, and have positive impacts on academic achievement and vocabulary acquisition compared to digital games [97-99]. We restricted our scoping review to digital gamified tools because the review was intended to provide an evidence base for digital game development. Although nondigital games are also potentially useful interventions, the implementation and distribution of such interventions is more challenging, especially in a geographically dispersed country, such as Canada. Fifth, and finally, as we used Google and private browsing in Google, there may be a possibility that different search engines would provide different results.

This study also has 2 main strengths. First, by systematically examining the current literature and currently available tools online, we were able to offer an updated overview of the potential effects of including gamification in digital tools about vaccination. Second, by conducting a scoping review to broadly map the literature, future work can more easily identify and select key outcomes for systematic reviews and meta-analyses in this domain.

Conclusion

Digital gamified tools have the potential to improve vaccine uptake by increasing knowledge and promoting positive attitudes, beliefs, behaviors, and vaccination intention. Further evaluations of these innovative digital tools, including head-to-head comparisons of different features and different platforms, will add more knowledge about what works and what does not in order to achieve public health goals more efficiently. In the wider context of health policy, digital gamified tools may be useful components of multifaceted strategies to improve vaccination rates throughout society.

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Acknowledgments

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Authors' Contributions

All authors provided substantial contributions to this paper's conception and edits and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[DOCX File , 20 KB - games_v12i1e47257_app1.docx]

Multimedia Appendix 2
PRISMA-ScR checklist.
[PDF File (Adobe PDF File), 498 KB - games_v12i1e47257_app2.pdf]

Multimedia Appendix 3
Characteristics of the studies included in the review.
[DOCX File , 25 KB - games_v12i1e47257_app3.docx]

Multimedia Appendix 4
Expanded version of Table 2 (general information about the studies) and Table 3 (tools from Google search and expert suggestions).
[DOCX File , 28 KB - games_v12i1e47257_app4.docx]

Multimedia Appendix 5
MMAT quality assessment. MMAT: Mixed Methods Appraisal Tool.
[XLSX File (Microsoft Excel File), 92 KB - games_v12i1e47257_app5.xlsx]

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Abbreviations

HPV: human papillomavirus
MMAT: Mixed Methods Appraisal Tool
PICO: Population, Intervention, Comparison, and Outcome
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

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Research Letter

Health Care Professional–Supported Co-Design of a Mime Therapy–Based Serious Game for Facial Rehabilitation

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Abstract

This research letter presents the co-design process for RG4Face, a mime therapy–based serious game that uses computer vision for human facial movement recognition and estimation to help health care professionals and patients in the facial rehabilitation process.

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KEYWORDS

serious game; serious games; facial recognition; face estimation; computer vision; facial rehabilitation; face; rehabilitation; physiotherapy; mime therapy; co-design; human face estimation; facial palsy; facial paralysis; motor rehabilitation; exergame; physiotherapists; psychologists; participation

Introduction

Facial paralysis is a consequence of damage or injury to the facial nerve, resulting in functional impairments. A challenge of rehabilitation through exercise repetition is maintaining patients' engagement and motivation in the intensive and repetitive execution of the exercises necessary for successful rehabilitation [1]. Repetitive and intensive movements are recommended for progress in treatment [2], and the variety of movements has significant effects on patient recovery [3].

In motor rehabilitation, exergames—serious games that require physical exercise to play—add fun to exercises and allow patients to forget about their condition and focus on the game [4]. Studies conducted with games for motor rehabilitation have achieved promising results [5] on patient motivation and engagement [4]. This study aimed to co-design *RG4Face*—an exergame for facial rehabilitation.

Methods

Ethical Considerations

This study was approved by the Research Ethics Committee of Universidade Federal do Delta do Parnaíba (5.632.311). The first author (DLS) provided explicit consent for use of his image in Multimedia Appendices 1 and 2.

Study Design

To develop *RG4Face*, a co-design procedure (Figure 1) was conducted with physiotherapists (n=16) and psychologists (n=5; Multimedia Appendix 3) to obtain the necessary knowledge on the game requirements.

In the first stage, a version of the game was developed with an initial idea (Multimedia Appendix 1). In the second, we recruited physiotherapists and psychologists to participate in co-design meetings (August to November 2022) and answer a questionnaire. We then presented the game to the participants and allowed them to make suggestions. The prototype was

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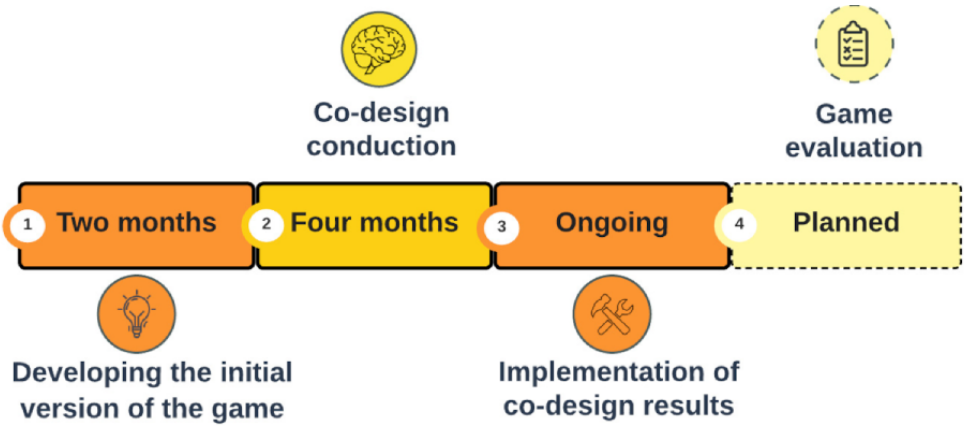
essential to encouraging participation during meetings. In total, 5 meetings were held—4 with physiotherapists and 1 with psychologists. The main activities of the meetings were brainstorming sessions, in which the generation of game requirements was encouraged for their incorporation into visual elements, gamification, and game mechanics. Meeting results allowed for the creation of a list of requirements. As a third stage, we are concluding the implementation of *RG4Face* based on the produced requirements. The game code was implemented in JavaScript to provide new features for facial rehabilitation via the Rehabilite Game platform [6].

Figure 1. Co-design timeline.



Results

Per its initial conception, *RG4Face* uses computer vision (via a camera) for capturing, recognizing, and estimating human facial movements. The game prototype was implemented via the MediaPipe face mesh [7] to enable the recognition and use of 1 movement (eg, raising eyebrows; ie, frontal muscle) to control game elements. The game involves a spaceship moving horizontally across the bottom of the captured video window and firing a projectile when face movement is detected. The main objective is to hit triangles that randomly appear on the player's face.

Table 1 presents participants' suggestions during co-design, game requirements, and rationales.

RG4Face is in the testing phase and, prior to evaluations, can recognize 6 movements used in mime therapy to improve facial muscle strength and mobility (Multimedia Appendix 2). To implement the recognition of these movements, MediaPipe was used [7]. The face mesh model allows for the real-time tracking of 468 3D landmarks on the human face that represent important facial features (eg, eyes, eyebrows, nose, and mouth). Distances between landmarks are calculated to recognize movements.

RG4Face provides a mirror therapy feature [8], which can mirror the healthy side of the face to create a visual illusion that can help reduce pain and improve function. *RG4Face* allows for parameter adjustment on the Rehabilite Game platform. Health care professionals can choose specific game mechanics for each rehabilitation case, thereby customizing the game according to patients' needs and difficulties.

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Table 1. Functional and nonfunctional game requirements from the co-design procedure.

Participants' suggestions	Refined requirement	Rationale
• Improve the game scenario • Improve the representation of the ship and projectiles • Choose attractive colors and contrasts	• Improve game colors and elements: border, ship, projectiles, and collision	• Enable the game to become more attractive and stimulating
• Include levels with difficulty levels	• Provide difficulty levels	• Gamification for each level, depending on the patient's condition
• Provide an option of mirror therapy for the game	• Implement a mirror therapy simulation	• Patients with Bell palsy can benefit from it
• Implement better game mechanics for rewards • Promote progression in the game	• Create a scoring and bonus system	• Increase patients' adherence to and engagement with treatment
• Movement sensitivity must be customized according to the patient's degree of disability	• Implementation of sensitivity levels for motion recognition	• The level of sensitivity respects the movement capacity of each patient
• Create metrics on the game platform to monitor the rehabilitation process	• Provide in-game metrics	• They are interesting for the health care professional to follow the patient's progress
• To avoid causing botheration to some types of patients, the sound should be optional	• Allow game sound to be optional (ie, turn off the sound)	• The sound may be unnecessary for some patients
• Consider visual acuity of the players • The game scenario should be full screen	• Make game screen full, automatically adjusting to the aspect ratio	• Game elements should be clearly visible
• Head movement should not influence the game • Calibration is essential to avoid false positives and false negatives of movements	• Perform a prior calibration of the player's face	• Adjustment of the distance between player's face and screen, in addition to improving movement recognition

Discussion

We co-designed a serious game for facial rehabilitation that represents a potential new approach to improving patients' adherence to facial rehabilitation. The co-design procedure allowed stakeholders to participate in defining game requirements, thereby empowering the tool to meet the needs and expectations of patients and be more engaging and motivating.

Although there are studies that focus on games for rehabilitating specific parts of the face (eg, eyes [9] and mouth [10]), to our knowledge, no serious game for facial rehabilitation has been proposed that can recognize the face movements used in mime therapy. This study proposes the first such exergame.

Our results demonstrate that the co-design approach was effective for creating a serious game with the potential to meet patients' needs. We plan to evaluate the game with health care professionals, healthy participants, and patients with facial paralysis.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Video presentation with the game prototype before the co-design procedure.
[MP4 File (MP4 Video), 7354 KB - games_v12i1e52661_app1.mp4]

Multimedia Appendix 2

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Video presentation with the game after implementing requirements from the co-design procedure.
[MP4 File (MP4 Video), 55743 KB - games_v12i1e52661_app2.mp4]

Multimedia Appendix 3
Demographic characteristics of participants.
[DOCX File , 15 KB - games_v12i1e52661_app3.docx]

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