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Contents

Original Papers

User Experience of a Semi-Immersive Musical Serious Game to Stimulate Cognitive Functions in Hospitalized Older Patients: Questionnaire Study

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Abstract

Background: Reminiscence therapy through music is a psychosocial intervention with benefits for older patients with neurocognitive disorders. Therapies using virtual or augmented reality are efficient in ecologically assessing, and eventually training, episodic memory in older populations. We designed a semi-immersive musical game called "A Life in Songs," which invites patients to immerse themselves in a past era through visuals and songs from that time period. The game aspires to become a playful, easy-to-use, and complete tool for the assessment, rehabilitation, and prevention of neurocognitive decline associated with aging.

Objective: This study aimed to assess the user experience (UX) associated with the newly designed serious game.

Methods: After one or several sessions of the game guided by the therapist, patients of the geriatric wards were asked to answer questions selected from 2 widely known UX scales (AttrakDiff and meCUE [modular evaluation of the components of user experience]) with the therapist's help. The internal consistency of the UX dimensions was assessed through Cronbach α to verify the validity of the dimensions. The level of engagement of the patient throughout the experimental session was also assessed following an internally developed scale, which included 5 levels (interactive, constructive, active, passive, and disengaged behaviors). UX mean scores were computed and presented graphically. Verbal feedbacks were reported to support the quantitative results.

Results: Overall, 60 inpatients with a mean age of 84.2 (SD 5.5) years, the majority of whom were women (41/60, 68%), were included. Their score on the Mini-Mental State Examination (MMSE) ranged between 12 and 29. A majority of patients (27/56, 48%) had no major neurocognitive disorder (MNCD), 22/56 (39%) had mild MNCD, and 7/56 (13%) had moderate MNCD. The results revealed very positive UX with mean values beyond the neutral values for every UX dimension of both scales. The overall mean (SD) judgment was rated 3.92 (SD 0.87) (on a scale of −5 to 5). Internal consistency was acceptable to good for the emotional dimensions of the meCUE. Questionable to unacceptable consistency was found for the other UX dimensions. Participants were mostly active (23/60, 38%) and constructive (21/60, 35%).

Conclusions: These findings demonstrated a very good appreciation of the game by geriatric inpatients. Participants' and health care professionals' verbal comments strongly aligned with the quantitative results. The poor internal consistency in the UX dimensions reflected the high heterogeneity among the included patients. Further studies are needed to evaluate the potential benefits of clinical factors such as neurocognitive functions, mood, depression, or quality of life.

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KEYWORDS

virtual reality; geriatrics; reminiscence; episodic memory; serious game; neurocognitive disorders; older adults; user experience

Introduction

Physical frailty and cognitive impairment are common age-related alterations. While the prevalence of cognitive frailty in the community-dwelling older population is low (<5%), it considerably increases in clinical settings [1] and will also increase due to the current demographic transition [2]. Among cognitive impairments, memory loss is one of the earliest signs before the onset of major neurocognitive disorder (MNCD) (ie, dementia) [3]. MNCD, as described by the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (*DSM-5*) [4], refers to a significant decline in cognitive functioning, affecting one or more cognitive domains such as attention, memory, and language. The deficits interfere with the person's ability to live independently, requiring assistance in daily activities.

Episodic (or autobiographical) memory is defined as the memory of personal life knowledge and personally experienced events [5]. It has a primordial role in personal identity, maintaining the feeling of time continuity [6]. In addition to the mental images that punctuate one's life, emotion is the privileged mediator of episodic memory. This form of memory is particularly vulnerable to age-linked changes, and its alteration is seen as a hallmark of early mild cognitive impairment and Alzheimer disease [7].

Aside from pharmacological interventions, psychosocial interventions have been developed and adopted with the objective of maintaining or improving the functions, relationships, and well-being of people with cognitive impairments [8]. Among these psychosocial interventions, reminiscence therapy is seen as a credible and efficient intervention. It consists of discussing past events or experiences with the patient, classically with the help of tangible prompts such as pictures, familiar items, music, or sounds [9]. It has been demonstrated in a recent meta-analysis that reminiscence therapy has positive effects on the quality of life, cognition, communication, and mood of people living with MNCD [10].

Virtual reality (VR) and, more recently, augmented reality (AR) (superimposition of VR elements onto the real-world environment) have become popular in the medical field [11]. They were found efficient not only in surgery education and training, but also in pain management, in motor and cognitive rehabilitation after stroke, and in mental health conditions such as anxiety and depression [11]. The advantage of using such supports is to stimulate both cognitive and motor functions [12]. The use of VR and AR has also been investigated in older populations to ecologically assess, and eventually train, episodic memory [7,13], thanks to the high level of immersion. The findings were in favor of positive effects on well-being as well as cognitive function improvements [14,15]. Depending on the immersion level, the technology can be categorized as immersive, semi-immersive, or nonimmersive; semi-immersive being certainly the most appropriate for older patients with cognitive impairments [14]. Nonimmersive VR was found to positively influence the rehabilitation of the most common geriatric syndromes [15].

In this context, a semi-immersive musical game called "A Life in Songs" ("*Une vie en Chanson*") has been designed. It immerses the user in a past decade (from 1950 to 2020), thanks to remarkable songs and events of this decade and thanks to a visual of a decade-related period living room (Figure 1). The game stimulates autobiographical memory without interpretative purpose, in a playful way while allowing to mentally relive autobiographical and semantic events of the user's life. "A Life in Songs" aspires to become a stand-alone tool for the assessment, rehabilitation, and prevention of neurocognitive decline associated with aging, thus promoting autonomy.

The design of the game required vigilance, in particular regarding ease of use, ergonomics, aesthetics, reliability, and adaptability. A good user experience (UX) is crucial for the success of any digital product. UX has recently emerged in the field of human-computer interaction as an extension of the concept of usability. It helps to consider the whole factors beyond the usefulness of a product, thus considering not only the pragmatic qualities but also the hedonic qualities, the emotions, and the intention to use [16]. This approach has been considered to include humans, their context, and their needs in the creative process. Before conducting a full-scale trial to assess the game's effectiveness, it is essential to first evaluate its UX.

This study thus aimed to evaluate the UX of the game among a geriatric hospitalized population. A secondary objective was to compare the UX between patients with and without MNCD. We hypothesized that overall UX would be found favorable (above the mean neutral value of the UX scales) and that UX would be similar for both groups of patients.

Figure 1. Overview of the game. (A) Virtual living room appearance of the decade 1960 - 1970. (B) The virtual reality (VR) device on the floor and the patient wearing VR glasses. (C) Examples of remarkable French singers and events of the decade 1960 - 1970. (D) Opened dialogue between the patient and the therapist.

Methods

Study Design

This study was a unicentric nonrandomized cross-sectional UX study using a "task-based experiment" method [17]. It was conducted in the Geriatric Department of Angers University Hospital, supported by the investigative team of its living lab [18], between October 2022 and May 2023.

Ethical Considerations

The protocol was approved by the ethical committee of Angers University Hospital (2022 - 024 and 2023 - 038), and it was declared to the National Commission for Information Technology and Civil Liberties (ar21-0159v0). Oral nonopposition to participation was obtained in accordance with French legal requirements for category 3 clinical research [19]. All data were deidentified. No compensation was provided to participants, as the study was integrated into their care program. Consent for publication was obtained from identifiable individuals featured in Figure 1 .

Description of the Serious Game

"A Life in Songs" ("*Une vie en Chanson*") is a musical game created in 2017 by LS, the first author of this paper and an art therapist, within the university hospital. The game was initially built on Microsoft PowerPoint support, based on the Goose Game principle where each square represented a year, starting from 1950 until 2020. A remarkable French song and French or international event were associated to each year (square), for instance, *La Javanaise* from Serge Gainsbourg and the assassination of John F Kennedy in 1963. In order to be more attractive and exploitable by other therapists, the game has been redesigned and incorporated into a plug-and-play semi-immersive VR solution (CADWall, Imagin-VR) in 2021. This solution consists of the 3D projection of a virtual living room on a screen wall (Figure 1B). The users wear VR glasses to explore the environment by moving their heads. The game is divided into 7 sections, corresponding to 7 decades (from 1950 to 2020). For each decade, the appearance of the virtual living room changes (decoration and objects according to the period) (Figure 1A). The therapist plays 5 songs from this decade and asks the participant to remember the singer's name. The 5 corresponding singer faces appear on the virtual wall for help. A total of 5 pictures related to 5 remarkable events of the decade appear on the wall as well (Figure 1C). The game is completely customizable to meet the needs of the patient, therapist, or caregiver. In summary, "A Life in Songs" in VR was designed to immerse patients in the past in an innovative, playful, and pleasant way, aiming to open the dialogue and stimulate episodic memory (Figure 1D). Immersion in the virtual environment promotes natural and instinctive interactions in real time via sensorimotor interfaces. This innovation was also thought to provide health care professionals with an interactive, collaborative, and turnkey tool tailored to their patients and offer the possibility to create their own training protocols. One advantage of the CADWall solution is that it is easily

transportable and simple to set up, thus usable in several units of the institution. At the time of the study, the game was not registered with the agency for the protection of programs. It is co-owned by Angers University Hospital and Imagin-VR.

Recruitment

Patients hospitalized in a geriatric care unit were informed about the study by the medical doctor if they were aged 75 years or older and if they were able to respond to a questionnaire (UX assessment). Interested patients were then approached by the art therapist to give oral and written detailed information about the study and the protocol. Patients under legal protection, as well as non-francophone patients, were not included.

Protocol

The patients were taken to a specific art therapy room within the geriatric unit by nursing assistants. The patient was allowed to participate on his or her own or accompanied by a relative or with other patients. The material and the game were presented, and the patient was given VR glasses. The investigator (the art therapist) stayed visible to the patient while wearing the glasses. After a few minutes of getting used to the device, the patient was asked to choose a decade to start the game. The investigator launched the corresponding decade: the appropriate living room 3D visual appeared on the virtual wall. A total of 5 songs (from 5 different years of the decade) were played and the patient was asked if he or she knew the singer after each of them. Additionally, after each song, a picture of a remarkable national or international event that happened during the same year appeared on the wall and the patient was asked to talk about this event if he or she remembered it. The investigator facilitated the session in order to guide the patients as much as possible and let them talk about their evoked memories. On the patient's willing basis, the session could be prolonged by playing with another decade or two.

At the end of the game session, the patient was asked to answer several questions about his or her UX. Finally, the investigator rated the engagement of the patient. Throughout the entire experimental session, the investigator manually recorded verbal feedback. At a later time, health care professionals' opinions were collected through brief, unrecorded interviews.

UX Assessment

UX was assessed through 2 self-administered (with the therapist's assistance if needed) questionnaires inspired from 2 standardized and well-known questionnaires: the AttrakDiff [20] and the modular evaluation of the components of user experience (meCUE) [21] in their French versions [22,23]. The AttrakDiff is composed of 28 items assessing 4 UX dimensions: pragmatic quality (PQ), hedonic quality identification (HQI), hedonic quality stimulation (HQS), and attractiveness (ATT). Each item is presented as a Likert scale semantic differential that represents opposites (eg, "simple-complicated"). The rates range between −3 and 3. To avoid the tendency of acquiescence, the valence of the items was mixed: words on the left of the Likert scale were sometimes positive, sometimes negative [22]. The meCUE is composed of 30 items, structured in 4 modules (product perceptions, emotions, consequences, and global assessment). Each item is presented as a sentence to which the user agrees or disagrees on a Likert scale (from 1 "strongly disagree" to 7 "strongly agree," except for the item of global assessment which is from −5 "bad" to 5 "good"). The items of the meCUE are categorized into 10 components (usefulness, usability, visual aesthetics, status, commitment, positive and negative emotions, product loyalty, intention to use, and overall evaluation) [24].

Some items have been removed from the standardized questionnaires due to the expected difficulties of understanding the patients with neurocognitive disorders. In total, 12 items were kept from the AttrakDiff (3 of each dimension), and 17 were kept from the meCUE (6 in the module "product perception," 8 in the module "emotions," 2 in the module "consequences," and 1 item of "global assessment").

Engagement Behavior

The level of engagement during the whole game session was rated by the experimenter using an internally designed scale called "ICAPD" (interactive, constructive, active, passive, and disengaged), which was inspired from the ICAP (interactive, constructive, active, and passive) hypothesis proposed by Chi et al [25,26]. The ICAPD scale differentiated five engagement behaviors as follows: (1) interactive—the patient discussed, questioned, and debated with the experimenter; (2) constructive—the patient asked questions, constructed his answers, justified them, and offered ideas to the experimenter; (3) active—the patient followed the experimental procedure and answered to the questions; (4) passive—the patient participated summarily in the experimental procedure and answered summarily to the experimenter's questions; (5) disengaged—the patient did not follow the experimental procedure. The scale is provided in Multimedia Appendix 1. The investigator attributed the level of engagement according to the patient's dominant behavior during the whole game session.

Data Collection

The age and sex of the participants, the 29 UX scores, and the engagement levels were collected. The level of neurocognitive disorders assessed through the Mini-Mental State Examination (MMSE) [27] was collected from the computer-based patient record. The MMSE provided a brief screening test that quantitatively assessed the severity of the cognitive disorder. The cutoff value of ≤26 out of 30 was used to dichotomize the cohort into 2 groups: without MNCD (MMSE≥26) and with MNCD (MMSE<26) [28], for the purpose of the secondary objective of this study.

Data Analysis

The scoring for the items of the AttrakDiff was adapted in order to report negative values for negative valence and positive values for positive valence. In addition, the scoring for the items of the meCUE relative to negative emotions were inverted so that a higher score in this dimension corresponded to fewer negative emotions, and thus better UX. Quantitative variables were presented as mean (SD) or median (IQR), according to the data distribution. Qualitative data were described in terms of numbers and percentages. The UX scores were presented graphically as means and SDs as recommended in a previous study [16].

Comparison of the UX scores between the patients with and without MNCD was performed through Wilcoxon unpaired tests given the low number of participants in each group. Patients with missing MMSE scores were excluded from this analysis. The distribution of each engagement behavior was reported. All descriptive statistics and graphical representations were performed using R (v4.1.1) and the RStudio interface (v1.4) [29]. The internal consistency of the UX dimensions was assessed through Cronbach α when possible (number of items >2 per dimension). Internal consistency was interpreted as excellent if $\alpha \geq 0.9$, good if $0.8 \leq \alpha < 0.9$, acceptable if $0.7 \leq \alpha < 0.8$, questionable if $0.6 \leq \alpha < 0.7$, poor if $0.5 \leq \alpha < 0.6$, and unacceptable if $\alpha < 0.5$ [30]. The artwork was created in Inkscape.

The analyses and reporting of the results followed the CONSORT-eHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) guidelines [31].

Results

UX results are presented in Figures 2 and 3. The scores to the AttrakDiff items were all positive (Figure 2) with a mean score of 1.81 (SD 0.2) across all items. The mean (SD) scores obtained for each dimension were as follows: 1.99 (1.01) for ATT, 1.76 (1.04) for HQI, 1.78 (1.19) for HQS, and 1.68 (1.04) for PQ. The scores to modules I, II, and III of the meCUE were also above the neutral value of 4, with a mean score of 5.58 (SD 0.44) across all items of these modules (Figure 3). The lower bounds of the error bars (SDs) for 3 of the 16 meCUE items extended beyond the neutral value 4. Global assessment (module IV) was rated 3.92 (0.87). The details of the scores for each item and each dimension are available in Multimedia Appendix 2.

A total of 60 patients, 41 women and 19 men, with a mean age of 84.5 (SD 5.5) years were included in the study between October 2022 and May 2023. Out of these 60 patients, 4 patients did not have an MMSE score recorded in their computer-based records. Among the 56 patients with available MMSE scores, the mean score was 24.4 (SD 3.9), with a minimum of 12 and a maximum of 29. Using the cutoff value of 26/30, 27 out of 56 (48%) were categorized without MNCD and 29 out of 56 (52%) with MNCD. The main reasons for hospitalization were repeated falls, fractures, memory loss, associated anxiety-depressive disorders, poststroke rehabilitation, Parkinson disease, neurological pathologies, and chronic pain.

Figures 4 and 5 provide the UX results for the groups of patients with and without MNCD. Among all UX items, no statistical difference was observed between the groups of patients with and without MNCD, with the exception of one item (1/29), the meCUE module I—"The product would enhance my standing among peers" (P=.04).

Figure 2. Mean (SD) scores to the AttrakDiff items. ATT: attractiveness; HQI: hedonic quality identification; HQS: hedonic quality stimulation; PQ: pragmatic quality.

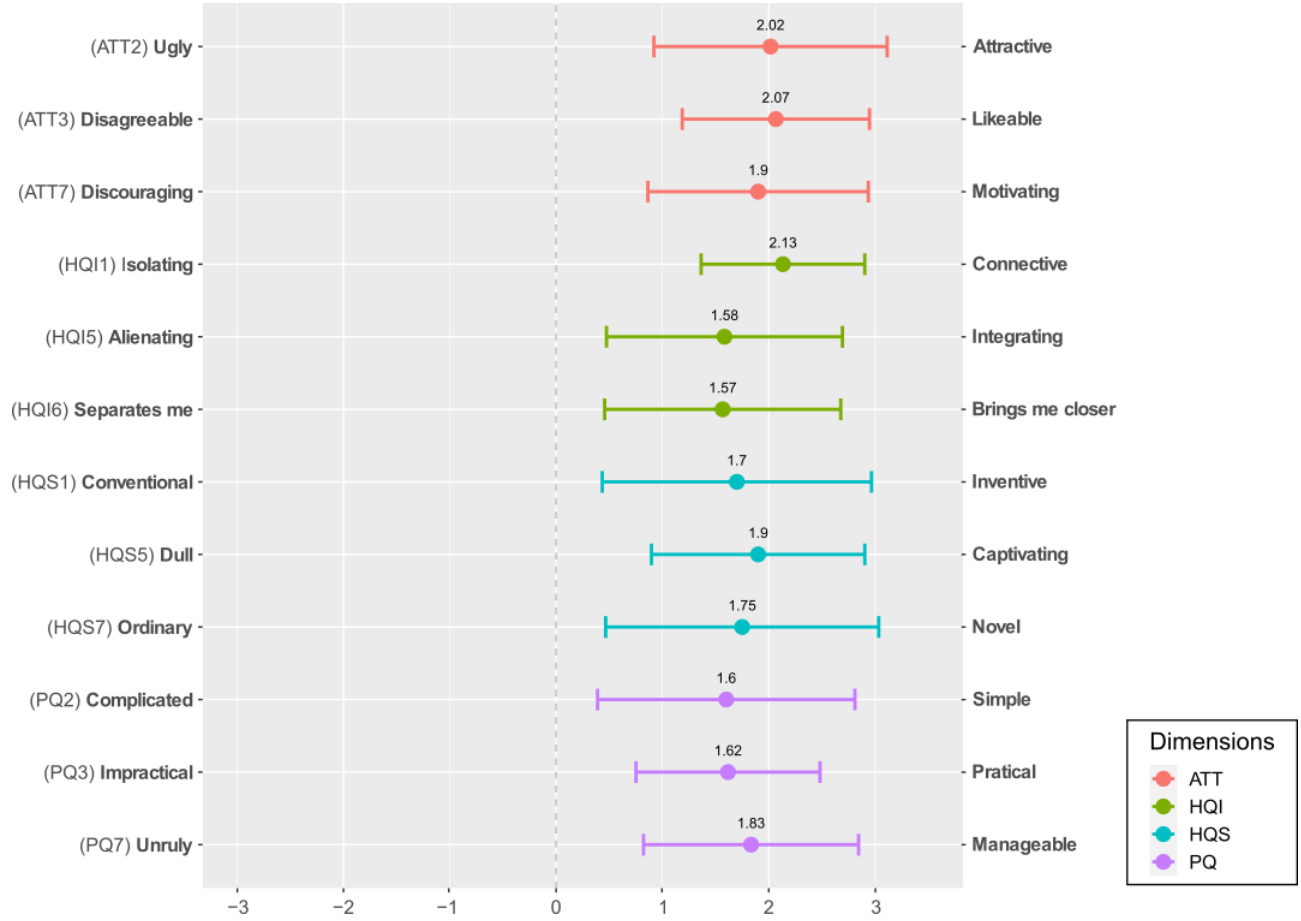

Figure 3. Mean (and SD) scores to the meCUE (modular evaluation of the components of user experience) items: (I) module I: product perceptions; (II) module II: emotions; (III) module III: consequences; (IV) module IV: global assessment.

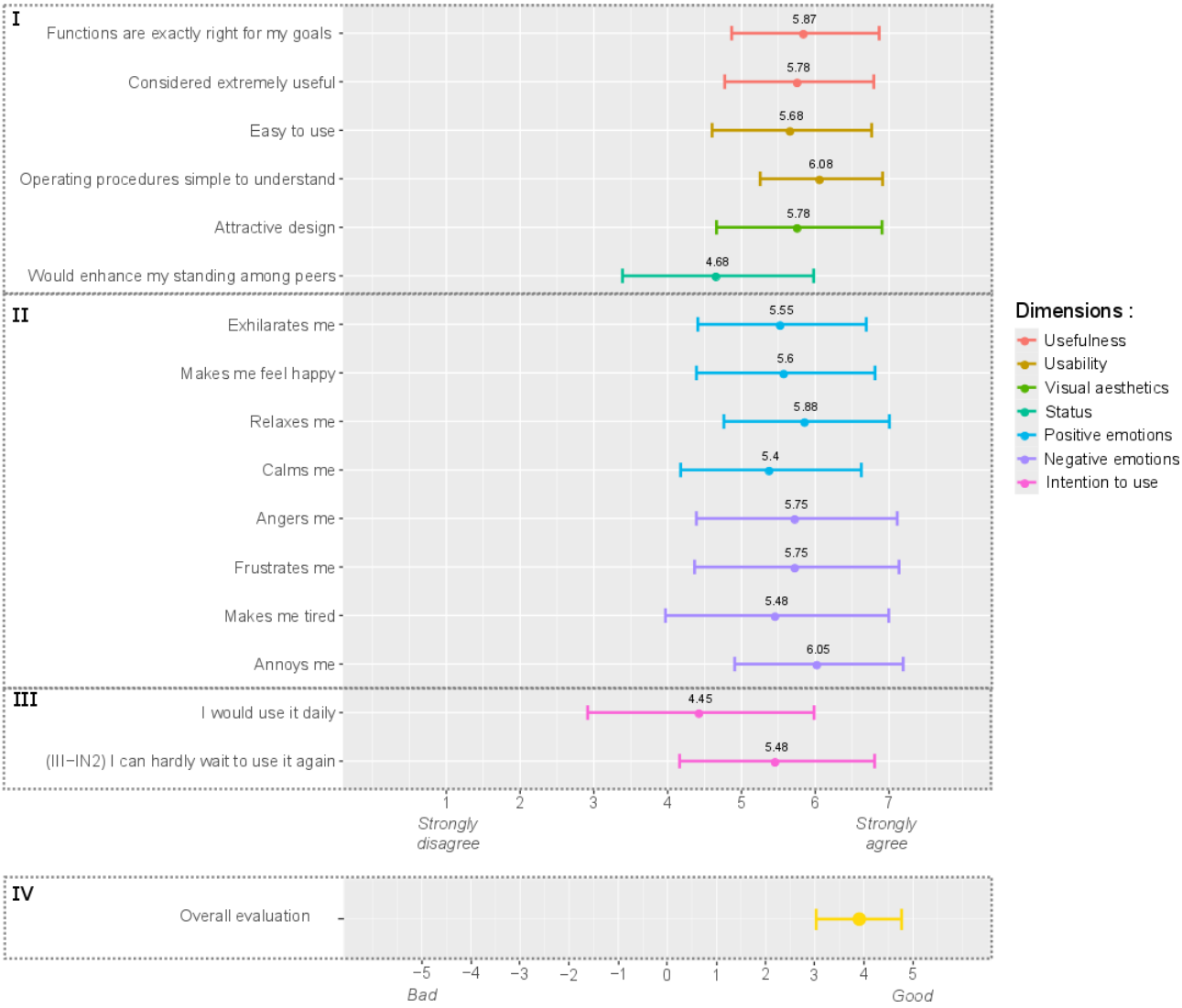

Figure 4. Mean (SD) scores to the AttrakDiff items for the 2 groups of patients with and without major neurocognitive disorder (MNCD). ATT: attractiveness; HQI: hedonic quality identification; HQS: hedonic quality stimulation; PQ:pragmatic quality.

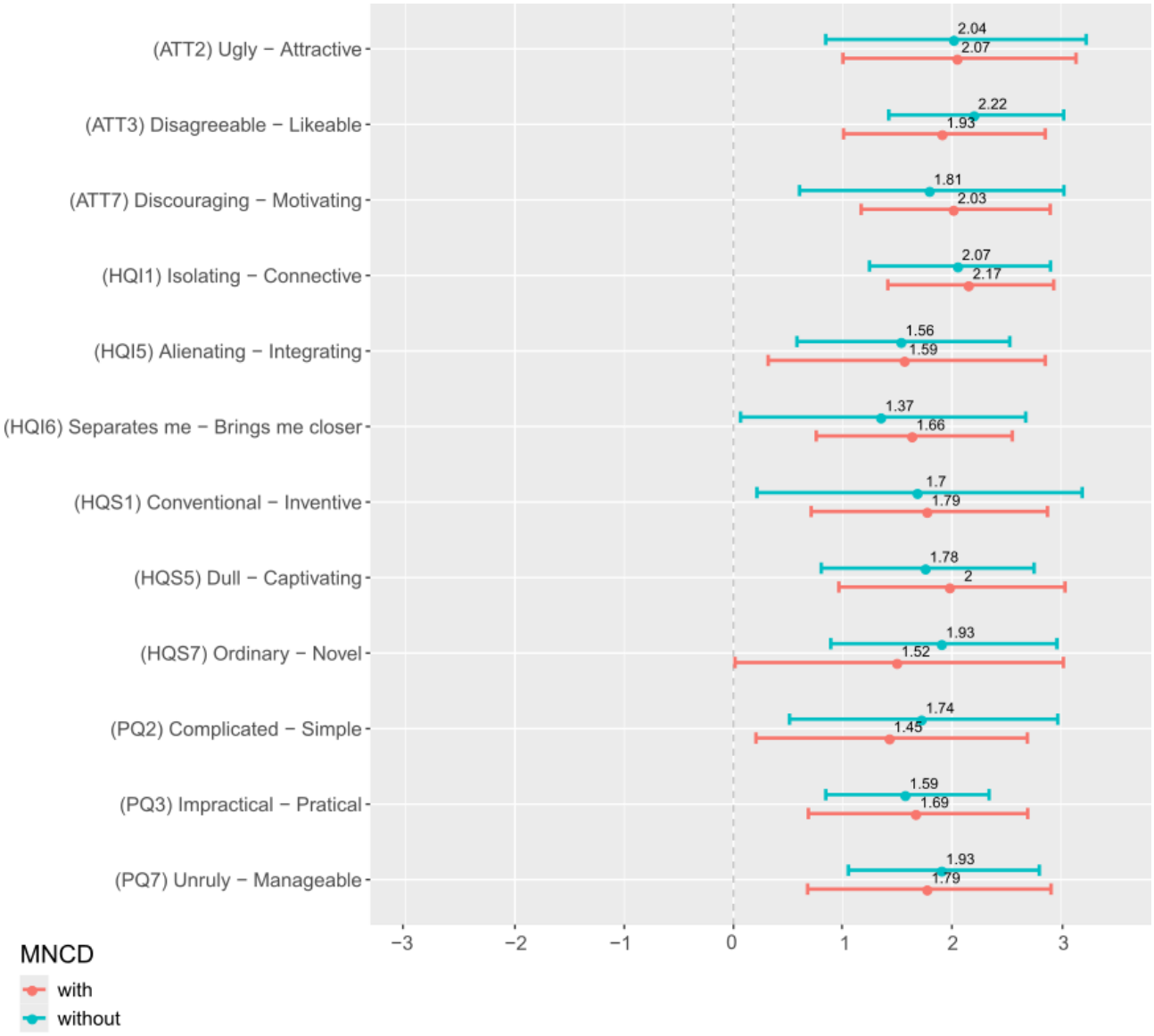

Figure 5. Mean (SD) scores to the meCUE (modular evaluation of the components of user experience) items for the 2 groups of patients with and without major neurocognitive disorder (MNCD). * stands for statistical difference (*P*=.04) between the groups, tested through Wilcoxon unpaired test.

Regarding the levels of engagement, 10 (17%) out of 60 participants were passive, 23 (38%) were active, 21 (35%) were constructive, and 6 (10%) were interactive. None of the participants was rated as disengaged.

Internal consistencies of the UX dimensions assessed are presented in Table 1.

Emotions and perceptions modules showed good and acceptable internal consistency, respectively. ATT, PQ, and consequences modules showed questionable to poor consistency. HQI and HQS showed unacceptable consistency.

Table . Internal consistency of the assessed user experience dimensions.

		Cronbach α (95% CI)
AttrakDiff		
	Pragmatic quality	0.579 (0.256 - 0.738)
	Hedonic quality identification	0.411 (0.097 - 0.612)
	Hedonic quality stimulation	0.422 (0.011 - 0.664)
	Attractiveness	0.608 (0.397 - 0.752)
meCUE[a]		
	Module I: Perceptions	0.701 (0.541 - 0.804)
	Module II: Emotions	0.844 (0.754 - 0.899)
	Module III: Consequences	0.655 (0.471 - 0.779)

[a]meCUE: modular evaluation of the components of user experience.

Discussion

Principal Findings

This study aimed to assess the UX of geriatric inpatients regarding a semi-immersive musical game designed to stimulate cognitive functions. The findings showed that the game was largely evaluated positively by the targeted population. The patients were mostly actively engaged in the experimentation showing great interest in the game. Patients with and without MNCD appreciated the game similarly.

Comparison to Prior Work

The instrumental (pragmatic) qualities of the game were well perceived. The patients considered the system useful and usable (meCUE, module I) and simple, practical, and manageable (AttrakDiff, PQ). These results were beyond what could have been expected assuming that the use of VR could be limited due to factors associated with old age [9]. None of the participants complained about discomfort wearing the glasses, nor criticized some aspects of the game such as fluidity, realism, vision difficulties, or cybersickness. In fact, cybersickness and presence were not quantitatively assessed like in studies testing VR in older adults [9,13,32], considering that the game was semi-immersive and the patient saw the therapist guiding the whole session.

It could have been argued that the diversity of support (music, living room visuals, objects, and events) could bring confusion to the patients, especially those with neurocognitive impairment, but this study showed the contrary. Patients acknowledged the variety (“I liked the diversity” [patient 23]). Although most participants indicated they would not play the game daily (meCUE item close to the neutral value), their overall intention to use it was largely positive. The strength of the game was to propose multiple angles of attack to ensure immersion and eventually trigger reminiscence, unlike any other traditional test and therapy [6].

Noninstrumental qualities were also appreciated with good rates on visual aesthetics especially ”meCUE, module I”. While both hedonic qualities were highly recognized, HQIs were particularly highlighted. Notably the connective aspect of the game (AttrakDiff item “HQI1: isolating-connective”) received the highest score. Based on Lallemand et al’s guidelines [16], scores higher than 2 on the AttrakDiff scale can be considered particularly interesting for the product. This was again not expected at this level. This finding demonstrated the success of the game regarding its potential to open the dialogue between the patient and the therapist. A participant commented that the game “is full of life, brings back memories, is cheerful, brings comfort, relaxation and conviviality” [patient 40]. The “status” dimension (item “the product would enhance my standing among peers”) of the meCUE was very close to the neutral value (with the SD extending beyond) and was one of the lowest scores attributed to the game. This could reflect the item being too complex or unsuitable for the population and the product in question.

As reflected by some patients’ comments—“it moved me” [patient 53] or “it pleased me and did me good” [patient 56], and the scores to the “meCUE, module II”, emotions were also highly positive. The current version of the components of the UX model by Thüring and Mahlke [33] claims that emotions, in addition to perceived product qualities, determine the overall judgment of a product, thus the consequences of use [24]. Our results showed that the overall evaluation (meCUE, module IV) and ATT were closely aligned with the emotions appreciation achieving high scores, and 100% of the participants rated the game positively (minimum rate=2 on a scale of −5 to 5).

From an interviewed psychologist’s point of view, one advantage of the game is to promote the patient’s persistent cognitive capacities without putting him or her in a difficult position. This aspect was also evidenced by patients’ comments (“it makes me realize that I still have memory capacities” [patients 28 and 33]. Game sessions were thus seen as moments of pleasure. This was supported by the results of the AttrakDiff in the ATT dimension, notably with the items “ATT3: disagreeable-likeable” and “ATT7: discouraging-motivating.”

The game was natively designed to suit every patient in geriatric wards. For the purpose of this study, only those capable of answering the UX questionnaires were included. It is worth mentioning that they were all able to play at least with 2 decades of the game, and they perceived it very positively. Their overall judgment (meCUE, module IV) was rated between 3 and 5 (on a scale of −5 to 5). The objective of the game session was not

to test the patients' memory by asking them to name songs or singers but rather to evoke memories and stimulate conversation. This was particularly true for patients with severe neurocognitive impairments (MMSE≤18) [34]. A comparison between patients with lower and higher levels of neurocognitive impairment revealed similar game perceptions. This finding aligns with a larger-scale study involving 313 patients with varying degrees of MNCD, which were enrolled in "task-based experiment"-type UX studies. The conclusions indicated that although engagement may be less active and participation rates lower, patients with severe MNCD were still able to complete the experiments as long as the sessions were properly guided [35].

Strength and Limitations

Study limitations must be acknowledged. First, nonstandardized sets of UX items were used. The AttrakDiff and meCUE were not used in their complete versions to avoid difficulties with patients presenting neurocognitive disorders. This is why an analysis of internal consistency through Cronbach α tests was carried out. This analysis showed that some dimensions were not consistent (HQI and HQS notably). This is not likely to be attributed to the insufficient number of participants, since the number of participants was higher than usually found in the literature (between 5 and 57 participants) [14]. The absence of using complete questionnaires likely limited the ability to accurately measure certain nuances of the UX and prevented an analysis by dimensions, leading instead to an item-level analysis. Additionally, the ICAPD scale was an innovative method designed to assess engagement. However, since its validity and reliability have not yet been confirmed, this could also be a potential drawback. The ICAPD provided a preliminary estimate of engagement levels, but further validation is needed. In total, the results obtained with the UX and engagement scale may not be comparable with those of other studies using validated methods.

Second, the heterogeneity of the cohort regarding their level of neurocognitive functions should be acknowledged and may have contributed to the low internal consistency of the questionnaires. Detailed results for each item are thus provided in Multimedia Appendix 2, to provide a better insight into the heterogeneity of the results. Third, this study reported verbatim comments heard during the experimental sessions but no proper qualitative study, such as semidirective interviews, was conducted. The investigator did his best to accurately transcribe the verbal comments in order to enrich the present quantitative data. Fourth, cybersickness was not assessed via structured validated scores such as the "virtual reality sickness questionnaire" [36] as recently suggested by Bruno et al [32] for all VR or AR studies. However, it was assessed through spontaneous questions to the participant, and no symptom related to cybersickness was reported.

Future Directions

Further studies are now needed to assess the impact of the game on clinical aspects. Music therapy or music-based interventions have shown some benefit in people with MNCD [37]. Small short-term benefits on cognitive functions associated with reminiscence therapy were found in a recent Cochrane meta-analysis [10]. The changes in cognitive performance, notably in memory capacity, should thus be assessed when using "A Life in Songs." It is also possible that not only cognitive function but also quality of life and communication, as well as mood, functioning in daily activities, agitation, and relationship quality, may be improved with the serious musical game [10]. This should not be limited to older populations.

Conclusions

Because feedback from users is essential in the process of developing new tools, the UX of geriatric inpatients was evaluated regarding the semi-immersive musical game that is aimed to be used for the assessment, rehabilitation, and prevention of neurocognitive disorders in older adults. The 60 patients who tested the musical game in VR reported highly positive UX. Instrumental and noninstrumental qualities as well as emotions were positively perceived, leading to excellent scores of attractiveness and global assessment. Further studies are needed to examine long-term benefits on cognitive functions, mood, and quality of life.

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Data Availability

The datasets generated during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization was performed by LS and FN. Methodology was carried out by FN. Investigation was conducted by LS. Formal analysis was performed by LC. Data curation was handled by LS and LC. Visualization was conducted by LC. Writing—original draft preparation was done by LC. Writing—review and editing was done by LS, LC, FN, SN, HVL, and CA. Funding acquisition was managed by FN, LS, and CA. Resources were handled by FN, SN, HVL, and CA. Project administration was performed by LS, HVL, SN, and FN. Supervision was performed by CA.

Conflicts of Interest

The first author, LS, was the inventor of the game but has no direct financial interest related to the publication of this study. The developers of the virtual reality solution (Imagin-VR) were not involved in the data collection, analysis, or writing of this paper.

Multimedia Appendix 1
The internally developed ICAPD (interactive, constructive, active, passive, and disengaged) scale.
[DOCX File, 21 KB - games_v13i1e57030_app1.docx]

Multimedia Appendix 2
Detail of the scores obtained for each item of the AttrakDiff and the meCUE (modular evaluation of the components of user experience).
[XLSX File, 18 KB - games_v13i1e57030_app2.xlsx]

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Abbreviations

AR: augmented reality
ATT: attractiveness
CONSORT-eHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth
HQI: hedonic quality identification
HQS: hedonic quality stimulation

ICAP: interactive, constructive, active, and passive
ICAPD: interactive, constructive, active, passive, and disengaged
meCUE: modular evaluation of the components of user experience
MMSE: Mini-Mental State Examination
MNCD: major neurocognitive disorder
PQ: pragmatic quality
UX: user experience
VR: virtual reality

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Original Paper

Effectiveness of a Virtual Reality Serious Video Game (The Secret Trail of Moon) for Emotional Regulation in Children With Attention-Deficit/Hyperactivity Disorder: Randomized Clinical Trial

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Abstract

Background: Difficulties in emotional regulation are often observed in children and adolescents with attention-deficit/hyperactivity disorder (ADHD). Innovative complementary treatments, such as video games and virtual reality, have become increasingly appealing to patients. *The Secret Trail of Moon* (MOON) is a serious video game developed by a multidisciplinary team featuring cognitive training exercises. In this second randomized clinical trial, we evaluated the impact of a 20-session treatment with MOON on emotional regulation, as measured by the Strengths and Difficulties Questionnaire.

Objective: We hypothesize that patients with ADHD using MOON will show improvements in (1) emotional regulation, (2) core ADHD symptoms, (3) cognitive functioning, and (4) academic performance, compared to a control group; additionally, we anticipate that (5) changing the platform (from face-to-face using virtual reality to the web) will not affect emotional regulation scores; and (6) the video game will not cause any clinically significant side effects.

Methods: This was a prospective, unicentric, randomized, unblinded, pre- and postintervention study with block-randomized sequence masking. Participants included individuals aged between 7 and 18 years who had a clinical diagnosis of ADHD and were receiving pharmacological treatment. They were randomized into 2 groups using an electronic case report form: the MOON group, receiving standard pharmacological treatment plus personalized cognitive training via a serious video game, and the control group, receiving standard pharmacological treatment. We provided both the groups with psychoeducational support on ADHD. Analysis was conducted using the Student 2-tailed *t* test and 2-factor ANOVA. An independent monitor supervised the study.

Results: A total of 76 patients with ADHD participated in the trial, with an equal randomization (MOON: n=38, 50% and control: n=38, 50%) and a total dropout rate of 7. The primary hypothesis, a 3- or 4-point reduction in the global Strengths and Difficulties Questionnaire score, was not met. However, significant improvements were observed in material organization (*P*=.03), working memory (*P*=.04), and inhibition (*P*=.05), particularly among patients more engaged with the MOON treatment.

Conclusions: Serious video games, when integrated into a multimodal treatment plan, can enhance outcomes for symptoms associated with ADHD.

Trial Registration: ClinicalTrials.gov NCT06006871; https://clinicaltrials.gov/study/NCT06006871

International Registered Report Identifier (IRRID): RR2-10.2196/53191

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KEYWORDS

attention-deficit/hyperactivity disorder; ADHD; emotional regulation; serious video games; virtual reality; cognitive training; music; chess

Introduction

Attention-deficit/hyperactivity disorder (ADHD) is characterized by a persistent pattern of inattention, hyperactivity, and impulsivity, affecting approximately 5% of children and adolescents worldwide [1,2]. These symptoms significantly impair daily functioning across social, academic, cognitive, behavioral, and family domains. In addition to the core symptoms, emotional problems and poor self-regulation are increasingly seen as central features of ADHD [3-5]. Emotional regulation allows modifying the emotional state by promoting adaptive behaviors to achieve a goal [6]. Children and adolescents with ADHD often struggle with emotional regulation, exhibiting low frustration tolerance, irritability, and emotional lability. A recent meta-analysis highlighted difficulties associated with ADHD in emotional lability (*d*=0.95), emotional regulation (*d*=0.80), empathy (*d*=0.68), and emotion recognition or understanding (*d*=0.64), with differences associated with gender, age, and the existence of executive dysfunction or behavioral problems [7]. Internalizing and externalizing problems are common among individuals with ADHD [8]. In fact, comorbidity is highly prevalent in ADHD with internalizing disorders such as anxiety or depression as well as externalizing disorders such as conduct disorder and oppositional defiant disorder [9]. The camouflaging of symptoms [10] often leads to underdiagnosis and treatment delays, resulting in misdiagnosis, higher rates of accidents, use of public services, increased likelihood of substance use, delinquency, and even suicide attempts [11-13].

Multimodal treatment for ADHD includes pharmacological treatment, psychological treatment, and psychoeducation for parents and teachers. While multimodal treatment is the most effective for ADHD, it can sometimes be insufficient, requiring complementary treatments [14]. Pharmacological treatment is the treatment of choice in children and adolescents with severe ADHD [15]. Stimulant treatment reduced behaviors linked to emotional instability, such as substance use, suicide rate, or criminal behavior [5,13]. Behavioral therapy, particularly focused on problem-solving and social skills training, is the recommended form of psychotherapy for ADHD [16,17]. Nevertheless, some areas, such as executive function, emotional regulation, and core ADHD symptoms, may show limited improvement through multimodal treatment alone. Motivation, especially intrinsic motivation, and responsiveness to insufficient reward plays a critical role in ADHD [18]. Individuals with ADHD often seek higher levels of immediate reward, which can lead to neglect tasks, dropped jobs, or incomplete treatments. Complementary treatments have emerged that are more attractive to patients, such as the use of games or video games or new technologies such as virtual reality (VR) [19,20]. Children with ADHD who engaged in working memory training incorporating game elements demonstrated longer training durations, completed more sequences with fewer errors, and achieved higher scores compared to those who underwent standard cognitive training [21]. When motivated, children with ADHD perform comparably to typically developing children on most cognitive tasks and may even outperform them on engaging computer-based tasks, despite the need for sustained attention [18].

In this prospective, unicentric, unblinded, pre- and postintervention randomized clinical trial (NCT06006871), we investigated the efficacy of *The Secret Trail of Moon* (MOON) for improving emotional regulation in people with ADHD aged between 7 and 18 years. MOON is a serious video game designed for health purposes, developed by a multidisciplinary team; the environment is composed of a forest with the intention of immersing the player through the sensation of presence that VR facilitates [22,23]. VR favors a lower perception of the real physical environment [22] and, therefore, a lower distraction by stimulation, a key aspect for a treatment for individuals with ADHD [15,24]. The video game experience can be immersive and exciting. A very low level of arousal can lead to boredom and reduced attention to the game. Conversely, if the player experiences too much arousal, it can also divert attention [22]. Music can help modulate these emotional states besides facilitating flow and immersion while playing video games [25]. Particularly in ADHD, music can be beneficial in reducing environmental distraction, especially in monotonous tasks [25,26]. Elements of music therapy have been both passively and interactively incorporated into this new version of the game [25,27]. Finally, an additional rhythm-based game mechanic (active music therapy) could not be added in the clinical trial due to its nonapproval by the ethics committee. The video game integrates bright but calm colors in a cartoon style, friendly characters that accompany the patient in the process, and varied cognitive training games based on neuropsychological tests: (1)

Smasher (sustained attention and inhibitory control); (2) Teka Teki (planning); and (3) Kuburi (visuospatial capacity), Chess (reasoning), and Enigma (working memory). The games increase in difficulty level according to patient performance [28]. A previous clinical trial (NCT04355065) showed promising results in emotional intelligence, emotional regulation, and performance in the school context in both self-reports and parent reports [29]. Contrary to our expectations, no significant differences were observed in the improvement of executive functions, as measured by the Behavior Rating Inventory Executive Function, version 2 (BRIEF-2), between the video game group and the control group. Compared to the previous clinical trial, this time the study design is simplified into 2 branches: experimental (play MOON in the hospital and at home during 20 sessions) versus control (do not play MOON and telephone follow-up to parents). Both groups have stable pharmacological treatment and psychoeducation to parents. We anticipated a 3- to 4-point reduction in the global Strengths and Difficulties Questionnaire (SDQ) score between the baseline assessment (day 0) and the final assessment (day 90), reflecting an improvement in emotional regulation. As secondary measures, we propose 6 additional hypotheses:

- Hypothesis 1—ADHD patients using the MOON video game improve emotional regulation compared to the control group
- Hypothesis 2—patients with ADHD using the MOON video game improve core ADHD symptoms compared with the control group
- Hypothesis 3—patients with ADHD using MOON improve their cognitive functioning compared to the control group
- Hypothesis 4–patients with ADHD using MOON improve in academic performance with respect to the control group
- Hypothesis 5—a change in platform (hospital-based, face-to-face VR vs home-based, web-based computer version) will not result in differences in emotional regulation outcomes
- Hypothesis 6—there is no clinically meaningful side effects associated with the video game

Methods

Study Design

Prospective, unicentric, randomized, unblinded, pre- and postintervention study with a masked randomization sequence by blocks (NCT06006871) [30]. Participants were randomized by electronic case report form (eCRF) in 2 groups: group 1 (MOON), which received standard pharmacological treatment combined with personalized cognitive training through a serious video game designed for patients with ADHD, along with psychoeducational support for parents; and group 2 (control), which received standard pharmacological treatment and psychoeducational support for parents, without the video game intervention. The study followed a parallel assignment model (MOON vs control) with a 1:1 allocation ratio.

No major changes were made to the methodology before the commencement of the clinical trial. In this randomized clinical trial, the study design and reporting adhered to the CONSORT 2010 guidelines, specifically following the CONSORT checklist for reporting information in randomized trials (Multimedia Appendix 1). The research questions were formulated using the Population, Intervention, Comparison, Outcomes and Study framework. The study protocol is published [30] and registered on ClinicalTrials.gov (NCT06006871) with International Registered Report Identifier (DERR1-10.2196/53191).

Ethical Considerations

This study received approval from the Research Ethics Committee of the Puerta de Hierro University Hospital on December 14, 2022 (PI 106/22). Authorization was subsequently granted by the Spanish Agency of Medicines and Health Products on February 14, 2023 (1061/22/EC-R). The study was monitored by an independent monitor. All participants signed the informed consent form. Data were anonymized through the assignment of a clinical trial-specific code. The data were treated confidentially in accordance with the Organic Law 3/2018 of December 5 on the protection of personal data and guarantee of digital rights. This study complied with the standards of good clinical practice and the declaration of Helsinki. Participants were not compensated financially.

Study Population

Children and adolescents aged between 7 and 18 years (mean age 12.68, SD 2.75 years) with a clinical diagnosis of ADHD according to the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*, were enrolled in the study. All participants had a clinical diagnosis of ADHD in any presentation and were receiving stable pharmacological treatment for ADHD. Patients were clinically stable, with a Clinical Global Impression (CGI) score between 3 and 6 before entering the clinical trial. Comorbidity was not an exclusion criterion in the study, except for those patients with suicide risk, lack of ability to follow verbal instructions, or motor difficulties that make it difficult to play a video game. Exclusion criteria also included participation in similar video games studies or the intention to initiate psychotherapeutic treatment during the 3-month study period. Medication was not altered during the study, unless adjustments were necessary for clinical reasons. A dropout rate of 15% was expected.

The randomized clinical trial had a total duration of 7 months, concluding on December 15, 2023. Recruitment took place between May and October 2023. The first evaluation was performed on May 9, 2023. The last evaluation was performed on October 31, 2023.

The intention-to-treat (ITT) population was defined as randomized participants who completed at least 10 sessions. The per-protocol (PP) population was defined as participants who completed 100% of the training. Only 32% (12/38) participants in the MOON group completed all 20 treatment sessions (PP), so we have not performed the analyses with this small sample size. In the ADHD population, adherence difficulties are common in long-term treatments; therefore, we planned to conduct the analyses on the premise of the ITT analysis. An additional analysis was also included to evaluate those participants who engaged with the intervention by completing 80% treatment (16 sessions in the MOON group or engagement for 8 weeks in the control group). Recognizing that

the number of sessions could be a relevant covariate, we performed an analysis of covariance (ANCOVA), which was not initially included in the protocol. Only half of the parents (38/76, 50%; Multimedia Appendix 2) provided information on academic grades. Therefore this primary outcome (hypothesis 4) was excluded due to insufficient data.

Procedure

All participants were recruited from the child and adolescent psychiatry outpatient clinics of Hospital Universitario Puerta de Hierro Majadahonda. The MOON group had 12 face-to-face visits, whereas the control group had only 2 presential visits: one at the preevaluation visit (D0) and another at the postevaluation visit (D90). The total duration of the research was 3 months for each participant. During the preinclusion phase, the principal investigator (HB-F) informed eligible patients about the procedure and research protocol. A total of 155 participants were assessed for enrollment. The study coordinator (MM-M) provided a detailed explanation of the research procedure and summoned the prerecruited participants. In total, 7.7% (12/155) of the patients did not meet the inclusion criteria (main reasons were clinical CGI, no medication, or age); 43.2% (67/155) of the patients declined to participate (the most common reason being lack of availability).

During the inclusion visit (D0), the research procedure was thoroughly explained, the informed consent form was signed, and the preevaluation was conducted (refer to the Study Outcomes section). Afterward, participants were randomly assigned to groups. Group randomization (MOON vs control) was performed using block randomization through the electronic eCRF REDCap (Research Electronic Data Capture; Vanderbilt University) with a 1:1 allocation ratio.

The intervention training (D1-D90) varied according to the assigned group. Parents in the control group received weekly telephone monitoring. For the MOON group, 20 sessions with the video game were scheduled: 10 sessions were conducted in the hospital with the researchers, and 10 sessions took place on the web at home, with participants using their computers under the researchers' supervision (twice a week, adjusted according to the availability of the participants). Patients aged >12 years played MOON with VR, while those aged <12 years performed the video game sessions on a computer, following PlayStation guidelines. MM-M and MB-F assisted participants during their initial use of the video game, providing instructions, encouraging progress, and helping them manage any frustration caused by mistakes made while playing MOON. They also monitored for signs of motion sickness with VR, ensured proper use of the software, and addressed any potential frustration resulting from bugs in the video game. If a patient reported dizziness, even mild, they were instructed to remove the device and were given the option to decide whether or not to continue using it. All participants followed the same order pattern of the MOON games during 20 minutes of gameplay (refer to the study by Martin-Moratinos et al [30] for details).

In week 5 (D45), all participants' parents receive a follow-up questionnaire with the main variable (SDQ). For the MOON group, both parents and children were trained on how to use the video game at home, using a flash drive. Parents and patients were additionally given an instruction manual. Monitoring was provided by telephone where the researchers checked the correct playability at home. The web-based sessions conducted were monitored by MM-M through the PlayFab data server (Microsoft Corporation). All participants had their personal username and password connected with PlayFab data server.

In the final visit (D90), a postevaluation was conducted using the same questionnaires, and participants were provided with feedback on the most relevant changes observed.

Materials

The MOON video game was designed with the Unity (version 2020.3.7; Unity Technologies) software tool by a multidisciplinary team. Autodesk 3ds Max, Autodesk Maya, Adobe Photoshop, and PreSonus Studio 4 programs were used for the modeling of characters and landscape elements. In relation to the narrative and identity features [31,32], the player is immersed in a forest with archaic chess statues of an ancient civilization [29,31]. The raccoon Movi and the fox One will help the player to solve the puzzles (game mechanics). MOON is mainly composed of a menu screen and 5 different game mechanics focused on cognitive training.

To provide manipulation and control features [32], each player has their own user profile with saved progress. Each test is set in a closed environment with distinct esthetics and game mechanics. The manipulation of the environment and interactivity are carefully controlled to avoid distractions or dizziness in the VR setting [28]. For example, in Kuburi, blocks can be rotated and moved within the space, while in Chess, the player can shift positions to view the board from different perspectives. The mobility within environments is restricted based on the individual's cognitive capacity. In cases where mobility could cause distraction—such as in tests of sustained attention or working memory, which are more challenging for individuals with ADHD—exploration is limited.

In all game mechanics, players begin at a base level (tutorial, level 1) to ensure they understand the task. The difficulty increases in a personalized manner based on performance, ensuring the game is neither too easy (and thus boring) nor too difficult (and thus frustrating). Emotional regulation maturity, specifically the ability to reappraise, can be trained through controlled exposure to negative emotional stimuli, helping players overcome levels and obstacles within the game [31]. Regarding reward and punishment features [32], the MOON video game uses a star system based on player performance (0 stars=poor performance, must repeat the level; 1 star=acceptable; 2 stars=good; and 3 stars=excellent). Player progress in each game mechanic is communicated through level advancements, performance parameters, and the number of stars earned [30].

In terms of music, each game mechanic features different tracks [25]. The music was specifically designed to align with cognitive abilities. For example, sustained attention, which requires more effort for individuals with ADHD [24], benefits from dynamic soundtracks. To prevent monotony and boredom, more epic, fast-paced music was composed for Smasher to maintain motivation through its rhythm. Feedback is not only visual but also auditory, with distinct sounds depending on user

interactions. Different sounds were created to indicate level selection and hits or misses, as well as to signal conditions of victory (successfully completing a level) or defeat (repeating the level after earning 0 stars due to poor performance) [25]. In this clinical trial, the same version of the video game was proposed in 2 platforms: VR and computer (Table 1) [30].

Table 1. Hardware and software specifications categorized by The Secret Trail of Moon (MOON) gameplay on virtual reality (VR) or computer.

MOON	Patients' target	Hardware	Software
VR	• For children aged >12 years (following PlayStation guidelines) • Only the first 10 sessions with on-site supervision at the hospital by researchers	• PlayStation 4 Dev Kit and Test Kit • PlayStation VR headset • PlayStation camera • Computer screen • Controller: DualShock 4 • Headphones with 3D stereo sound and noise cancelation	• Gameplay: the player's camera is the VR viewer
Computer	• For patients aged between 7 and 11 years • All participants played MOON on their home computers after session 10	• Any computer with operating system 8/10/11, DirectX 11 support (32 or 64 bits), 1.9-GH processor (Intel core i5 or AMD equivalent), 8 GB RAM, NVIDIA GTX 660 or AMD Radeon HD 7950 with at least 3-GB storage space, and internet connection • Controller: mouse and keyboard	• Gameplay: the player's camera depends on the mouse pointer

A PlayStation 4 Dev Kit and Test Kit were used for VR version. The Dev Kit and Test Kit are development consoles equipped with debug firmware that allow the execution of unsigned builds; access to memory and performance analysis tools; real-time error trace logging; as well as software compatibility, optimization, and development testing in a controlled environment. The PlayStation VR for PlayStation 4 is a VR headset featuring a 5.7-inch OLED display with a resolution of 1920×1080 (960×1080 per eye), a field of view of approximately 100°, and a refresh rate of 90/120 Hz. A PlayStation camera was used for motion tracking through an accelerometer, gyroscope, and 9 LEDs. The participants had to be placed at a distance of 1.5 to 2 m with a not very intense light for the correct calibration of the PlayStation camera with the LED lights. The researchers monitored what each participant experienced in VR by viewing it on a computer screen.

The PlayStation 4 VR goggles weigh approximately 600 g, so they could be uncomfortable for some participants. Regarding the added weight of sound equipment, patients were given a choice between basic stereo headphones and over-the-ear headphones. Both had 3D stereo sound and noise cancelation.

A Stealth 15M A11SDK (MSI) laptop was used for participants aged between 7 and 11 years to play MOON in the hospital. The laptop specifications were as follows: Microsoft Windows 11 Home ×64 bits; 11th Gen Intel Core i7-1185G7, 3.00 GHz, 16 GB RAM, 8 GB storage memory; GeForce GTX 1660 Ti.

Study Outcomes

Primary Outcome

The SDQ is a brief 25-item questionnaire that examines difficulties related to emotions, behavior, and social relationships. SDQ includes 5 subscales: emotional symptoms (somatic, worries, unhappy, clingy, and fears), behavioral problems (tempers, not obedient, fights, lies, and steals), hyperactivity (restless, fidgety, distractible, not reflective, and not persistent), peer problems (solitary, not good friend, not popular, bullied, and best with adults), and prosocial behavior (considerate, shares, caring, kind to kids, and helps) [33,34]. The authors propose an alternative three-factor model: (1) prosocial behavior; (2) internalizing difficulties (composed of the subscales of "emotional symptoms" and "peer problems"; cutoff point=7) as an indicator of the presence of excessive worry, somatization with headache, depressive mood, nervousness in unfamiliar situations, and tendency to startle easily; and (3) externalizing difficulties (composed of the subscales "hyperactivity" and "behavior problems"; cutoff point=4), to assess the tendency to lose control, fighting with other children, deceiving, and stealing. The questionnaire has shown adequate psychometric properties in the grouping of these 3 factors and good sensitivity and specificity for detecting children with ADHD [35,36].

The face-to-face web-based change will be measured by comparing the 3 SDQ measures. Subsequently, 3 parent SDQ measures were assessed: initial assessment (D0), midterm assessment (D45), and final assessment (D90) to evaluate hypothesis 5 (switching from face-to-face to web-based methods do not lead to differences in emotional regulation).

Secondary Outcomes

The core ADHD symptomatology was measured using 3 subjective scales for parents: the Swanson, Nolan, and Pelham Rating Scale (SNAP-IV); the Conners Abbreviated Symptom Questionnaire (CPRS); and CGI. SNAP-IV [37] is an 18-item questionnaire that assess attention deficit (cutoff point is 1.78) and hyperactive impulsive (cutoff point is 1.44) with a Likert scale ranging from 0 to 4. The CPRS [38] also assesses ADHD symptoms with cutoff points of 16 for boys and 12 for girls. It is a 10-item questionnaire using a Likert scale of 0 to 3 (0=not true at all or never, 1=just a little true or occasionally, 2=pretty much true or often, and 3=very much true or very often). The CGI-40 [39], adapted for parents, allows them to rate their child's general condition using a Likert scale ranging from 1 to 10.

Executive function refers to a set of top-down processes that allow us to be flexible and to direct behavior toward a goal. Executive function was measured with a parent questionnaire and 3 objective tests for the participants. BRIEF-2 [40] is a 63-item questionnaire with 3 answer options (never, sometimes, and frequently) that provides 4 indices: emotional regulation, cognitive regulation, behavioral regulation, and global index of executive function. For objective testing of patients, we assessed them using the Conners' Continuous Performance Test Third Edition (CPT-3); Corsi cubes; and the Comprehensive Trail-Making Test, Second Edition (CTMT-2). CPT-3 [41,42] is a computerized, standardized, and validated application test for screening ADHD in clinical practice. CPT-3 provides results on hits, errors of omission, commission error, hit mean reaction time, and variability. Corsi cubes are used to measure visuospatial working memory. CTMT-2 is used to measure cognitive flexibility, with 3 indexes: inhibitory control, task switching, and total index.

Additional school information was collected due to its potential impact on emotional regulation and executive functions. Information about academic performance will be obtained via the patients' grades.

Safety Outcomes

During the development of the video game, risk control measures were applied, especially those related to the possible adverse consequences of VR. We followed recommendations from Sony Interactive Entertainment (Project Morpheus PlayStation Virtual_000010933011) regarding best practices for VR interfaces, including interaction, navigation, user interface, game environments, player comfort, and safety. In addition, risk prevention measures, particularly those related to VR, were implemented (Textbox 1). Before conducting the clinical trial, programming adjustments were made. The game was tested for correct playability using a quality assurance tester. Development was an iterative process using a user-centered model in which game bugs were corrected based on the usability study and the previously conducted clinical trial [28,29].

Textbox 1. Risk prevention and control measures in The Secret Trail of Moon clinical trial.

Programming

- Control latency and frame rate, maintaining a minimum of 90 frames per second. Ensure synchronization between player movements and virtual reality (VR) visuals
- Minimize motion blur
- Maintain a field of view between 90 and 110°
- Avoid artificial or conflicting movements that may cause motion sickness by incorporating static or low-motion scenes where possible
- Reduce loading times and ensure smooth transitions to prevent player discomfort
- Limit intense visual effects that may cause fatigue and provide regular breaks
- Manage proximity and positioning of the user interface
- Control the height of the viewfinder or horizon line

Optimal playability and adjustment

- Maintain a player distance of 1.5 m from the PlayStation Camera, with the camera positioned slightly above the eye level to capture head and body movements
- Ensure moderate lighting for better motion detection
- Address visual accommodation: calibrate eye settings and clean lenses regularly
- Assess user comfort, including helmet weight, sound volume, and potential issues such as blurred vision

Predictable misuse of software and hardware in children and adolescents with attention-deficit/hyperactivity disorder

- Reduce sudden camera movements with aid of the researcher
- Ensure a clear play space of approximately 2 m around the player, taking special care to manage cables
- Monitor for excessive hyperkinesia or hypokinesia, assessing the potential stress of using new technologies
- Remove VR gear gradually to prevent dizziness
- Evaluate the risk of video game addiction using the Game Addiction Scale for Adolescents and Udvalg für Kliniske Undersogelser (UKU) tests
- Assess fatigue and motivation levels related to gameplay using the UKU test and usability measures
- Monitor drowsiness and arousal levels with the UKU and Sleep Disturbance Scale for Children tests
- Cease use immediately if dizziness occurs. If dizziness arises in ≥2 sessions, consider restricting gameplay to the computer only

Safety outcomes focused on measuring the risk of video game addiction and associated sleep difficulties. Motion sickness may occur with VR, especially in the early adaptation sessions. The group that played MOON with VR was additionally given a

measure to control for this possible effect. According to the protocol, the sponsor must notify the Spanish Agency of Medicines and Health Products within 15 calendar days of receiving the Serious Adverse Event report, in the case of any serious adverse events.

The Game Addiction Scale for Adolescents (GASA) is a 7-item questionnaire to assess video game addiction [43,44]. The version of GASA used was the 7-item Spanish version, which measures salience, tolerance, mood modification, relapse, withdrawal, conflict, and problems. A higher score indicates more problematic gaming behavior. Video game addiction is calculated by obtaining a score of ≥3 on at least 4 items or a total score with a cutoff point of 21.

The Sleep Disturbance Scale for Children is a 26-item questionnaire whose subscales measure disorders of initiating and maintaining sleep, sleep breathing disorders, disorders of arousal nightmares, sleep-wake transition disorders, disorders of excessive somnolence, and sleep hyperhydrosis [45]. A higher score indicates more sleep disturbance. Sleep problems are calculated by obtaining a total score with a cutoff point of 39.

Only for MOON group participants aged >12 years and mainly due to the possibility of motion sickness with VR, the questionnaire Udvalg für Kliniske Undersogelser (UKU) was applied after each session. UKU evaluate psychic, neurological, autonomic, and other side effects [46]. The most relevant side effects evaluated with UKU were those associated with ADHD symptoms (concentration difficulties, failing memory, depression, tension, emotional difference, and hyperkinesia), those associated with side effects after using VR (accommodation disturbances, nausea, dizziness, and headache), those associated with the use of video games (physical and psychic dependence), and those associated with sleep (fatigue, sleepiness or sedation, reduced or increased duration of sleep, and increased dream activity).

Statistical Analyses

Sample Size Calculation

To calculate the sample size, we referenced the means of the main measure (SDQ) in similar studies. To account for most possibilities with a significance level of P=.05 and a statistical power of 80%, while considering a dropout rate of 15%, the author AR calculated that a total of 152 participants with an ADHD diagnosis were needed. We performed the sample size calculation to contrast a mean decrease of 3 points (symptomatologic improvement) in the experimental group with a SD of 4.

Randomization and Masking: Sequence Generation and Allocation

A randomized block sequence of 76 times “number 1 block” (experimental) and 76 times “number 2 block” (control) was generated in 4 blocks of 38 numbers (19 times for number 1 and 19 times for number 2) using the program R (R Foundation for Statistical Computing) by MB-F. The sequence was unknown to the recruiters and was enclosed in the eCRF. The randomization was done through REDCap (eCRF) after the initial evaluation was completed.

Statistical Methods

A 2-way ANOVA were performed, with time (pre and post; pre-mid-term-post in the SDQ questionnaire) and group (experimental vs control) as factors and each measure as dependent variable. The difference between the groups was considered significant when P<.05. In addition, clinical trends of improvement have been described due to noncompliance with the proposed sample size. These analyses were performed with SPSS (IBM Corp) and R software.

Analyses were performed under the ITT assumption following the protocol; analyses were not performed on PP (only 12 participants completed 20 sessions); an additional analysis has been added regarding the MOON subgroup that completed 80% of the treatment (16 sessions) and, therefore, had a higher involvement in the treatment. As this variable was relevant to the results, an ANCOVA was performed using the number of sessions as a covariate, which had a mean of 18.22 (SD 3.12; range 0-20) sessions. The adjusted means of the groups were calculated based on this mean value.

The ANOVA for hypothesis 4 could not be conducted due to insufficient data. The mean and SD for each academic grade are provided in Multimedia Appendix 2.

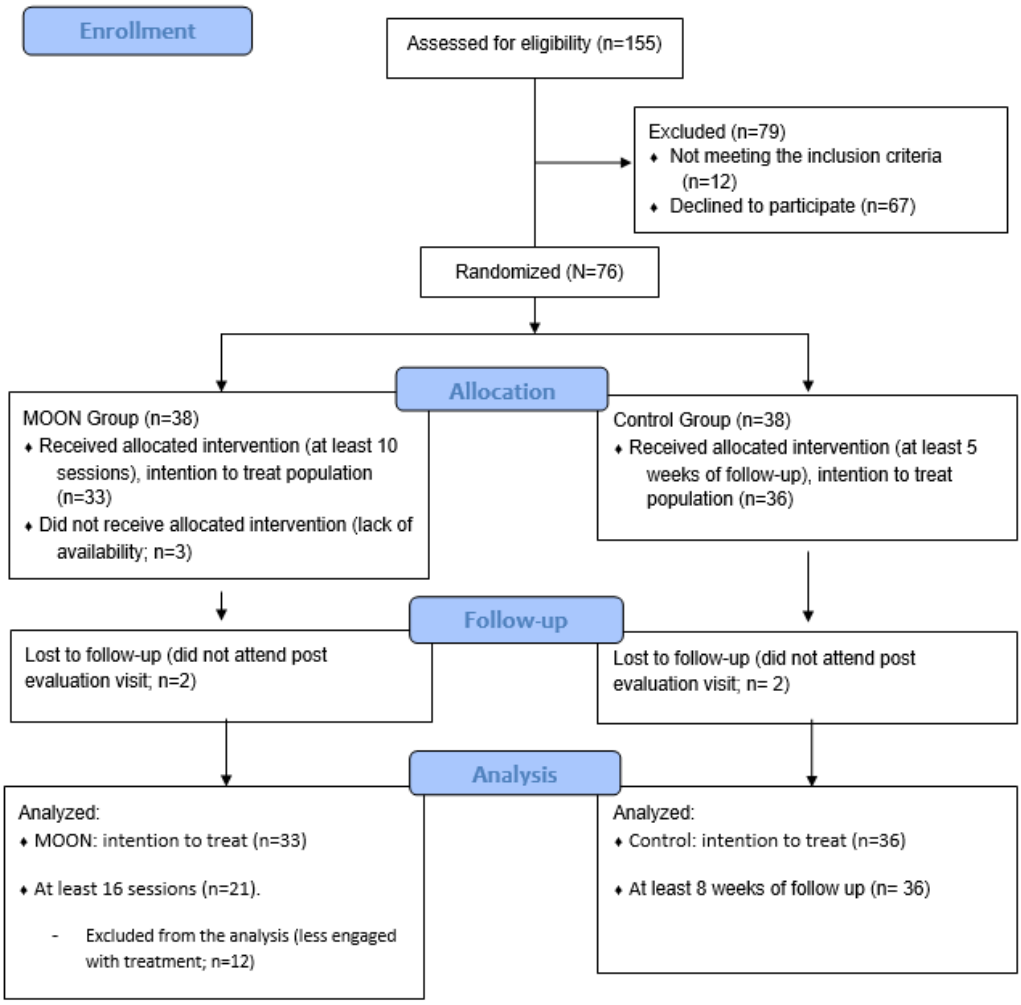
Results

Recruitment: Patient Inclusion and Randomization

The recruitment period was between May 9, 2023, and October 31, 2023. The enrollment target was not completed (n=152) [30]. The last post evaluation was performed on December 13, 2023. The clinical trial ended on December 15, 2023. A total of 76 patients with ADHD participated in the clinical trial and signed a reported consent form. No patients were excluded. The 76 participants were randomized 1:1 (MOON: n=38, 50% and control: n=38, 50%).

The total dropout rate was 9% (7/76) of the participants (n=5, 71% MOON and n=2, 29% control) and did not exceed expectations (12/76, 15%). Lack of availability was the reason mentioned by the dropout cases for not participating. In total, 3% (2/38) of the patients requested to switch to the control group after preassessment and randomization to MOON due to insufficient time to commit to the study, which was not allowed. Another MOON participant had to drop out of treatment due to lack of availability after 2 sessions. In total, 5% (4/76) of the participants (n=2, 50% MOON and n=2, 50% control) were not assessed at postevaluation and were lost to follow-up (Figure 1). The ITT population was analyzed for the primary and secondary outcomes. The ITT population included 87% (33/38) of the patients assigned to the MOON group and 95% (36/38) of the patients assigned to the control group.

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram for the number of participants in the clinical trial. ITT: intention-to-treat; MOON: The Secret Trail of Moon.



Baseline Characteristics

Table 2 shows the sociodemographic variables for all participants who completed a preevaluation (N=76). The mean age of the groups were 12.79 (SD 2.86) years for MOON and 12.58 (SD 2.67) years for control. In total, 80% (61/76) of the sample was composed of male participants.

Regarding multimodal treatment, 30% (23/76) of the participants were receiving >1 medication per day. The remaining 70% (53/76) were taking only their ADHD pharmacological treatment. As much as possible, ADHD patients were instructed not to change their medication during the study, except for clinical reasons (eg, side effects or inadequate medication adjustment at the time of examination). For ethical reasons, the needs of the patients were prioritized, and there were 11 changes: 8 dose increases of the usual medication and 3 dose decreases of the usual medication. Of the abovementioned changes, 3 occurred in the MOON group (1 decrease and 2 dose increases) and 8 occurred in the control group (2 decreases and 6 dose increases). Currently, 41% (30/73) of the participants are receiving psychological treatment, and 30% (22/73) had received it before the study. In addition, all participants received weekly psychoeducation and counseling on ADHD.

School, social, and recreational data have been included in Table 3. Regarding difficulties with peers, 19% (14/76) of the participants experienced bullying and 31% (23/76) had difficulty making friends, as reported by parents. Additional clinical information was collected. Regarding medical history, 45% (34/76) of the mothers had difficulties during pregnancy. Regarding the developmental alterations of the participants, 26% (20/76) had delayed speech development, 15% (11/76) had slow gait development, and 24% (18/76) had delayed sphincter control. Of the participants, 35% (26/76) needed previous speech therapy support, 9% (7/76) needed psychomotor therapy, and 11% (8/76) needed early stimulation.

The results are listed in the primary and secondary outcome sections, ordered according to the hypotheses. Analysis was performed with the ITT population (69/76, 91%) and patients who completed 80% of treatment (57/76, 75%).

Table 2. Baseline demographic variables.

Baseline variables	Total (N=76)	MOON[a] (n=38)	Control[b] (n=38)	Chi-square (*df*)	*t* test (*df*)	*P* value
Sex (female), n (%)	15 (20)	7 (18)	8 (21)	0.0 (1)	N/A[c]	.77
Age (y), mean (SD)	12.68 (2.75)	12.79 (2.86)	12.58 (2.67)	N/A	0.3 (74)	.74
Nationality of birth, n (%)				0.3 (2)	N/A	.84
European (Spain)	71 (93)	35 (92)	36 (95)			
Hispanic America	2 (3)	1 (3)	1 (3)			
Asian	3 (4)	2 (5)	1 (3)			
Adopted, n (%)	4 (5)	2 (5)	2 (5)	—[d]	—	—
Family background, n (%)						
Lives with both parents	63 (83)	34 (90)	29 (76)	2.3 (1)	N/A	.12
Lives with mother	12 (16)	4 (11)	8 (21)	1.5 (1)	N/A	.20
Family socioeconomic status (€ per month; €1=US $1.4), n (%)				0.4 (3)	N/A	.93
500-1500	5 (7)	2 (5)	3 (8)			
1500-2000	7 (9)	4 (11)	3 (8)			
2000-2500	13 (17)	6 (16)	7 (18)			
>2500	51 (67)	26 (68)	25 (66)			

[a]MOON: The Secret Trail of Moon (the experimental group with the serious video game).

[b]Control: control group without the serious video game.

[c]N/A: not applicable.

[c]Not available.

Table 3. Clinical characteristics of each group.

Clinical variables	Total (N=76), n (%)	MOON[a] (n=38), n (%)	Control (n=38), n (%)	Chi-square (*df*)	*P* value
Medical history					
ADHD[b] subtypes					
Combined	48 (66)	23 (62)	25 (69)	0.4 (1)	.51
Primarily inattentive	25 (34)	14 (37)	11 (31)	__[c]	—
Medication					
Elvanse	53 (55)	29 (62)	24 (49)	8.5 (10)	.58
Equasym	8 (9)	3 (7)	5 (11)	—	—
Intuniv	7 (7)	3 (6)	4 (8)	—	—
Medikinet	5 (5)	2 (4)	3 (6)	—	—
Risperdal	6 (6)	2 (4)	4 (8)	—	—
Concerta	3 (3)	1 (2)	2 (4)	—	—
Other: atenza, atomoxetina, rubifen retard, and rubicrono	4 (4)	2 (4)	2 (4)	—	—
Invega and zyprexa	2 (2)	1 (2)	1 (2)	—	—
Fluoxetina and sertralina	8 (9)	4 (9)	4 (8)	—	—
Psychological therapy				1.2 (2)	.52
Current	30 (41)	13 (34)	9 (25)		
Previous	22 (29)	13 (34)	17 (47)		
School background					
Repeating a school year	21 (8)	11 (29)	10 (27)	0.3 (1)	.85
Special education	8 (11)	3 (8)	5 (14)	0.6 (1)	.43
Curricular adaptation	35 (47)	21 (55)	14 (37)	2.2 (1)	.13
Private teacher	24 (32)	10 (26)	14 (37)	1.1 (1)	.28
High abilities program	6 (8)	5 (13)	1 (3)	2.7 (1)	.09
Peer problems					
Bullying	14 (19)	4 (11)	10 (26)	3.3 (1)	.06
Tendency to isolate	14 (19)	7 (18)	7 (19)	0.0 (1)	.95
Difficulty in making friends	23 (31)	10 (26)	13 (35)	0.6 (1)	.40
Behavioral problems	13 (17)	5 (13)	8 (22)	0.9 (1)	.33
Recreation					
Sports	60 (79)	30 (83)	30 (88)	—	—
Play a musical instrument	11 (14)	5 (13)	4 (11)	—	—
Regular video game use (h)	53 (74)	28 (76)	25 (71)	0.1 (2)	.68
0.25-1	21 (44)	10 (39)	11 (50)	0.9 (1)	.62
1.5-2	14 (29)	9 (35)	5 (23)	—	—
2.5-5	13 (27)	7 (18)	6 (27)	—	—
Regular mobile use (h)	50 (67)	—	—	—	—
0.25-1	10 (24)	6 (27)	4 (20)	0.8 (2)	.66
1.5-2	16 (38)	7 (32)	9 (45)	—	—
2.5-6	16 (38)	9 (41)	7 (35)	—	—

[a]MOON: The Secret Trail of Moon.

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

[c]Not available.

Primary Outcome: Emotional Regulation

The main hypothesis of a 3- or 4-point drop in the primary end point of global SDQ was not achieved. We found no statistically significant differences in the primary variable (SDQ) in our pretest and posttest comparison ($F_{1,64}$=0.51; P=.47; η^2=0.00; 1–β=0.11). The preassessment overall SDQ scores for the experimental group (mean 27.48, SD 5.64; 95% CI 25.45-29,51) and the control group (mean 26.61, SD 6.03; 95% CI 24.57-28.63) were higher than the post scores of the experimental group (mean 26.09, SD 5.74; 95% CI 24.06-28.12) and the post scores of the control group (mean 25.94, SD 5.93; 95% CI 23.90-27.97). Significant differences were found in the prosocial scale in favor of the control group ($F_{1,66}$=3.73; P=.05; η^2=0.05; 1–β=0.47). These results are shown in Table 4 and Multimedia Appendix 3.

Table 4. Primary outcome: pre-post comparison of the Strengths and Difficulties Questionnaire (SDQ) scores.

	Emotional symptoms	Behavior problems	Hyperactivity	Peer problems	Prosocial scale	Internalizing	Externalizing	SDQ global
Intention-to-treat (at least 10 sessions; n=69)								
MOON[a] (n=33), mean (SD)								
Pre	9.18 (2.54)	6.39 (1.56)	8.03 (2.00)	3.88 (2.53)	12.18 (2.37)	13.06 (4.39)	14.42 (2.68)	27.48 (5.64)
Post	8.85 (2.19)	6.27 (1.66)	7.27 (2.28)	3.70 (2.55)	11.78 (2.56)	12.55 (4.10)	13.55 (3.15)	26.09 (5.74)
Control (n=36), mean (SD)								
Pre	9.00 (2.44)	6.19 (1.93)	7.83 (2.39)	3.91 (2.35)	12.78 (1.88)	12.86 (4.04)	14.09 (3.52)	26.79 (6.03)
Post	8.89 (2.23)	6.08 (1.85)	7.33 (2.49)	4.00 (2.60)	13.08 (1.76)	12.74 (3.99)	13.42 (3.82)	26.09 (5.91)
F test (*df*)	0.50 (1)	0 (1)	0.40 (1)	0.70 (1)	3.73 (1)	0.96 (1)	0.21 (1)	0.51 (1)
P value	.48	.97	.52	.40	.05	.33	.64	.47
η^2	0.00	0.00	0.00	0.01	0.05	0.01	0.00	0.00
16 sessions (n=57)								
MOON (n=21), mean (SD)								
Pre	9.67 (2.45)	6.57 (1.56)	7.90 (1.84)	4.24 (2.54)	11.33 (2.24)	13.90 (4.19)	14.48 (2.54)	28.38 (5.54)
Post	9.00 (2.12)	6.33 (1.56)	7.38 (2.24)	3.76 (2.36)	11.14 (2.15)	12.76 (3.83)	13.71 (3.28)	26.48 (5.76)
Control (n=36), mean (SD)								
Pre	9.00 (2.44)	6.19 (1.93)	7.83 (2.39)	3.91 (2.35)	12.78 (1.88)	12.86 (4.04)	14.09 (3.52)	26.79 (6.03)
Post	8.89 (2.23)	6.08 (1.85)	7.33 (2.49)	4.00 (2.60)	13.08 (1.76)	12.74 (3.99)	13.42 (3.82)	26.09 (5.91)
F test (*df*)	1.95 (1)	0.10 (1)	0.02 (1)	2.28 (1)	1.85 (1)	3.35 (1)	0.05 (1)	1.08 (1)
P value	.16	.75	.87	.13	.17	.07	.81	.30
η^2	0.03	0.00	0.00	0.04	0.03	0.05	0.00	0.02

[a]MOON: *The Secret Trail of Moon*.

In the most engaged subgroup (16 sessions), clinical trends of improvement on the SDQ of 2 points were observed but did not approach significance. This improvement trend is particularly notable in internalizing difficulties ($F_{1,53}$=3.35; P=.07; η^2=0.05; 1–β=0.43), peer problems ($F_{1,54}$=2.28; P=.13; η^2=0.04; 1–β=0.31) and emotional symptoms ($F_{1,54}$=1.95; P=.16; η^2=0.03; 1–β=0.27; Table 4; Multimedia Appendix 3). At the SDQ follow-up, parents in the MOON group reported that their children felt "a little better," while parents in the control group reported their children felt "about the same."

All participants completed the 10 face-to-face sessions. However, the number of sessions decreased when there was no direct face-to-face supervision by the investigators in the MOON web-based intervention. The results of the main variable (SDQ) of the 3 measures (pre-mid-term-post comparison) are shown in Table 5 and Multimedia Appendix 4. The change of modality (face-to-face and on the web) could have influenced adherence to treatment. The MOON group had an average of 16 sessions, with 3 participants having the minimum number of sessions (10) and 12 patients having the maximum number (20; Multimedia Appendix 5). Most participants in the MOON group (26/33, 79%) played the video game in VR, as they were aged >12 years, following PlayStation's recommendations. A comparative statistical analysis was conducted within the MOON group, comparing participants who played the face-to-face VR version (26/33, 79%) with those who used the computer version for the entire treatment (7/33, 21%). We found

that the VR subgroup improved most on emotional symptoms ($F_{1, 31}$=7.79; P=.004; η^2=0.20; 1–β=0.77), internalizing ($F_{1, 31}$=4.18; P=.04; η^2=0.11; 1–β=0.50) and, to a lesser extent, global SDQ ($F_{1, 31}$=2.99; P=.09; η^2=0.08; 1–β=0.38).

The ANCOVA for the main hypothesis—which posited that the MOON group would exhibit improved emotional regulation, reflected by a 3- to 4-point decrease in global SDQ scores compared to the control group—was conducted with the number of sessions included as a covariate. The results approached significance ($F_{1, 63}$=3.25; P=.07; η^2=0.04; 1–β=0.42; Figure 2; Table 6). Significant improvements were found in the MOON group in the variables of emotional symptoms ($F_{1, 65}$=4.47; P=.03; η^2=0.06; 1–β=0.54) and internalizing problems ($F_{1, 64}$=6.57; P=.01; η^2=0.09; 1–β=0.71).

Table 5. Primary outcome: pre-mid-term-post comparison of the Strengths and Difficulties Questionnaire (SDQ) scores.

	Emotional symptoms	Behavior problems	Hyperactivity	Peer problems	Prosocial scale	Internalizing	Externalizing	SDQ global
Intention-to-treat (at least 10 sessions; n=69)								
MOON[a] (n=33),mean (SD)								
Pre	9.18 (2.54)	6.39 (1.56)	8.03 (2)	3.88 (2.53)	12.18 (2.37)	13.06 (4.39)	14.42 (2.68)	27.48 (5.64)
Midterm	8.91 (2.28)	6.09 (1.52)	7.58 (2.18)	3.88 (2.80)	12.06 (2.46)	12.79 (4.38)	13.67 (2.88)	26.45 (5.71)
Post	8.85 (2.19)	6.27 (1.66)	7.27 (2.28)	3.70 (2.55)	11.78 (2.56)	12.55 (4.10)	13.55 (3.15)	26.09 (5.74)
Control (n=36), m ean (SD)								
Pre	9 (2.44)	6.19 (1.93)	7.83 (2.39)	3.91 (2.35)	12.78 (1.88)	12.86 (4.04)	14.09 (3.52)	26.79 (6.03)
Midterm	8.69 (2.30)	6.25 (2.08)	6.97 (2.55)	3.97 (2.43)	12.72 (1.95)	12.67 (3.89)	13.22 (3.72)	25.89 (5.80)
Post	8.89 (2.23)	6.08 (1.85)	7.33 (2.49)	4 (2.60)	13.08 (1.76)	12.74 (3.99)	13.42 (3.82)	26.09 (5.91)
F test (*df*)	0.44 (2)	0.71 (2)	0.94 (2)	0.72 (2)	2.33 (2)	0.86 (2)	0.13 (2)	0.39 (2)
P value	.64	.49	.39	.48	.10	.42	.87	.67
η^2	0	0.01	0.01	0.01	0.03	0.01	0	0
16 sessions (n=57)								
MOON (n=21), mean (SD)								
Pre	9.67 (2.45)	6.57 (1.56)	7.90 (1.84)	4.24 (2.54)	11.33 (2.24)	13.90 (4.19)	14.48 (2.54)	28.38 (5.54)
Midterm	9.29 (2.10)	6.10 (1.37)	7.57 (1.96)	4.05 (2.90)	11.76 (2.11)	13.33 (4.16)	13.62 (2.72)	26.95 (5.81)
Post	9 (2.12)	6.33 (1.56)	7.38 (2.24)	3.76 (2.36)	11.14 (2.15)	12.76 (3.83)	13.71 (3.28)	26.48 (5.76)
Control (n=36), mean (SD)								
Pre	9 (2.44)	6.19 (1.93)	7.83 (2.39)	3.91 (2.35)	12.78 (1.88)	12.86 (4.04)	14.09 (3.52)	26.79 (6.03)
Midterm	8.69 (2.30)	6.25 (2.08)	6.97 (2.55)	3.97 (2.43)	12.73 (1.95)	12.67 (3.89)	13.22 (3.72)	25.89 (5.80)
Post	8.89 (2.23)	6.08 (1.85)	7.33 (2.49)	4 (2.60)	13.08 (1.76)	12.74 (3.99)	13.42 (3.82)	26.09 (5.91)
F test (*df*)	1.30 (2)	1.01 (2)	0.45 (2)	1.51 (2)	3.15 (2)	2.41 (2)	0.03 (2)	0.65 (2)
P value	.27	.36	.63	.22	*.04*	.09	.96	.51
η^2	0.02	0.01	0	0.02	0.05	0.04	0	0.01

[a]MOON: *The Secret Trail of Moon*.

Figure 2. Results of analysis of covariance of the main hypothesis (decrease in The Secret Trail of Moon [MOON] group of 3 or 4 points in global Strengths and Difficulties Questionnaire [SDQ] compared to the control group). The number of sessions was used as a covariate.

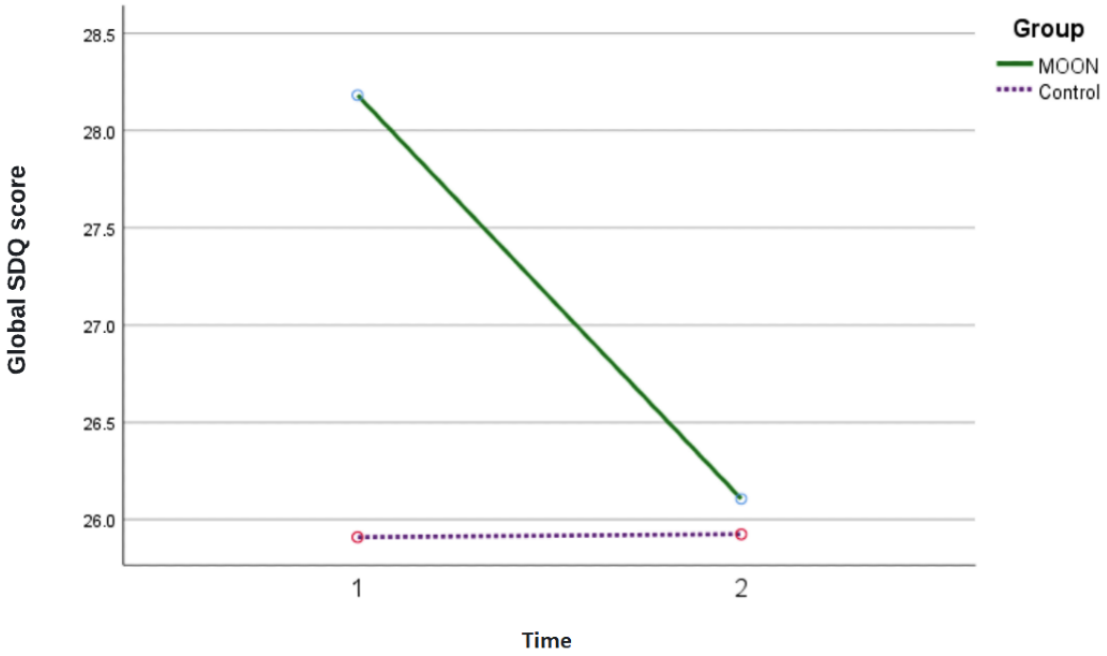


Table 6. Analysis of covariance of the Strengths and Difficulties Questionnaire (SDQ) using the number of sessions as a covariate (N=69).

SDQ	Intention-to treat (at least 10 sessions)							
	MOON[a] (n=33), mean (SD)		Control (n=36), mean (SD)		*F* test (*df*)	*P* value	η^2	1–β
	Pre	Post	Pre	Post				
Emotional symptoms	9.18 (2.54)	8.85 (2.19)	8.91 (2.43)	8.89 (2.23)	4.47 (1)	.03	0.06	0.54
Behavior problems	6.39 (1.56)	6.27 (1.66)	6.19 (1.93)	6.08 (1.85)	0.32 (1)	.56	0	0.08
Hyperactivity	8.03 (2.00)	7.27 (2.28)	7.83 (2.39)	7.40 (2.49)	0.43 (1)	.51	0	0.10
Peer problems	3.88 (2.53)	3.70 (2.55)	3.91 (2.35)	4.00 (2.60)	2.74 (1)	.10	0.04	0.37
Prosocial scale	12.09 (2.36)	11.78 (2.56)	12.78 (1.88)	13.08 (1.76)	1.19 (1)	.27	0.01	0.19
Internalizing	13.06 (4.39)	12.55 (4.10)	12.68 (3.96)	12.74 (3.99)	6.57 (1)	*.01*	0.09	0.71
Externalizing	14.42 (2.68)	13.55 (3.15)	14.09 (3.52)	13.51 (3.83)	0.57 (1)	.44	0	0.11
SDQ global	28.18 (1.10)	26.10 (1.12)	25.90 (1.10)	25.94 (1.12)	3.25 (1)	.07	0.04	0.42

[a]MOON: *The Secret Trail of Moon*.

Secondary Outcomes

Core ADHD Symptoms

No significant differences (*P*>.05) were found in the main ADHD symptoms in SNAP-IV and CPRS.

Clinical trends of improvement were seen in the MOON group versus control in the subscales of hyperactivity ($F_{1, 66}$=3.06; *P*=.08; η^2=0.04) and inattention ($F_{1, 66}$=2.41; *P*=.12; η^2=0.03) and in the total scale of SNAP-IV ($F_{1, 67}$=2.63; *P*=.11; η^2=0.03) and CPRS ($F_{1, 65}$=2.06; *P*=.15; η^2=0.03). In the participants who more engaged in the MOON treatment (at least 16 sessions), clinical trends of improvement were also observed in hyperactivity ($F_{1, 54}$=2.51; *P*=.11; η^2=0.04) and CPRS total scale ($F_{1, 53}$=2.05; *P*=.15; η^2=0.03; Table 7; Multimedia Appendix 6).

Table 7. Secondary outcomes related to hypotheses 2 and 3 (patients with attention-deficit/hyperactivity disorder [ADHD] using The Secret Trail of Moon [MOON] improve in core ADHD symptoms [hypothesis 2] and cognitive functioning compared with the control group; N=69).

	Intention-to-treat (at least 10 sessions; n=69)							16 sessions (n=57)						
	MOON (n=33), mean (SD)		Control (n=36), mean (SD)		*F* test (*df*)	*P* value	ηp^2	MOON (n=21), mean (SD)		Control (n=36), mean (SD)		*F* test (*df*)	*P* value	ηp^2
	Pre	Post	Pre	Post				Pre	Post	Pre	Post			
Core ADHD														
SNAP-IV[a]														
Inattention	28.73 (5.51)	25.91 (6.44)	26.67 (6.59)	25.78 (6.06)	2.41 (1)	.12	0.03	28.05 (6.16)	26.33 (6.32)	26.67 (6.59)	25.78 (6.06)	0.37 (1)	.54	0.00
Hyperactivity	23.12 (5.93)	20.18 (5.37)	23.42 (7.81)	21.91 (7.50)	3.06 (1)	.08	0.04	24.43 (5.10)	21.33 (4.99)	23.42 (7.81)	21.91 (7.50)	2.51 (1)	.11	0.04
Total	51.85 (8.96)	45.30 (10.97)	50.08 (12.69)	47.08 (11.88)	2.63 (1)	.11	0.03	52.48 (8.86)	47.67 (9.11)	50.08 (12.69)	47.08 (11.88)	0.53 (1)	.46	0.01
CPRS[b]														
ADHD symptoms	26.67 (5.17)	23.97 (6.02)	25.23 (6.17)	23.86 (6.60)	2.06 (1)	.15	0.03	27.95 (4.45)	25.00 (5.74)	25.23 (6.17)	23.86 (6.60)	2.05 (1)	.15	0.03
CGI[c]														
General condition rate	6.9 (11.28)	7.1 (12.65)	6.6 (15.59)	6.7 (12.55)	0.13 (1)	.71	0.00	7.2 (9.82)	7.0 (10.94)	6.6 (15.59)	6.7 (12.55)	0.25 (1)	.61	0.00
Cognitive functioning														
BRIEF-2[d]														
Inhibition	66.00 (12.64)	63.09 (12.60)	63.92 (12.19)	63.67 (12.86)	1.79 (1)	.18	0.02	68.48 (12.17)	63.81 (12.47)	63.92 (12.19)	63.67 (12.86)	3.89 (1)	.05	0.06
Self-supervision	66.58 (12.20)	63.76 (12.52)	63.19 (10.07)	61.14 (14.18)	0.17 (1)	.68	0.00	68.76 (11.36)	65.43 (12.08)	63.19 (10.07)	61.14 (14.18)	0.17 (1)	.68	0.00
Flexibility	69.00 (16.96)	67.82 (16.18)	66.81 (15.00)	65.86 (17.41)	0 (1)	.93	0.00	72.67 (16.53)	70.90 (15.46)	66.81 (15.00)	65.86 (17.41)	0.05 (1)	.80	0.00
Emotional control	63.45 (12.07)	59.76 (11.65)	62.25 (10.91)	61.03 (11.08)	1.25 (1)	.26	0.01	66.24 (10.09)	61.86 (10.72)	62.25 (10.91)	61.03 (11.08)	1.51 (1)	.22	0.02
Initiative	65.85 (11.71)	64.18 (12.38)	59.39 (11.76)	59.86 (13.68)	0.90 (1)	.34	0.01	65.62 (12.91)	65.62 (13.17)	59.39 (11.76)	59.86 (13.68)	0.03 (1)	.85	0.00
Working memory	71.27 (10.15)	66.36 (12.40)	67.22 (11.52)	65.94 (12.90)	3.49 (1)	.06	0.05	71.48 (11.69)	64.33 (16.17)	67.22 (11.52)	65.94 (12.90)	4.08 (1)	.04	0.06
Planning and organization	67.88 (9.83)	66.52 (11.29)	62.61 (11.21)	62.39 (11.70)	0.49 (1)	.48	0.00	68.62 (10.70)	67.14 (11.72)	62.61 (11.21)	62.39 (11.70)	0.56 (1)	.45	0.01
Task supervision	65.36 (11.92)	62.82 (13.00)	62.47 (10.12)	61.03 (12.50)	0.40 (1)	.52	0.00	64.57 (13.73)	61.95 (13.82)	62.47 (10.12)	61.03 (12.50)	0.44 (1)	.65	0.00
Material organization	73.76 (13.01)	71.03 (12.71)	65.44 (13.96)	64.36 (16.19)	0.61 (1)	.43	0.00	75.95 (13.23)	70.00 (12.16)	65.44 (13.96)	64.36 (16.19)	4.75 (1)	.03	0.08
Behavioral regulation Index	67.73 (12.38)	64.70 (12.95)	64.92 (12.25)	63.94 (12.41)	1.06 (1)	.30	0.01	70.29 (11.77)	65.95 (12.72)	64.92 (12.25)	63.94 (12.41)	2.29 (1)	.13	0.04
Emotional regulation Index	68.55 (15.28)	65.30 (13.97)	66.39 (12.27)	64.97 (13.78)	0.64 (1)	.42	0.01	72.14 (14.01)	68.10 (12.19)	66.39 (12.27)	64.97 (13.78)	0.96 (1)	.33	0.01
Cognitive regulation index	72.64 (11.31)	69.36 (12.98)	66.28 (11.93)	65.56 (13.90)	2.52 (1)	.11	0.03	73.10 (13.09)	69.33 (13.92)	66.28 (11.93)	65.56 (13.90)	3.42 (1)	.07	0.05
Global executive function	75.88 (16.29)	70.39 (13.13)	71.44 (17.28)	70.44 (19.40)	3.56 (1)	.06	0.03	76.05 (11.83)	71.38 (12.87)	71.44 (17.28)	70.44 (19.40)	3.58 (1)	.06	0.06

	Intention-to-treat (at least 10 sessions; n=69)							16 sessions (n=57)						
	MOON (n=33), mean (SD)		Control (n=36), mean (SD)		*F* test (*df*)	*P* value	ηp^2	MOON (n=21), mean (SD)		Control (n=36), mean (SD)		*F* test (*df*)	*P* value	ηp^2
	Pre	Post	Pre	Post				Pre	Post	Pre	Post			
CPT-3[e]														
Detectability	45.97 (11.71)	46.88 (13.11)	47.67 (8.70)	45.25 (9.35)	3.29 (1)	.07	0.04	46.81 (11.38)	49.57 (13.60)	47.67 (8.70)	45.25 (9.35)	5.92 (1)	.01	0.09
Omissions	50.67 (13.62)	52.27 (15.08)	49.00 (8.07)	48.97 (11.69)	0.43 (1)	.51	0.00	52.95 (15.99)	56.10 (17.68)	49.00 (8.07)	48.97 (11.69)	1.08 (1)	.30	0.01
Commissions	44.73 (9.78)	45.33 (10.29)	46.25 (8.65)	43.97 (7.77)	2.92 (1)	.09	0.04	43.81 (8.75)	46.00 (10.20)	46.25 (8.65)	43.97 (7.77)	5 (1)	.02	0.08
Perseverations	51.55 (11.57)	54.15 (15.76)	50.64 (10.97)	50.11 (8.71)	1.07 (1)	.30	0.01	52.67 (13.39)	58.10 (18.55)	50.64 (10.97)	50.11 (8.71)	2.66 (1)	.10	0.04
HRT[f]	57.76 (12.82)	56.91 (11.14)	56.22 (8.58)	58.19 (10.95)	2.61 (1)	.11	0.03	59.81 (13.67)	58.76 (11.47)	56.22 (8.58)	58.19 (10.95)	1.98 (1)	.16	0.03
HRTsd[g]	51.21 (14.38)	53.52 (15.64)	51.19 (9.21)	51.56 (11.98)	0.63 (1)	.43	0.00	53.90 (16.18)	58.81 (16.28)	51.19 (9.21)	51.56 (11.98)	2.49 (1)	.12	0.04
Variability	50.69 (12.80)	49.52 (9.87)	51.53 (10.19)	50.69 (8.77)	0.40 (1)	.52	0.00	50.90 (13.73)	52.53 (11.00)	51.53 (10.19)	50.69 (8.77)	0 (1)	.93	0.00
Block change	48.28 (8.69)	50.73 (9.84)	50.42 (10.09)	52.08 (12.43)	0.03 (1)	.85	0.00	48.45 (10.25)	51.52 (12.01)	50.42 (10.09)	52.08 (12.43)	0.08 (1)	.76	0.00
Inter stimulus change	52.67 (12.77)	57.30 (13.44)	51.97 (10.31)	54.14 (12.01)	1.25 (1)	.26	0.01	55.67 (14.06)	61.81 (13.83)	51.97 (10.31)	54.14 (12.01)	2.20 (1)	.14	0.03
Corsi														
N span (items recalled)	5.66 (1.15)	5.79 (1.21)	5.17 (0.98)	5.03 (1.20)	0.38 (1)	.53	0.00	5.55 (1.35)	5.67 (1.35)	5.17 (0.98)	5.03 (1.20)	0.27 (1)	.60	.00
CTMT-2[h]														
Inhibitory control	44.24 (14.41)	52.33 (15.42)	46.06 (13.77)	53.72 (13.62)	0.15 (1)	.69	0.00	41.43 (15.66)	50.95 (17.40)	46.06 (13.77)	53.72 (13.62)	0.74 (1)	.39	.01
Set shifting	43.55 (16.72)	52.24 (15.33)	45.60 (12.79)	49.97 (12.09)	4.06 (1)	.04	0.05	41.24 (17.19)	50.00 (16.15)	45.60 (12.79)	49.97 (12.09)	3.05 (1)	.08	.05
Total	43.82 (14.86)	52.76 (15.59)	45.74 (12.37)	52.39 (11.82)	1.95 (1)	.16	0.02	41.19 (15.58)	51.00 (17.33)	45.74 (12.37)	52.39 (11.82)	2.45 (1)	.12	.04

[a]SNAP-IV: Swanson, Nolan, and Pelham Rating Scale.

[b]CPRS: Conners Abbreviated Symptom Questionnaire.

[c]CGI: Clinical Global Impression.

[d]BRIEF: Behavior Rating Inventory Executive Function, version 2.

[e]CPT-3: Conners' Continuous Performance Test Third Edition.

[f]HRT: Hit Reaction Time.

[g]HRTsd: Hit Reaction Time SD.

[h]CTMT-2: Comprehensive Trail-Making Test, Second Edition.

Cognitive Functioning

In the BRIEF-2 questionnaire evaluated by parents, statistically significant differences were observed in the MOON group that was more involved (at least 16 sessions) in material organization ($F_{1, 55}$=4.75; *P*=.03; η^2=0.08), working memory ($F_{1, 55}$=4.08; *P*=.05; η^2=0.06), and inhibition ($F_{1, 55}$=3.89; *P*=.05; η^2=0.06). Some statistically significant differences were also found in the cognitive tests performed by the participants. In the CPT-3 test, improvements in detectability were found ($F_{1, 55}$=5.92; *P*=.01; η^2=0.09) in MOON group; however, significant differences in commissions ($F_{1, 55}$=5.00; *P*=.02; η^2=0.08) were found in favor of the control group; in the CTMT-2 test, an improvement in the MOON group was found in set shifting ($F_{1, 66}$=4.06; *P*=.04; η^2=0.05; Table 7; Multimedia Appendices 6 and 7).

Clinical trends of improvement with MOON versus control (ITT=69) were observed in working memory ($F_{1, 67}$=3.49; *P*=.06; η^2=0.05), inhibition ($F_{1, 67}$=1.79; *P*=.18; η^2=0.02),

cognitive regulation index ($F_{1, 67}$=2.52; P=.11; η^2=0.03), and global executive function ($F_{1, 6}$=3.56; P=.06; η^2=0.03).

Side Effects

There were no interruptions due to adverse events. None of the participants had side effects related to the VR treatment lasting >1 hour after use. In total, 2 patients reported discomfort from the weight of the VR headset, so the researchers offered the possibility of using the computer game.

We found no significant differences in video game addiction between the groups assessed with the GASA questionnaire.

No mild, moderate, or notable side effects were found (Multimedia Appendix 8). Patients who described a causal relationship with the video game through the UKU questionnaire (possible or probable) reported dizziness and increased dream activity (Figure 3; Multimedia Appendices 9 and 10). The mean score for dizziness across the 10 sessions was 0.10 (SD 0.08); the mean score for increased dream activity was 0.31 (SD 0.13; 0=no side effects and 1=mild side effects that do not interfere with patient performance) and was decreasing across sessions; however, some participants (15/26, 58%) reported increased dream activity across sessions.

In relation to sleep problems measured with the Sleep Disturbance Scale for Children questionnaire, no significant differences were found in the number of hours slept (mean in both groups=8-9 h) or in the time taken to fall asleep (mean 15-30 min). Nonetheless, an improvement in favor of the MOON group was found in the disorders of excessive somnolence scale ($F_{1, 65}$=4.55; P=.03; η^2=0.06; Table 8).

Figure 3. (A) Total mean of the side effects per session, specifically for the most relevant side effects: (B) dizziness (mean 0.10) and (C) increased dream activity (mean 0.31). UKU: Udvalg für Kliniske Undersogelser.

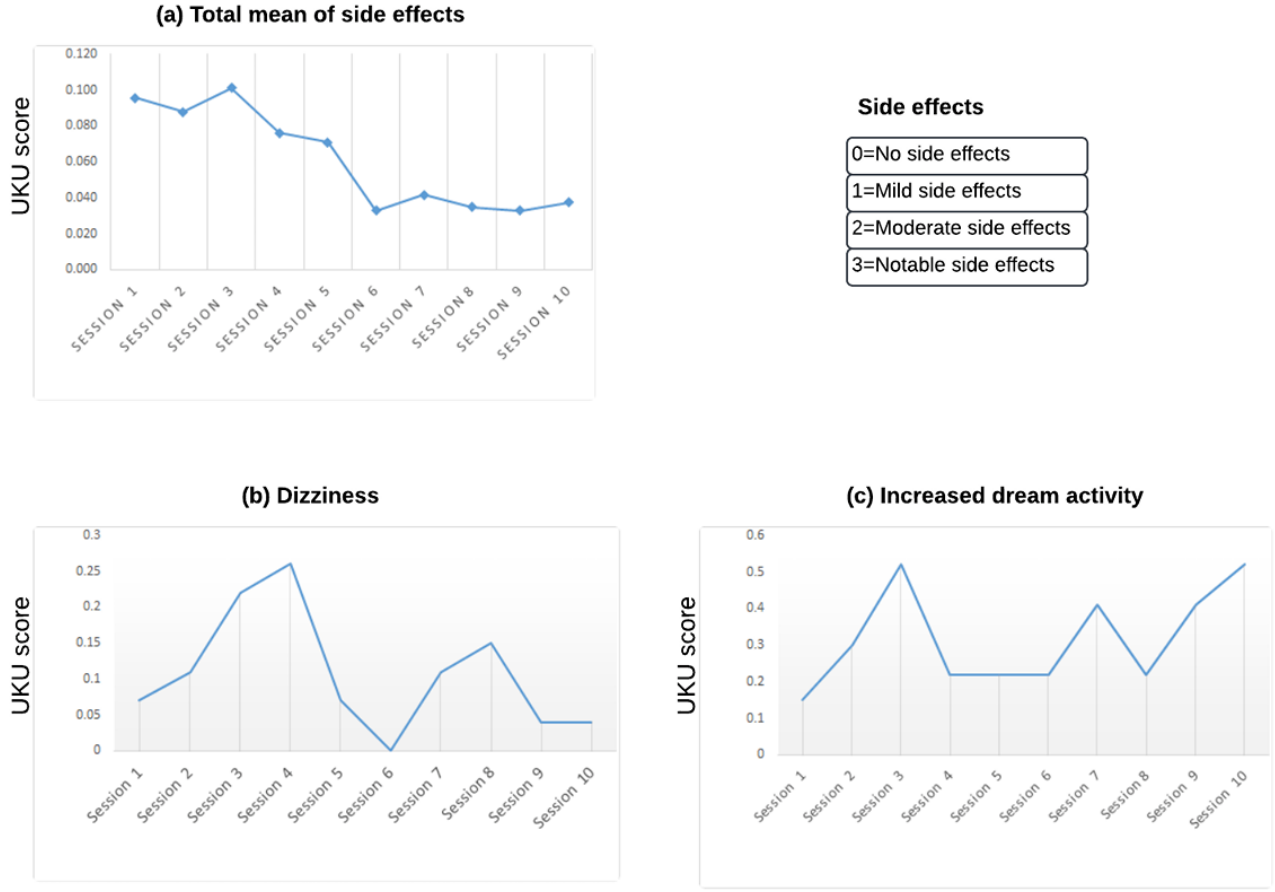


Table 8. Secondary outcomes related to hypothesis 6: there are no clinically meaningful side effects associated with the video game (N=69).

Safety outcomes	Intention-to-treat (at least 10 sessions)					
	MOON[a] (n=33), mean (SD)		Control (n=36), mean (SD)		*F* test (*df*)	*P* value
	Pre	Post	Pre	Post		
Game addiction (GASA[b])	17.42 (5.75)	15.70 (5.48)	17.06 (5.25)	15.89 (5.24)	0.32 (1)	.57
Sleep disorders (SDSC[c])						
Sleeping hours	2.37 (0.94)	2.39 (0.65)	2.33 (0.92)	2.50 (0.56)	0.57 (1)	.44
Time to sleep	2.52 (1.30)	2.15 (0.79)	2.38 (1.24)	2.05 (0.71)	0.00 (1)	.99
DIMS[d]	15.53 (4.70)	15.72 (4.60)	15.24 (5.97)	14.74 (5.62)	0.04 (1)	.83
SBD[e]	4.13 (1.99)	3.87 (1.47)	4.22 (1.80)	4.36 (1.93)	1.70 (1)	.19
DA[f]	4.38 (1.86)	4.15 (1.58)	3.97 (1.40)	3.86 (1.24)	0.13 (1)	.71
SWTD[g]	11.88 (4.15)	11.56 (3.78)	11.37 (4.56)	11.64 (5.05)	0.18 (1)	.67
DOES[h]	12.09 (4.05)	11.09 (3.97)	9.51 (3.28)	10.00 (4.27)	4.55 (1)	*.03*
SHY[i]	3.47 (1.91)	3.42 (1.78)	4.19 (2.60)	4.11 (2.43)	0.01 (1)	.90
Total	55.40 (10.63)	55.00 (10.57)	55.43 (14.59)	53.28 (14.79)	1.04 (1)	.31

[a]MOON: *The Secret Trail of Moon*.

[b]GASA: Game Addiction Scale for Adolescents.

[c]SDSC: Sleep Disturbance Scale for Children.

[d]DIMS: disorders of initiating and maintaining sleep.

[e]SBD: sleep breathing disorders.

[f]DA: disorders of arousal nightmares.

[g]SWTD: sleep-wake transition disorders.

[h]DOES: disorders of excessive somnolence.

[i]SHY: sleep hyperhidrosis.

Adherence and Acceptability

Additional information was collected using an unvalidated scale (previously applied in our usability study [47] to obtain the patients' opinion of the video game). Of the 33 participants who played MOON, 21 (64%) played video games on a habitual basis and 20 (61%) had tried VR before. In total, 82% (27/33) of the participants liked the experience; 79% (26/33) of the participants would recommend it to other people with ADHD.

Additional information was collected on fatigue, boredom, or dizziness (in the case of VR). In total, 24% (8/33) of the participants experienced fatigue (not surprising in cognitive training), 13% (4/33) found it boring, and 7% (2/33) were dizzy on ≥1 occasions. The overall experience was considered positive, as reported by the parents. Some parents mentioned perceiving improvement in thinking before acting, responsibility, autonomy, and organization; others did not perceive changes. Some parents considered that we should have held more weekly sessions.

Most of the participants and their parents preferred face-to-face sessions to web-based sessions. Bugs (video game errors) were considered especially frustrating in the web-based sessions by both children and parents, especially in the interface or in games such as chess. The levels were considered well balanced, except for Kuburi (too demanding and frustrating). Overall, the video game music was liked by the participants; some patients said it helped them to concentrate.

Discussion

Principal Findings

In this prospective, single-center, randomized, unblinded pre-post evaluation study, our primary hypothesis of a 3-point decrease in the global SDQ score for emotional regulation after 3 months of MOON cognitive training in clinically stable, medicated children and adolescents with ADHD was not confirmed. However, we observed improvement trends in specific areas among patients who were more engaged with the MOON treatment. After conducting an ANCOVA with the number of sessions as a covariate, we found values approaching significance for the main hypothesis, with a 2-point drop in the global SDQ. This suggests that motivation may have played a key role in the improvement of emotional regulation in the participants. Given that motivation is a crucial factor in individuals with ADHD, it likely influenced these outcomes [21,24,31].

Considering the number of sessions as a covariate, significant differences in emotional symptoms and internalizing problems were found in favor of the experimental group. No behavioral improvement trends were observed. While externalizing difficulties are related to temperamental negative affect and

anger dysregulation (bottom-up processes), internalizing difficulties suggest an overregulation of negative emotion through maladaptive cognitive strategies such as blaming and ruminating (top-down processes, more closely linked to executive functions) [48-50]. Participants with externalizing problems may have found the video game lacking in external rewards (eg, prizes), unlike those participants with greater intrinsic motivation (eg, self-improvement and sense of progress). This clinical trial had significantly more sessions than the previous one (20 vs 12) [29], increasing the need for novelty, change, and reinforcement. However, as participants noted in their feedback, the game did not seem to meet these reward-based needs effectively.

Our results also showed improvements in material organization, working memory, and inhibition in the 16-session MOON group. The improvement in working memory is in accordance with other investigations whose improvement in working memory occurred especially in those individuals who had a higher level of motivation and voluntary commitment to training [21,51] as well as the organization [52]. The ITT group also had an improvement close to significance. However, in the Corsi cubes (objective task of working memory), no significant differences were found; the MOON group had higher memory span than the control group, but this difference was very small. These results are consistent with other randomized controlled trials that showed significant improvements in ADHD symptoms and working memory but no improvements in other cognitive functions tested, such as planning or self-monitoring [53]. Regarding cognitive flexibility, significant differences were found in favor of the MOON group in set shifting on the CTMT-2 test, but it was not significant on the parent-reported flexibility subscale on the BRIEF-2 questionnaire.

Findings may point at a more powerful experience when using the VR experience. At least theoretically, VR may be more effective in tricking the brain than regular video games [28-30,47] suggesting a heightened sense of presence in the virtual environment and reduced perception of the real world, leading to fewer distractions [22]. In addition our findings may also just be a matter of age and brain maturity, perhaps related to the age of the VR users (aged >12 years years). Another putative explanation is that those who played on the computer experienced a more bugged and, consequently, more frustrating version of the game.

Furthermore, the use of MOON was well tolerated, as no clinically significant side effects were reported. There were no adverse events to report to the Spanish Agency of Medicines and Health Products. The VR intervention reported a mean dizziness score of 0.31 on the UKU scale, where 0 indicates no side effects and 1 indicates mild side effects, which did not interfere with patient performance. No significant differences were found in the GASA scale on video game addiction. In ADHD, this variable is especially important as there is a higher risk of addiction [54]. Serious video games versus commercial games allow controlling design variables about addiction [28].

Here, we found significant differences related to sleep in the subscale disorders of excessive somnolence in favor of the MOON group. As for the MOON group that played through VR, we also found that some of them remembered more of their dreams after the sessions, as assessed with the UKU scale. This phenomenon (although neither significant nor interfering) was consistent with the previous clinical trial [29]. While we do not consider this a concerning side effect, it is worth exploring the potential impact of VR on sleep.

This clinical trial has important limitations, particularly the smaller-than-planned sample size (n=152) that affected its statistical power [30]. Trends of improvement were observed in various areas, but a larger sample may have yielded statistically significant results. In addition, this investigation, such as the previous one, was not blinded [29]. The effect sizes are small, and we must interpret these results cautiously. The sessions were decreasing with the intervention with MOON on the web, and this suggests that the game was insufficiently developed, as mentioned by the users themselves. The reward system in the video game was only partially developed, which may have impacted motivation and caused the game to become repetitive. In addition, usability study would have been necessary before the clinical trial (as in the previous study [47] to refine the gameplay and correct bugs). Another limitation of the study was that hypothesis 4 could not be tested, and the corresponding analyses could not be performed, as academic grades were not collected consistently (only half of the parents provided this information).

Nonetheless, our results provide additional, albeit partial, support for incorporating serious video games into the multimodal treatment approach for ADHD. After conducting our second clinical trial, we considered that video games do not have to be for everyone. Heterogeneity in ADHD is substantial. While some patients found improvements related to cognitive training with MOON, others did not. Other training methods exist. To optimize the treatment of patients with ADHD, it is crucial to focus on individual interests and their strengths and difficulties to personalize the treatment to what the person needs. Video games can be another addition to complement multimodal treatment along with other interventions such as music training, physical exercise, regular interaction with nature, or learning a new language accompanied by a healthy peer support network and appropriate parenting. For example, to improve externalizing symptomatology, behavioral psychological therapy intervention strategies may be more effective, especially early in the preschool years [17]. Combining training with pharmacological treatment seems to enhance the benefits more than pharmacological treatment alone [23].

Conclusions

Serious video games combined with multimodal treatment can improve symptoms associated with ADHD. In this study, significant differences in inhibition, working memory, and material organization were observed in participants who were more engaged in the MOON treatment.

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Authors' Contributions

MM-M, MB-F, and HB-F carried out the research. HB-F was the principal investigator. MM-M and HB-F recruited the patients, and they performed the data collection. MM-M monitored the Calendly appointments and *The Secret Trail of Moon* home training data collection via PlayFab and designed the electronic case report form (REDCap [Research Electronic Data Capture]). MB-F entered the data into the program. MM-M, MR-Y, CG-T, and HB-F designed the video game. CL and PW provided research design ideas and statistical input. MB-F, AR, MM-M, and HB-F performed the statistical analyses. PL-G and HB-F supervised the study.

Conflicts of Interest

HB-F has received lecture fees from Takeda Pharmaceuticals and the laboratories BIAL, Rubio, and Rovi. He has also been granted 3 prizes for developing serious video games to treat attention-deficit/hyperactivity disorder: the Shibuya Prize by Takeda, first prize from the College of Psychologists of Madrid, and a prize for the best innovative health initiative within the Health Start campaign. He is the principal investigator of predoctoral contracts for training in health research (IFI16/00039); the coprincipal investigator of a Ministry of Economy, Trade, and Enterprise research grant (RTI2018-101857-B-I00); and the principal investigator of a Sincronia research project funded by the Start-up Bitsphi. Moreover, he is the recipient of (1) a Foundation for Innovation and Foresight in Health in Spain grant and (2) a Puerta de Hierro Segovia de Arana Institute of Health Research intensification grant and is involved in 2 clinical trials (Mensia Koala, Newrofeed study; ESKETSUI2002). He is also a cofounder of Haglaia Solutions and an employee and member of the advisory board of ITA Salud Mental (Korian).

Multimedia Appendix 1
CONSORT (Consolidated Standards of Reporting Trials) 2010 checklist of information to include when reporting a randomized trial.
[PDF File (Adobe PDF File), 69 KB - games_v13i1e59124_app1.pdf]

Multimedia Appendix 2
Secondary outcomes related to hypotheses 4: Patients with attention-deficit/hyperactivity disorder using The Secret Trail of Moon improve in academic performance compared with the control group.
[DOCX File , 17 KB - games_v13i1e59124_app2.docx]

Multimedia Appendix 3
Estimated marginal means pre-post measured with the Strengths and Difficulties Questionnaire (SDQ) for group 1: The Secret Trail of Moon (green solid line) and group 2: control (purple dashed line). The drop in score indicates symptom improvement. The prosocial scale of the SDQ is an exception, where improvement is indicated by an increase in the score.
[DOCX File , 219 KB - games_v13i1e59124_app3.docx]

Multimedia Appendix 4
Estimated marginal means measured with the Strengths and Difficulties Questionnaire (SDQ) at 3 time points (pre, mid, and post) for group 1: The Secret Trail of Moon (green solid line) and group 2: control (purple dashed line). The drop in score indicates symptom improvement. The prosocial scale of the SDQ is an exception, where improvement is indicated by an increase in the score.
[DOCX File , 101 KB - games_v13i1e59124_app4.docx]

Multimedia Appendix 5
Number of web-based sessions completed by The Secret Trail of Moon group.

[PNG File , 11 KB - games_v13i1e59124_app5.png]

Multimedia Appendix 6
Estimated marginal means of pre-post attention-deficit/hyperactivity disorder symptoms measured with the Swanson, Nolan, and Pelham Rating Scale and Conners Abbreviated Symptom Questionnaire for group 1: The Secret Trail of Moon (green solid line) and group 2: control (purple dashed line). The drop in both scores indicates symptom improvement.
[DOCX File , 110 KB - games_v13i1e59124_app6.docx]

Multimedia Appendix 7
Estimated marginal means of pre-post cognitive functioning measured with T scores of the Behavior Rating Inventory Executive Function, version 2, questionnaire for parents. Pre-post comparisons for the 2 groups: The Secret Trail of Moon (green solid line) and group 2: control (purple dashed line). Decreasing scores indicate symptom improvement.
[DOCX File , 300 KB - games_v13i1e59124_app7.docx]

Multimedia Appendix 8
Estimated marginal means of pre-post cognitive functioning measured with T scores of neuropsychological tests (Corsi cubes; and Comprehensive Trail-Making Test, Second Edition [CTMT-2]) for patients with attention-deficit/hyperactivity disorder. Pre-post comparisons for the 2 groups: The Secret Trail of Moon (green solid line) and group 2: control (purple dashed line). Decreasing scores indicate symptom improvement, except in Corsi cubes and CTMT-2 whose improvement is a rise in score.
[DOCX File , 306 KB - games_v13i1e59124_app8.docx]

Multimedia Appendix 9
Total means of relevant symptoms and side effects assessed with the Udvalg für Kliniske Undersogelser questionnaire (all 1).
[PNG File , 161 KB - games_v13i1e59124_app9.png]

Multimedia Appendix 10
List of side effects measured with the Udvalg für Kliniske Undersogelser test during 10 face-to-face sessions.
[DOCX File , 32 KB - games_v13i1e59124_app10.docx]

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
ANCOVA: analysis of covariance
BRIEF-2: Behavior Rating Inventory Executive Function, version 2
CGI: Clinical Global Impression
CPRS: Conners Abbreviated Symptom Questionnaire
CPT-3: Conners’ Continuous Performance Test Third Edition
eCRF: electronic case report form
GASA: Game Addiction Scale for Adolescents
ITT: intention-to-treat
MOON: The Secret Trail of Moon
PP: per-protocol
REDCap: Research Electronic Data Capture
SDQ: Strengths and Difficulties Questionnaire
SNAP-IV: Swanson, Nolan, and Pelham Rating Scale
UKU: Udvalg für Kliniske Undersogelser
VR: virtual reality

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Virtual Reality High-Intensity Interval Training Exergaming Compared to Traditional High-Intensity Circuit Training Among Medical Students: Pilot Crossover Study

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Abstract

Background: This study evaluated the effectiveness of a virtual reality (VR) high-intensity interval training (HIIT) boxing protocol compared to traditional high-intensity circuit training (HICT) in improving exercise motivation, engagement, and physiological responses among 30 healthy medical students.

Objective: The purpose was to compare the VR HIIT protocol, which involved using an Oculus Quest 2 for a futuristic exoskeleton game experience, with a traditional 12-exercise HICT.

Methods: In total, 30 medical students engaged in both VR HIIT, using an Oculus Quest 2 for a futuristic exoskeleton game experience, and a traditional 12-exercise HICT. Metrics included heart rate (HR) and blood lactate levels before and after exercise alongside ratings of perceived exertion and the Situational Motivation Scale.

Results: VR HIIT showed significantly higher mean HR (mean 161, SD 15 vs mean 144, SD 11 bpm; d=1.5; P<.001), peak HR (mean 182, SD 15 vs mean 176, SD 11 bpm; d=0.8; P=.001), and ratings of perceived exertion (mean 16, SD 2 vs mean 15, SD 2; d=0.4; P=.03). Postexercise lactate levels were higher in HICT (mean 8.8, SD 4.5 vs mean 10.6, SD 3.0 mmol/L; d=0.6; P=.006). Intrinsic motivation and other psychological measures showed no significant differences, except for lower fatigue in HICT (d=0.5; P=.02).

Conclusions: VR HIIT significantly enhances physiological parameters while maintaining intrinsic motivation, making it a viable alternative to traditional HICT. However, the short-term nature of this study is a limitation, and future research should explore the long-term engagement and therapeutic impacts of VR exercise in diverse and clinical populations.

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KEYWORDS

virtual reality; VR; high-intensity interval training; exercise motivation; exergame; physical activity; exercise; heart rate

Introduction

Exercise and physical activity contribute to enhanced health outcomes, leading to a reduction in the risk of chronic diseases such as cardiovascular disease, diabetes, and various types of cancer [1]. Despite the well-documented benefits of regular moderate- and high-intensity exercise in reducing health risk factors, a significant portion of the global population remains physically inactive. According to the World Health Organization [2], approximately 28% of adults worldwide do not engage in sufficient physical activity, as detailed in the "Global Action Plan on Physical Activity 2018‐2030" report. Physical inactivity has been identified as the fourth leading cause of mortality globally, accounting for approximately 6% of deaths, while obesity contributes to about 5% of mortality [1]. This lack of physical activity significantly increases the risk of heart

disease and diabetes across various countries and social groups regardless of income level [1]. Furthermore, it has been demonstrated that physical exercise is fundamentally important for energy balance and body mass control [3] and for mental health and sleep quality [4]. One of the most cited barriers to exercising is the lack of time and motivation [5].

High-intensity interval training (HIIT) offers a solution to these barriers by providing a time-efficient and engaging exercise modality. HIIT consists of alternating short "bursts" of intense exercise with passive rest or active periods of low-intensity exercise [6,7]. Studies show that HIIT is equally beneficial, or perhaps even superior, to traditional continuous aerobic exercise in many variables related to health and fitness, such as cardiovascular endurance, metabolic rate, and muscle strength [7]. Specifically, for exercise to be considered true HIIT, it must include periods of exercise reaching 85% - 95% of the maximum heart rate (HR) during the high-intensity intervals [8].

Additionally, HIIT's design facilitates sustaining high-intensity activity peaks during exercise sessions. The high-intensity nature of HIIT protocols means that a complete exercise session can be performed in a shorter period (7-minute exercise) compared to classic continuous or endurance exercise protocols, making it a practical solution for time-restricted individuals [8]. However, sustaining the high intensity of HIIT can be challenging and uncomfortable, which can potentially decrease motivation for individuals [9].

In recent years, exergames (a combination of video games and exercise) have been proposed as a solution to improve motivation and engagement in physical exercise practice [9,10], and it has already demonstrated that exergames can bring benefits to the physical and mental health of players of different ages [11]. For example, exergames have been shown to improve physical fitness parameters such as cardiovascular endurance and muscle strength as well as enhance mental health outcomes such as motivation, affect, and mood restoration [12,13]. The advancement of virtual reality (VR) technologies, which allow greater sensory immersion, has provided an evolution of these devices from mere entertainment tools to potential serious games with significant health benefits [14,15]. A study suggested that playing VR exergames helps to promote enhancements in mood in young adults [16]. In addition, VR games using stationary bikes have incorporated HIIT protocols, effectively achieving the intensity required for cardiovascular and metabolic benefits. Studies have shown that VR enhances performance during HIIT [14], improves motivation [5], and maintains the necessary exercise intensity for health outcomes [17].

VR boxing may be a suitable exercise activity, given that it is feasible and effective with an HIIT protocol and logistically compatible without the need for specialized equipment. Boxing has been demonstrated to be feasible in VR [18], and high-intensity boxing training has been shown to be effective for improving fitness, making it suitable for HIIT [19]. This is endorsed by a recent study, which suggests that engaging in VR fitness boxing games can lead to vigorous physical activity with high energy expenditure comparable to traditional forms of exercise [20].

To distinguish an HIIT VR exergame from existing models [20], we emphasize a design that prioritizes greater freedom of movement, enabling players to engage in high-intensity exercises without the constraints of rigid gameplay mechanics [21,22]. Unlike traditional VR games that synchronize movement to specific patterns or beats, where players must ever dodge or hit approaching orbs and objects [20], the new approach allows for dynamic and unrestricted physical activity within a clear HIIT time structure [6,23]. During each bout, players are encouraged to deliver as many shots as possible, reinforcing the all-out effort characteristic of HIIT [6], while maintaining a more immersive and intense workout experience [21,22]. In this study, we focused on the acute effects of a single session of the game to analyze exercise intensity using HR and blood lactate concentration, standard metrics in HIIT for assessing exercise intensity and physiological stress [6,23], and the immediate motivation to perform at higher intensities. This approach was chosen over a chronic study to directly assess how the game influences the intensity and motivation during high-intensity exercise sessions.

The objective was to evaluate how a VR exergame, Move Sapiens, influenced acute physiological responses and exercise motivation in comparison to a traditional high-intensity circuit training (HICT) model. The primary outcome of this study was the physiological response to VR HIIT compared to the control, a traditional HICT, measured by HR and blood lactate levels. Secondary outcomes included psychological measures such as intrinsic motivation, identified regulation, external regulation, and amotivation, assessed using the Situational Motivation Scale (SIMS). Exploratory outcomes included ratings of perceived exertion (RPE) and symptoms of simulator sickness.

Methods

Participants

The sample size calculation was based on the exergame study of Martin-Niedecken et al [9], which, although not identical in design, also focused on an HIIT exergame. With an effect size of d=0.73, guided by cardiac responses reported in their study, we aimed for 80% power and a 5% significance level. This necessitated at least 11 participants per condition or group to provide objective, quantifiable data critical for evaluating exercise intensity and effectiveness. G*Power software (Heinrich-Heine-Universität Düsseldorf) was used for this transparent and reproducible calculation. However, due to the convenience of the sample, this study increased the participant pool to 30 healthy individuals aged 18 to 30 years, consisting of both male and female medical students from the Federal University of Rio Grande do Sul School of Medicine (Table 1). Recruitment was conducted through advertising on social networks and within the university community. Participation in the research was entirely voluntary, with students given the option to freely choose whether to take part. Nonparticipation did not result in any detriment to their university activities, ensuring that the right to choose was fully respected without any prejudice or consequence. Maximal HR was calculated using the 220−age formula [24].

Participants were required to be healthy and free of major health issues, including severe psychiatric disorders, cardiovascular diseases such as congenital heart defects or arrhythmias, serious chronic conditions like uncontrolled type 1 diabetes, binocular vision anomalies, or upper and lower limb neuromuscular restrictions. Additionally, individuals with recent muscular injuries, flu-like symptoms, or any infectious conditions that could hinder HIIT performance were also excluded. Participants were classified as gamers or nongamers based on their self-reported video gaming habits. Nongamers were defined as those who reported playing less than 1 hour of video games per week over the past 2 years [25], a criterion that did not include experience with VR gaming, given that everyone reported having no previous experience with VR exergames.

Table . Demographic and physiological characteristics (N=30).

Characteristic	Values
Age (years), mean (SD)	24 (3)
Body mass (kg), mean (SD)	69.0 (11.3)
Height (m), mean (SD)	1.69 (0.09)
BMI (kg/m^2), mean (SD)	24.1 (2.8)
Maximum heart rate (bpm), mean (SD)	196 (3)
Sex, n (%)	
Female	12 (40)
Male	18 (60)
Gamer, n (%)	19 (63)
Nongamer, n (%)	11 (37)
IPAQ SF[a], n (%)	
High	16 (53)
Moderate	6 (20)
Low	8 (27)

[a]IPAQ SF: International Physical Activity Questionnaire—Short Form.

Ethical Considerations

All participants provided written informed consent prior to participation in the study. The study protocol was reviewed and approved by the Federal University of Rio Grande do Sul Institutional Review Board (approval 59636722.1.0000.5327). Data collected during the study were anonymized to ensure participant confidentiality, and all privacy measures adhered to institutional and legal requirements. No financial compensation was provided to participants, as participation was entirely voluntary and without any expectation of remuneration.

Experimental Design

The study was conducted using a crossover design consisting of 3 visits. During the first visit, participants were introduced to the Move Sapiens exergame on the Oculus Quest 2 VR device (Meta) and the 12-exercise HICT. The familiarization session involved participants completing a half session of the exergame, which included 6 blocks of 16 seconds of exercise, followed by 20-second pauses. Additionally, participants performed 10 seconds in each of the HICT exercises. For the randomization of activities, the Research Randomizer tool (Social Psychology Network) [26] was used to generate a random sequence for each participant. This tool is specifically designed for research purposes and provides a reliable method for randomization [26], involved either the Move Sapiens exergame or the control exercise condition (HICT). All sessions occurred within the School of Medicine at Clinics Hospital of Porto Alegre, performed 48 hours apart, and at consistent times of the day to control for circadian variation. On test days, participants were instructed to abstain from other exercises and to avoid alcohol and caffeine for 12 hours before testing. These restrictions were emphasized during the study briefing and reinforced through reminders sent to participants 24 hours before each test session. Compliance was self-reported by participants upon arrival on test days.

Mint chewing gum was provided as a preventive measure to mitigate any potential initial discomfort related to motion sickness during the first visit [27], which served as a familiarization with the VR equipment and protocol. This was intended to help participants acclimate to the VR environment. No formal scale was used during the familiarization session; only anecdotal records about discomfort with VR were kept, and no participants reported any symptoms of motion sickness. Consequently, chewing gum was not provided in subsequent VR sessions, as the initial preventive measure appeared sufficient to alleviate any discomfort during the first exposure.

Procedures

VR Headset and Game Setup

Participants interacted with Move Sapiens using the Oculus Quest 2 VR headset, which was selected because the game was specifically developed for the Oculus platform. The Oculus Quest 2 provides an immersive VR experience through its

head-mounted display and 2 handheld controllers, which allow players to engage fully in the game's mechanics. Before beginning the session, a 5-foot by 5-foot (1.5 m by 1.5 m) play area was calibrated for each participant to ensure safe movement within the virtual environment. The floor level was also adjusted, and the headset straps were customized to fit each participant comfortably, ensuring optimal performance during gameplay.

High-Intensity Interval Protocols

In Move Sapiens, players are immersed by VR in a futuristic laboratory while equipped with advanced exoskeleton armor that enhances their physical abilities set within a narrative of futuristic human augmentation via virtual exoskeletons [28]. This setting serves as the backdrop for the first mechanic of the prototype, where the objective is to punch a drone as many times as possible during timed intervals. The armor features a heads-up display that provides players with essential information, including round time, rest periods, the number of completed rounds, and the total punches thrown. Visual and auditory cues guide the players through each phase, ensuring that they follow the high-intensity interval structure. This "hypercasual" prototype focuses on a simple, effective mechanic—delivering rapid punches—while a ranking system tracks the best sessions to motivate continued performance improvement.

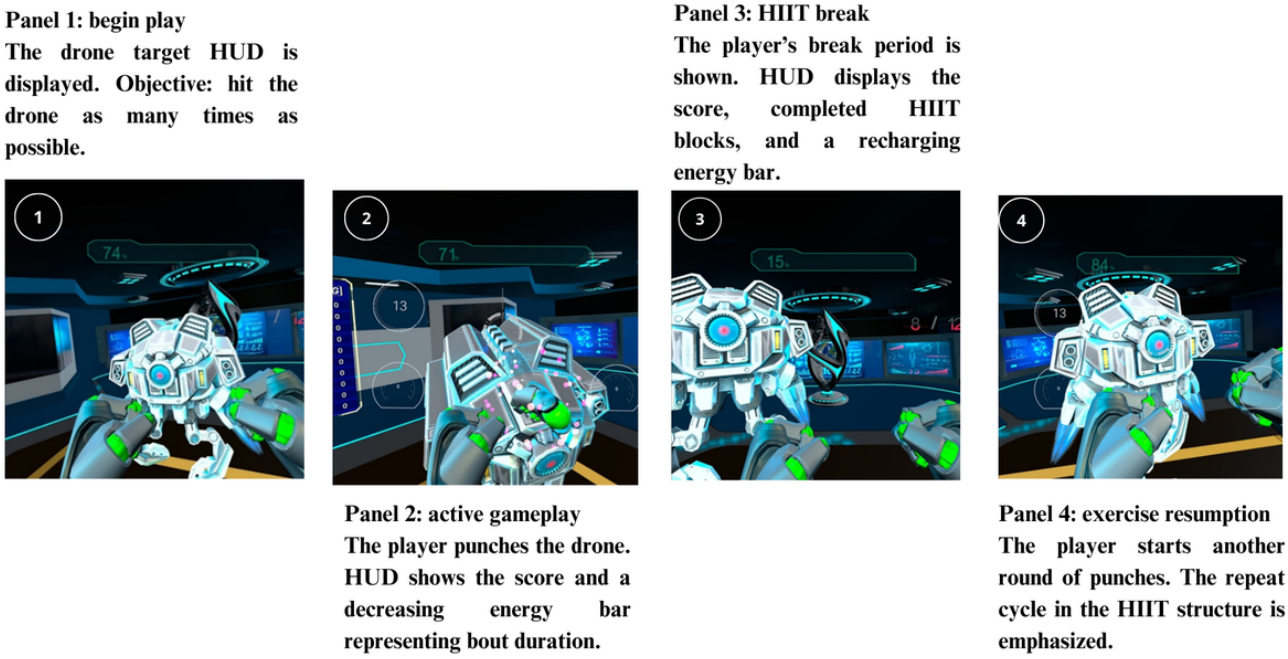
We used a low-volume HIIT protocol to mitigate typical VR usability issues such as dizziness [15], in addition to sweat and discomfort [29]. The following short HIIT shadow boxing all-out protocol was used: 12 sets of 16 seconds with 20 seconds of passive rest, lasting approximately 7 minutes, concluding with 1 minute of cooldown [6,23]. The HIIT protocol, including exact times for bouts and rest periods, was custom-integrated into the game. The bouts were controlled by the game itself, which provided cues to start and stop each bout, ensuring that participants followed the protocol accurately. During bouts, players were required to strike the virtual "dummy drone" as many times as possible with punches and scored points each time they hit the target.

The game mechanics are designed to reward the volume and speed of punches, encouraging players to deliver as many blows as possible at a high intensity. This approach motivates players to sustain a high level of effort, resulting in consistently vigorous exercise. In developing the simulation, we focused on creating a fast-punching experience by incorporating essential factors from existing VR boxing games [18,20] but with a more minimalist design [22,30]. This minimalist approach allows players greater freedom in their movements without being constrained by mechanics that require specific, predefined actions [22,31] (Figure 1). The game was developed using the Unreal Engine 4 platform (Epic Games).

As a comparator condition, we used an HICT protocol consisting of 12 exercises including jumping jacks, wall sits, push-ups, abdominal crunches, step-ups onto a chair, squats, triceps dips on a chair, planks, high knees running in place, lunges, push-up and rotation, and side planks [32]. Each exercise was performed for 30 seconds, with 10 seconds of transition time between sets. The total time for the entire circuit training was approximately 7 minutes.

The exercise and rest durations between the HIIT VR protocol and the HICT protocol differ, aimed at assessing external validity. The HICT protocol, with its 7-minute exercise duration, is widely used in home workouts and popularized by smartphone apps, making it a relevant comparison [32]. The objective was to compare 2 existing and widely available do-it-yourself exercise modalities.

Figure 1. Overview of Move Sapiens HIIT VR exergame mechanics. HIIT: high-intensity interval training; HUD: heads-up display; VR: virtual reality.



Subjective Measures

After each session, participants completed the Simulator Sickness Questionnaire, which uses a 0‐ to 3-point scale to measure simulator sickness symptoms across nausea, oculomotor, and disorientation subscales. This 16-item questionnaire rates symptoms from 0=none to 3=severe, enabling the evaluation of specific issues like stomach awareness, eyestrain, and dizziness. Responses provide subscale and total scores, quantifying the overall impact of simulator sickness [33]. Subjective perception of effort was recorded at the end of the test using a 6‐ to 20-point RPE scale [34]. The SIMS was used to evaluate both intrinsic and extrinsic motivation among participants, featuring 16 distinct items: (1) I think this activity is interesting, (2) I am doing it for my own good, (3) I am supposed to do it, (4) I do not see any good reasons for doing this activity, (5) I think this activity is pleasant, (6) this activity is good for me, (7) it is something I have to do, (8) I do this activity but do not see its value, (9) this activity is fun, (10) it aligns with how I choose to live my life, (11) I feel obligated to do it, (12) I do this activity but do not know what I gain from it, (13) I enjoy this activity, (14) this activity is important for me, (15) I feel forced to do it, and (16) I do not see what this activity brings me [35]. This comprehensive questionnaire is segmented into 4 motivational factors: intrinsic motivation, identified regulation, external regulation, and amotivation. Each factor is represented by specific items that participants respond to, rating their level of agreement or how applicable each statement feels to them on a nuanced 7-point scale. This scale ranges from 1=does not apply at all to 7=completely applies, facilitating a detailed exploration of participants' motivational states across various situations. The 16 items are designed to capture a wide range of motivational attitudes, from personal interest and enjoyment (intrinsic motivation) to compliance with external demands (external regulation) and lack of motivation (amotivation).

Objective Measures

HR was measured continuously during each 7-minute training session using an HR monitor (Polar H10) and was used to calculate average and peak HR. Blood samples were collected from the fingertip and immediately analyzed on a radiometer (ABL 800 flex, Radiometer; Radiometer Medical ApS) to determine blood lactate. Blood collections were performed twice: before the exercise and 5 minutes after the end of the exercise [36].

Data were analyzed using the RStudio software (version 2023.12.1, Build 402; RStudio PBC), and the significance level was defined at $P<.05$. Linear mixed models were used for all the analyses with condition (2 levels: HIIT VR vs HICT) as a fixed factor and participant ID as a random factor. Mean and peak HR as well as postexercise blood lactate were adjusted for baseline values with their addition to the model as a covariate. This was done to account for initial individual differences. This model was used due to its robustness to data missing at random. Data are represented as estimated means (emmeans) and 95% CIs, except stated otherwise. Cohen *d* was used to calculate effect sizes for objective and subjective data, offering a standardized way to evaluate the practical significance of the observed effects. For Cohen *d* calculation, a transformation from Student *t* values to Cohen *d* was performed:

$$d=2*t \div dferror$$

Cohen *d* classifications are interpreted as follows: a value below 0.2 indicates a very small effect, above 0.2 indicates a small effect, above 0.5 indicates a medium effect, and above 0.8 indicates a large effect.

Results

The results revealed significant differences in several metrics between VR HIIT and HICT. For mean HR, VR HIIT exhibited higher values (emmean 162 bpm, 95% CI 157-166) compared to HICT (emmean 143 bpm, 95% CI 138-147; $P<.001$; $d=2.07$; 95% CI 1.40-2.72; Figure 2A). Peak HR was also higher in VR HIIT (emmean 182 bpm, 95% CI 178-187) compared to HICT (emmean 175 bpm, 95% CI 170-180; $P=.001$; $d=1.20$; 95% CI 0.61-1.77; Figure 2B). Postexercise lactate concentration was higher following HICT (emmean 10.6 mmol/L, 95% CI 9.14-12.0) compared to VR HIIT (emmean 8.83 mmol/L, 95% CI 7.43-10.2; $P=.006$; $d=0.80$; 95% CI 0.25-1.34; Figure 2C). RPE were higher for VR HIIT (emmean 16, 95% CI 15-17) compared to HICT (emmean 15, 95% CI 14-16; $P=.03$; $d=0.61$; 95% CI 0.07-1.14).

Regarding reported symptoms, perceived fatigue (not RPE) was higher for VR HIIT (emmean 1.8, 95% CI 1.6-2.0) compared to HICT (emmean 1.5, 95% CI 1.3-1.7; $P=.02$; $d=0.67$; 95% CI 0.13-1.20). No other differences in symptoms were observed between conditions (all $P\geq.14$; Figure 3). There were no significant differences between VR HIIT and HICT for intrinsic motivation ($P=.06$; $d=0.53$), identified regulation ($P=.70$; $d=0.10$), external regulation ($P=.10$; $d=0.32$), or amotivation ($P=.35$; $d=0.26$).

Figure 2. Mean values of (A) mean HR, (B) peak HR, (C) postexercise lactate, and (D) RPE, along with their respective 95% CIs for the standard HIIT protocol (pink circles) and VR HIIT (blue circles). Individual participant data are represented by small dots, while a line connects their values between conditions. HICT: high-intensity circuit training; HIIT: high-intensity interval training; HR: heart rate; RPE: ratings of perceived exertion; VR: virtual reality. *Significant differences between protocols.

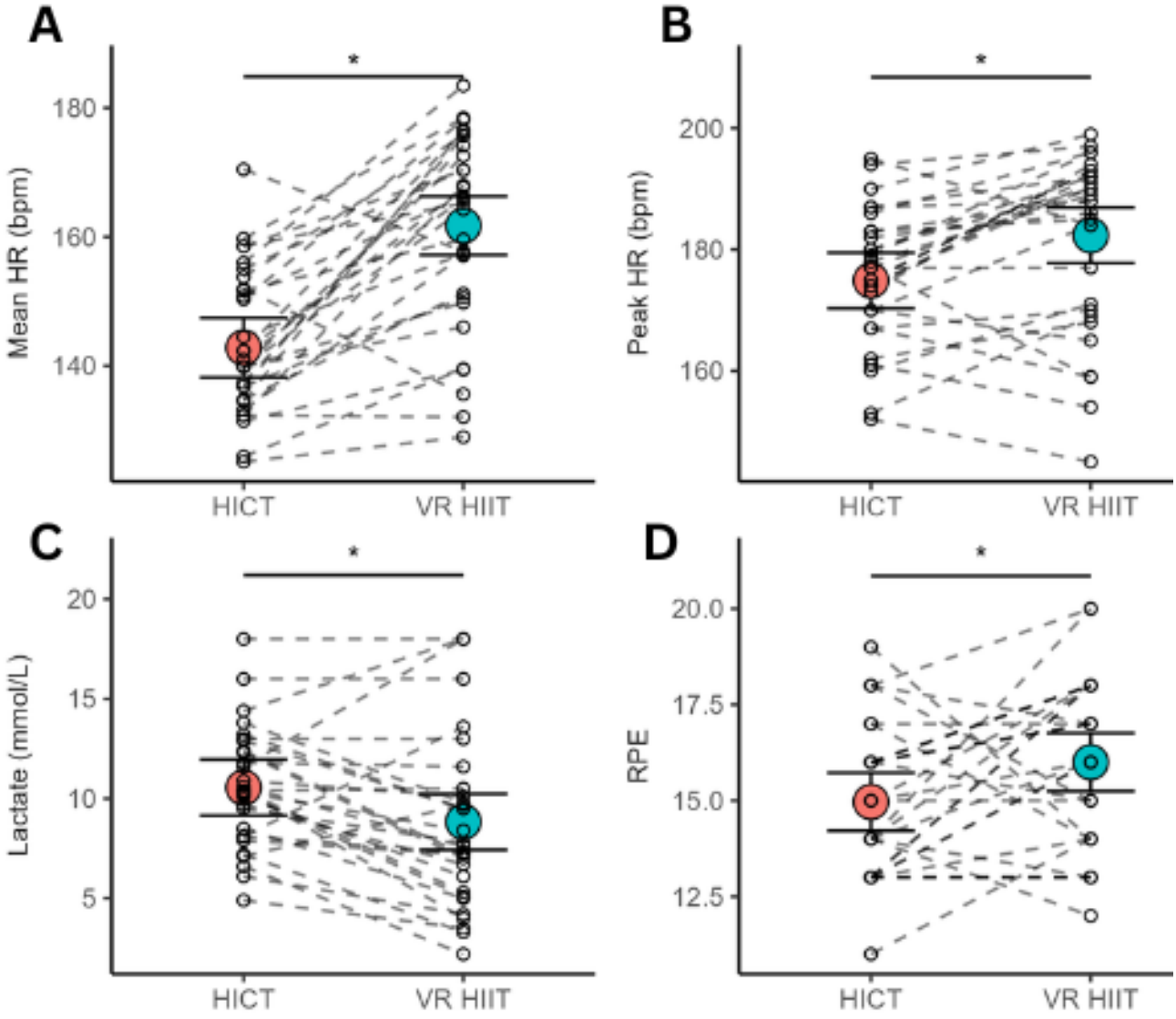
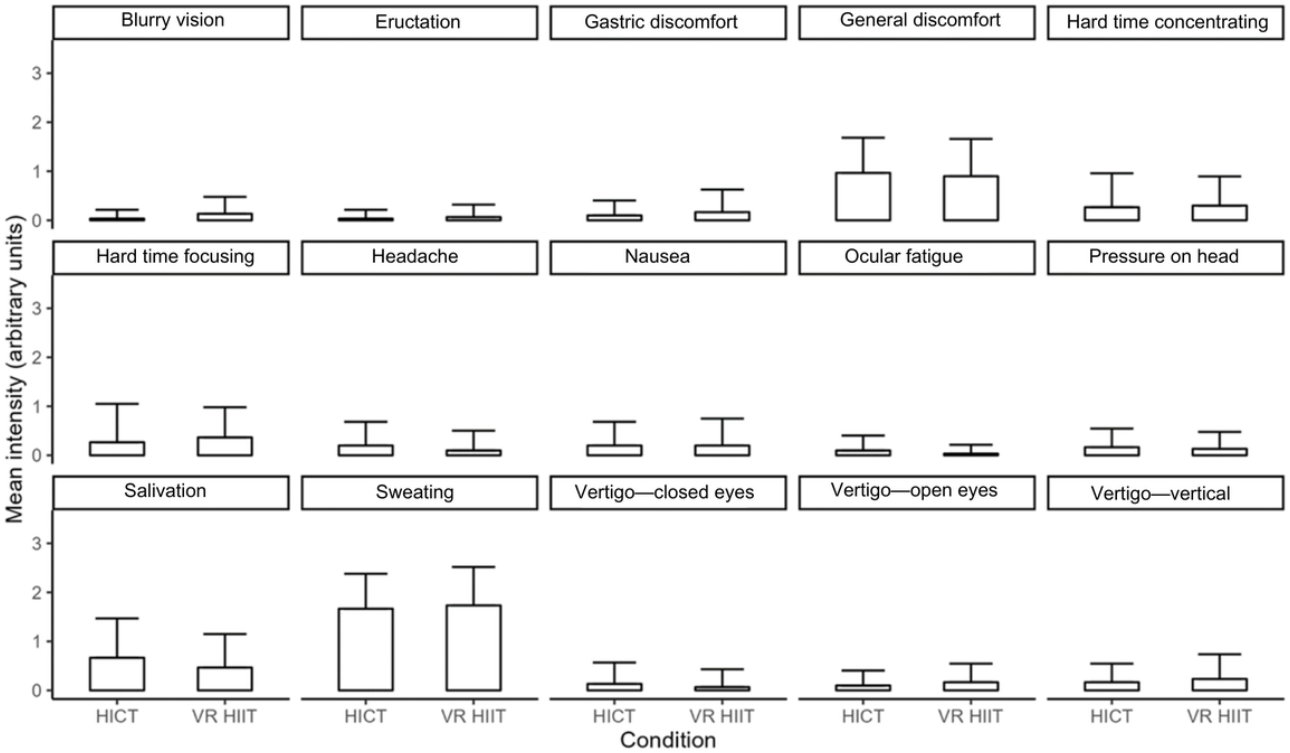


Figure 3. Summary of mean values for symptoms as reported by the participants. Values are represented as mean (SD). HICT: high-intensity circuit training; HIIT: high-intensity interval training; VR: virtual reality.



Discussion

Principal Findings

The findings from this study underscore the efficacy of VR HIIT exergaming to increase physiological measures such as HR and increase perceived exertion without reducing intrinsic motivation when compared to traditional HICT. This demonstrates that VR HIIT is not just effective in providing physical exercise benefits akin to those of HICT but also has the potential to maintain acute motivation for exercise. Despite the greater perceived exercise intensity, intrinsic motivation did not decrease, given the sensory stimuli of the VR environment. The immersive nature of VR HIIT, marked by interactive and engaging elements, may contribute to these positive outcomes [21,22]. This aligns with previous studies showing that VR exergaming effectively increases enjoyment during a single bout of HIIT in untrained individuals [14] and improves mood [16].

Lactate levels were substantially increased following both exercise sessions but were significantly higher in the HICT condition compared to the VR HIIT. This can be attributed to the nature of HICT, which typically incorporates a higher volume of strength exercises and calisthenics using body weight [32]. Such activities are known to facilitate a greater accumulation of metabolites due to the anaerobic nature of the exertion, leading to higher lactate production [37]. Despite this, the VR HIIT condition also achieved substantial blood lactate concentrations, indicative of significant metabolic stress [23,38]. Notably, this was achieved alongside higher values in HR during the exercise, suggesting that this VR HIIT boxing protocol effectively stimulates cardiovascular and metabolic responses even in the absence of traditional strength and calisthenic exercises [8]. Our HR results demonstrated that the VR HIIT boxing protocol achieved vigorous intensity levels comparable to the “Supernatural” VR fitness game’s flow and boxing modes. These modes are associated with significant caloric expenditure, ranging from approximately 12.01 to 13.11 kilocalories per minute, with metabolic equivalent of task values of 11.44 for flow and a peak of 12.49 for boxing at higher intensities. [20].

Importantly, the VR game, although a distinct exercise modality from HICT, induced metabolic stress like that of an exercise model validated to be performed independently [32]. This finding underscores the potential of VR HIIT to offer a comparable physiological challenge to HICT, leveraging the immersive and engaging qualities of VR technology to simulate a validated exercise environment effectively.

The exercise intensity within the VR setting is inherently self-selected, despite the game design being crafted to encourage engagement at the highest possible intensity levels [9,21]. Similarly, exercise intensity is also self-selected for HICT, as every type of exercise involves motivation, volition, and intensity self-regulation. The incentive to increase intensity in the game was a better score achieved via the greatest number of punches within the HIIT blocks [21,31]. The stimulus of the VR game may have led to increased effort during the activity, leading to increased HR. Whether this leads to greater health benefits or increased engagement in exercise over time remains to be investigated. Evidently, how to increase motivation response in VR is a considerable question ahead [39]. The foremost challenge lies in the evolution of game design, where the objective is to increasingly leverage game mechanics and sensory stimuli to foster higher motivation among users [21,22]. However, it is important to acknowledge that the novelty of VR may initially boost motivation and engagement, potentially

skewing performance in the short term [40]. This effect underscores the need for creating more compelling and immersive experiences that not only draw participants in [39] but also encourage them to exert themselves more vigorously during the exercise [9,14]. This endeavor requires a nuanced understanding of human motivation and behavior, alongside a mastery of VR technology, to craft experiences that are both engaging and physically demanding [41].

Future Directions

Integrating HIIT with VR in the study demonstrated a notable safety profile, with no adverse effects reported, particularly concerning motion sickness. The intersection of HIIT and VR with continuous innovation [42] represents a promising approach, particularly for improving engagement and motivation in exercise routines [21,43]. By combining the cognitive and physiological benefits of HIIT with the immersive qualities of VR, this approach holds the potential for a holistic method that addresses physical health. While this study did not specifically examine mental health special populations, the immersive and engaging nature of VR HIIT suggests potential applicability for these groups. This is particularly relevant for youth populations, such as patients with attention-deficit/hyperactivity disorder [44,45], who may benefit from such a different and multifaceted approach to exercise [21,46]. While the study confirmed safety among 30 medical students with heterogeneous physical activity levels, the findings are specific to this group. More research is needed to determine the effectiveness of VR HIIT exergames for these kinds of patients.

Limitations

This study acknowledges certain limitations, primarily its reliance on physiological markers, such as HR and blood lactate levels, and subjective motivation assessments [47]. The study uniformly administered the Simulator Sickness Questionnaire after the exercise across both experimental and control conditions. While this approach maintains comparability, it does not capture baseline symptom levels [48]. We chose to compare an HIIT VR protocol to a traditional HICT protocol, which may have led to some of the differences observed.

The study uniformly administered the SIMS after the exercise across both experimental and control conditions. While this approach maintains comparability, it does not capture baseline motivation or symptom levels [48], limiting our ability to assess changes in motivation due to the exercise protocols themselves. Additionally, the choice of highly active participants, who likely had high baseline motivation, may have introduced a ceiling effect, making it difficult to detect significant changes in motivation between the VR HIIT and HICT conditions. This limitation should be considered when interpreting the null findings in motivation, as the participants' pre-existing motivation levels could have constrained the potential for further increases. Importantly, we do not infer any superiority of either exercise type despite some differences in physiological responses, and further research should make comparisons between our VR HIIT protocol and other non-VR HIIT protocols.

The data derived from this study do not necessarily suggest that VR HIIT will be better adhered to over the long term nor that it will generate similar or better results when applied in a prolonged context. This points to a significant area for future investigation, emphasizing the need to assess the long-term adherence to, and effectiveness of, VR HIIT programs [16,39]. Despite these constraints, the findings contribute valuable information on the physiological responses to VR HIIT. Although the study did not show significant changes in intrinsic motivation, it demonstrated that VR HIIT does not reduce intrinsic motivation compared to HICT. Since subjective motivation plays a crucial role in determining whether participants will continue to engage in an activity [39,49], future research should aim to enhance subjective motivation and examine its impact on long-term adherence and engagement.

Conclusions

VR HIIT achieves acute significant increases in key physiological measures, affirming its effectiveness as an exercise modality comparable to traditional HICT in terms of likely long-term physical benefits. The combination of VR and HIIT has proven to be safe, with no adverse effects, and has maintained intrinsic motivation despite greater perceived exercise intensity due to the sensory stimuli provided by the VR environment. Additionally, VR HIIT's capacity to deliver immersive and tailored exercise experiences presents promising applications in therapeutic contexts, particularly for populations with specific needs where conventional exercise methods may fall short. While this study demonstrates the immediate benefits of VR HIIT, future research is essential to evaluate the sustained engagement and long-term health outcomes associated with this modality. Investigating its impact over extended periods will be crucial to fully understand the breadth of VR HIIT's benefits and to optimize its application for various exercise and therapeutic needs, particularly in clinical populations.

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Conflicts of Interest

PM is the chief executive officer and MCC is the chief technology officer of the startup Move Sapiens, and both are creators of the exergame used in this study.

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Abbreviations

emmean: estimated mean
HICT: high-intensity circuit training
HIIT: high-intensity interval training
HR: heart rate
RPE: ratings of perceived exertion
SIMS: Situational Motivation Scale
VR: virtual reality

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Tongue Muscle Training App for Middle-Aged and Older Adults Incorporating Flow-Based Gameplay: Design and Feasibility Pilot Study

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Abstract

Background: Complications due to dysphagia are increasingly prevalent among older adults; however, the tediousness and complexity of conventional tongue rehabilitation treatments affect their willingness to rehabilitate. It is unclear whether integrating gameplay into a tongue training app is a feasible approach to rehabilitation.

Objective: Tongue training has been proven helpful for dysphagia treatment. Following the development of a tongue training app, a feasibility trial aimed to identify physiological and psychological factors that affect user and flow experience and explored whether training specialized muscles could produce a flow experience for optimal immersion. We aimed to provide a useful tool for medical rehabilitation so that older adults could retain tongue muscle flexibility.

Methods: After consulting professional nurses, we developed a mobile gaming app for middle-aged and older adults to train their tongue muscles. This pilot study used an image recognition system to detect the tongue movements of 32 healthy middle-aged and older adults (7 males, 21.9%; 25 females, 78.1%) during 3 game training tasks, each requiring different reaction speeds. Their physiological and psychological signals, as well as the results of the Flow State Scale 2 (FSS2) questionnaire, were used for correlation analysis regarding relevant flow experiences to establish and evaluate the feasibility of our method.

Results: Through exploratory factor analyses, a 2-factor (operation and immersion) structure was confirmed to have an adequate model fit (χ^2_{36}=448.478; P<.001; Kaiser-Meyer-Olkin=0.757) and internal consistency reliability (Cronbach α=0.802). The slow, medium, and fast levels all significantly affected the FSS2 score for operation (P=.001), the National Aeronautics and Space Administration Task Load Index (P<.001), and flow distance (P<.001). K-means clustering revealed that participants could be further categorized into 3 groups. Through the analysis of changes in the participants' physiological and psychological signals for each given task, Pearson correlation indicated that changes were primarily related to flow distance. For the 12 indicators measured in this study, the low, medium, and high operation groups showed significance in 58% (7/12), 50% (6/12), and 25% (3/12) of the indicators, respectively. Similarly, the low, medium, and high immersion groups had changes in 50% (6/12), 33% (4/12), and 17% (2/12) of indicators, respectively.

Conclusions: Our research supports the further development of a gaming app to aid older adults with tongue muscle training and measure flow using physiological and psychological signals to enhance training accuracy and feasibility. Next, we aim to conduct a randomized pilot trial, improve app functions, offer alternative rehabilitation options, and encourage long-term participation. Future goals include enhancing long-term efficacy, diversifying training modes, and adding a multiuser interactive option for an added challenge.

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KEYWORDS

exergame; mobile app; flow; self-care; feasibility; older adults; dysphagia; tongue exercises

Introduction

Background

Compared with desktop-based platforms, mobile phones can provide on-demand leisure and game time [1], in addition to being a handy tool for daily life [2]. Mobile health has become a promising tool to assist older adults with self-care through health and personal care education, medication compliance support, dietary restriction support, setting exercise goals, stress reduction strategies, calling for assistance, and gaining skills for self-management [3]. Mobile health further provides patients with the ability to share data with caregivers and establishes a simple but proactive framework for health management [4].

Dysphagia can lead to rapid aging, disease, and weakened oral expression skills. In older adults, dysphagia is accompanied with a risk of aspiration pneumonia [5-8]. These effects and symptoms affect social activities as well as reduce the dignity and self-esteem of patients [9]. Therefore, the prevention of dysphagia and reduction of potential symptoms are critical.

Disease Prevention Through Tongue Exercise

Studies have used oral diadochokinesis assessments together with the 10-item Eating Assessment Tool (EAT-10) to evaluate swallowing function [10]. To reduce swallowing impairments in older individuals, the use of speech, tongue-resistance exercises, and head-raising exercises have been noted [11-13]. Tongue-strengthening training devices or exercises [14] are intended to improve swallowing [15-17]. In general, there are 3 different tongue-training methods: stimulus-response therapeutic tongue exercises, playing computer games with the tongue using a tongue drive system, and tongue-protrusion tasks. Findings derived from these tongue-training methods suggest a differential effect of tongue-training paradigms on training-induced cortical plasticity and subject-based scores of fun, motivation, and pain in healthy participants [18]. In addition, exergame training can result in neuroplasticity and cognitive improvement for older adults who are institutionalized [19], while increasing cognitive and physical function in healthy individuals. Exergame training incorporating both cognitive engagement and physical activity exerts greater benefits than cognitively engaging video game training alone [20].

Incorporating gameplay into rehabilitation and training can make such regimens more interesting. Most exergames have been used to improve balance, reduce the effects of Parkinson disease [21], alleviate depressive symptoms in adults [22], and also improve overall fitness [23]. To date, however, there have been very few studies regarding tongue muscle training.

Roles of Physiological Signals

Having a higher heart rate variability (HRV) is a biomarker reflecting autonomic function and is associated with a greater emotional well-being [24]. It is known that the effect of transcutaneous auricular vagus nerve stimulation on HRV is not regulated by the duration of stimulation. In fact, changes in HRV occur most substantially at the beginning of stimulation [25]. Physiological signals such as pulse, respiration, blood pressure, heart rate, and body temperature can be collected by physiological sensors [26,27]. For example, Garmin device monitors can collect accurate data on heart rate and the number of steps taken during the day [28]. There are also biosensors, which can recognize audio features [29], facial expressions [30], body gestures [31], and even touches on sensitive screens [32]. Furthermore, biosensors can be useful for the detection of emotions by monitoring autonomic nervous system activity [33,34]. Heart rate is a common measurement for cardiovascular strain during training and can provide a visualization of a participants's training data as well as inform detailed recommendations for training. Heart rate recordings can be performed precisely and in a noninvasive way, which reduces the need for specialized equipment. Exercising according to defined heart rate zones is already well established in professional and recreational endurance training [35]. To a large extent, HRV is modulated by stimulating sympathetic and repressing parasympathetic influences of the autonomic nervous system [36]. It is also known that age and sex have varying effects on heart rate [37].

Several important indicators of variability include heart rate, the root mean square of successive differences (RMSSD), the natural logarithm of the RMSSD (lnRMSSD), the SD of the NN interval (SDNN), low frequency power (LFP), high frequency power, the low frequency to high frequency (LF/HF) ratio, the number of pairs of successive NN intervals that differ by more than 50 milliseconds (NN50), and the proportion of the NN50 divided by the total number of NN intervals (PNN50) [38,39]. However, the complex interactions among physiological and psychological signals mean that they are rarely discussed and studied together in game mechanics.

Flow Definition and Measurement Questionnaire

Serious games, which are games designed for a purpose other than pure entertainment, can increase patient motivation. Meeting the needs of an individual is often a precursor of a flow state, which is a crucial yet often overlooked feature of serious games [40,41]. Flow is an immersive experience characterized by an optimal balance between one's current skills and the level of challenge [42-44]. It enables an individual to become highly absorbed, forget the passing of time, and enter a psychological state of ecstatic happiness and contentment. Flow encompasses the following eight dimensions: (1) a combination of challenge and skill, (2) the merging of actions with awareness, (3) clear task goals, (4) direct and immediate feedback, (5) concentration on the task at hand, (6) a sense of control, (7) a loss of self-consciousness, and (8) a perception of the transformation of time [45]. Subsequent studies have added the dimensions of learning and positive subjective experiences [46]. Skills and the degree of learning increase with experience, whereas attention, challenge, the sense of presence, flow, and exploratory behavior decrease with experience [47]. We found that generating feedback, challenge, and reward mechanisms in games can increase user interest. The qualities of the user experience generated in a game, such as hedonic quality and pragmatic quality, which can be determined using the net promoter score (NPS) and the User Experience Questionnaire (UEQ), can lead to the exploration of potential market opportunities [48,49].

The National Aeronautics and Space Administration Task Load Index (NASA-TLX) questionnaire is used to assess perceived workloads and determine the effectiveness of gaming tasks [50]. For the measurement of flow experience, the effectiveness of the Flow State Scale 2 (FSS2), the Dispositional Flow Scale 2, flow distance (FD), EGameFlow, and the Game Experience Questionnaire have been confirmed [24,51]. Among them, FD can be divided into 3 levels to distinguish the current state of experience: anxiety, flow, and boredom [52].

For flow during exercise, an electroencephalogram is often used to investigate the influence of music tempo (fast, slow, or no music control) on flow. An analysis of data collected using the short FSS2 revealed that music tempo exerts a significant impact on subjective experiences and objective physiological characteristics. Higher subjective flow levels have been observed in participants listening to fast-tempo music while walking briskly, showing that fast tempos are conducive to movement flow. These findings demonstrate the benefits of music during sports training to improve training effectiveness [53]. The evidence above highlights that physiological signals can be measured during exercise, and the results of flow questionnaires can reveal whether the user has entered a state of immersion. However, flow states during tongue muscle training have rarely been studied.

Study Aims

The purpose of this study was to evaluate our mobile health app, which incorporates gameplay for specialized tongue muscle training. The goal of the app is to enable older adults to rehabilitate unassisted and immerse themselves in the process, optimizing their flow. To determine the feasibility of integrating gameplay, we conducted a small, randomized pilot trial by recruiting 32 healthy middle-aged and older users and set up 3 training tasks at different speeds. Since the analysis of patients with dysphagia may be related to more complex variables, this study included healthy individuals for simplicity in the pilot run. This app, by combining tongue exercises with interactive games, could make the process of rehabilitating tongue muscles more interesting and engaging, emphasizing skill training rather than strength training and focusing on retaining users instead of short-term entertainment. The findings derived from our study could serve as a valuable reference for the next stage of development and evaluation. Our aim is to created an app that can help to alleviate and mitigate dysphagia-related conditions and enable older adults to maintain a healthy life.

Methods

Overview

The study was conducted in two phases. In the first phase, the study team designed and integrated the game into the tongue app. In the second phase, the study team evaluated the feasibility and acceptability of the integrated game using a single-arm trial.

Phase 1: Game Design and Development

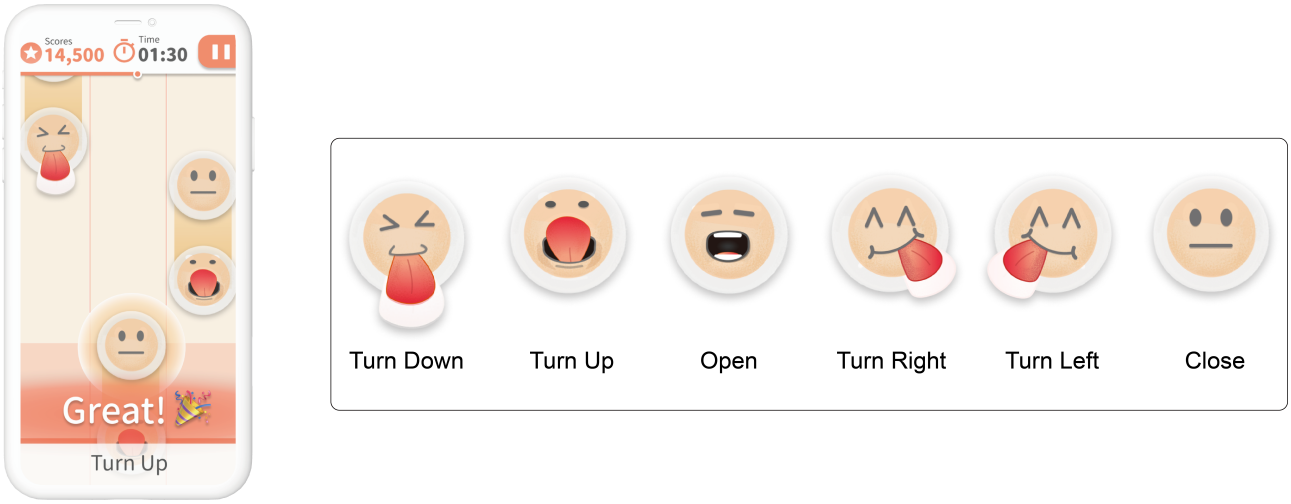
Registered professional nurses at Taipei Medical University designed the training movements used in the game based on the tongue exercises in the Guidance Manual for Care and Guidance of Eating and Swallowing Difficulties [54], including 6 tongue stretching exercises (Table 1). Once experts had confirmed the accuracy of the tongue exercises, we designed several game icons for the tongue movements, including up, down, left, right, close, and open.

Table . Descriptions of training movements designed by experts for a mobile game app.

No.	Explanation	Movement segments (image recognition definition)
A1	Extend tongue out of the mouth as far as possible and then retract. Repeat 5 times.	Extend tongue, retract, and close mouth.
A2-1, A2-2	Extend tongue to right corner of mouth as far as possible and then extend to left corner. Repeat 10 times.	Extend tongue to the right, retract, extend tongue to the left, retract, and close mouth.
A3-1, A3-2	Open mouth as much as possible, and circle tongue along lips clockwise. Repeat 10 times.	Open mouth, extend tongue, make a circle, and close mouth.
A4	Push tongue hard against upper front teeth and hold for 10 seconds. Repeat 10 times.	Extend tongue, tongue up, and close mouth.

We first photographed 60 participants and removed blurry sections. Teachable Machine version 1.0.1 (Google) was used for initial model training. We imported 200 images for each of the 6 tongue training movements (ie, a total of 1200 training images) to verify that the different movements could be accurately recognized by the camera. The recognition accuracy rates for up, down, left, right, close, and open were 100%, 82%, 96%, 83%, 90%, and 97%, respectively. The trained model was output in the Keras vesion 2.2.0 (Oneiros) and Tensorflow Lite version 1.9 (Google Brain Team) formats. We used the Unity Beats Detection module of Unity Engine version 2020.3.48f1 (Unity Technologies) to analyze the rhythm tempo, and we also used lively and fast-paced music, which began playing at the beginning of the game. In the program design, we generated training levels using the training movements to give the participants a gaming experience, thereby producing an exergame (Figure 1).

Figure 1. Mobile game interface and the schematic diagram of tongue training actions in the game.

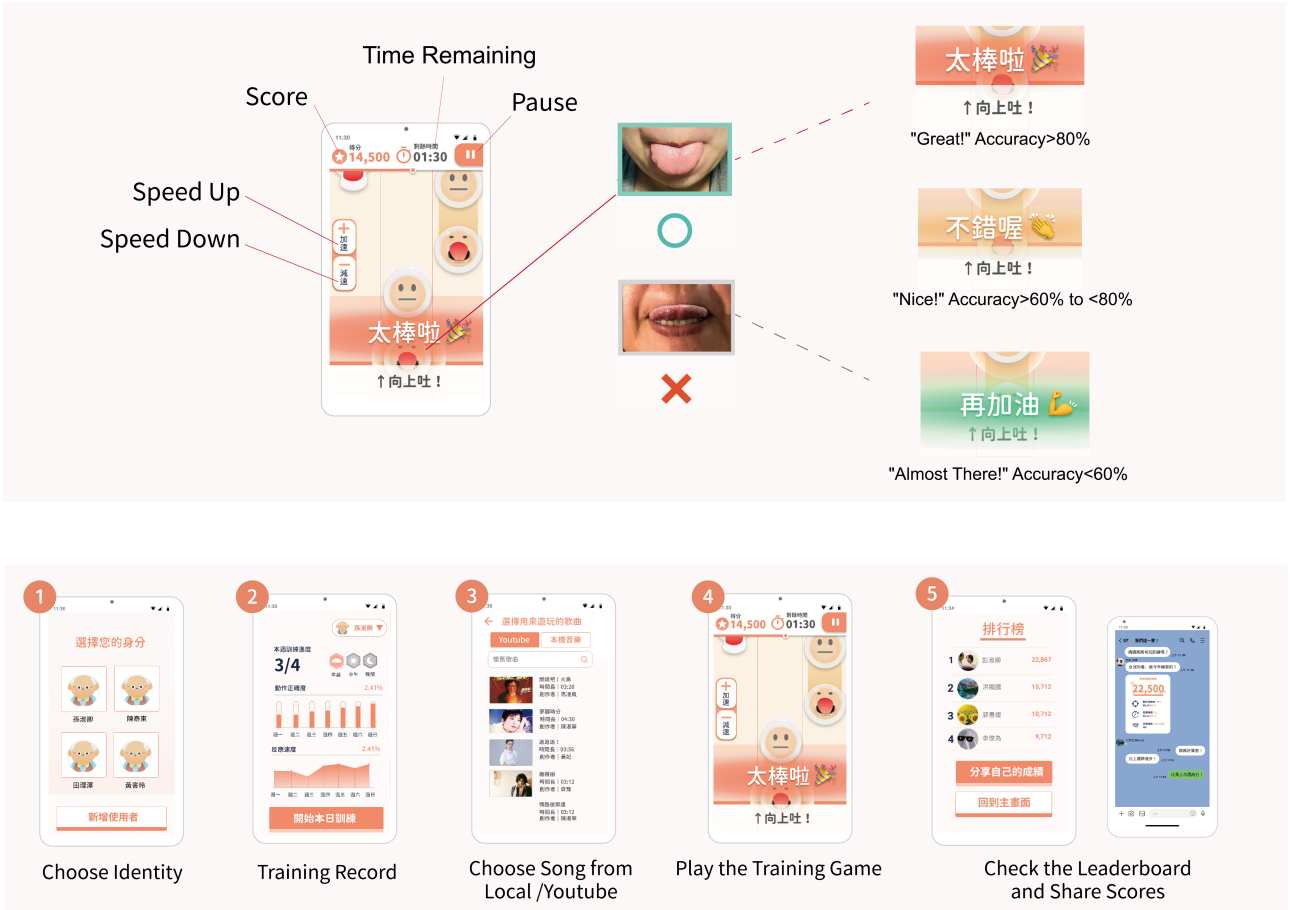


Furthermore, to ensure proper hygiene, image recognition methods that did not require invasion into the oral cavity were used. Images of tongue movements were detected, and suitable feedback and reward mechanisms were also provided. We set up 3 levels with varying speeds (slow, medium, and fast) and skill difficulty requirements to test the mental flow state of the participants under different conditions.

A smartphone was used to record the participant's heart rate (Garmin heart rate chest belt) and mental flow score. To set up the Garmin HRM-PRO activity tracker belt, we created an anonymous user account with the manufacturer that was not associated with any of the patients. Before beginning the game, the participants were separated into the 3 training modes (M1: slow speed; M2: medium speed; or M3: fast speed) by a Latin square method. They then filled out their personal information, read and reviewed their rights and interests, and gave their informed consent. They then put on the Garmin HRM-PRO belt and were asked to rest quietly for 5 minutes before beginning the game tasks. They were given instructions and allowed to practice for 3 minutes, and then played in assigned modes of different difficulties. Subsequently, they rested for 3 minutes and then played again. After each game, they were given a questionnaire (including the FSS2, FD, the NASA-TLX, the UEQ, pragmatic quality, hedonic quality, and NPS), and at the end, an interview was conducted. Using physiological and psychological signals, we explored and analyzed whether the tongue muscle training app could produce a positive flow experience.

After logging in to the daily training page, the homepage was shown. The subject could then select previous records or enter the song menu to choose their favorite music. By tapping the play icon, they could begin training, and after completion, the screen showed the resulting score and their ranking among friends and relatives, which could be shared on social networks (Figure 2). By emulating the correct tongue movements, the system presented encouraging sounds and words such as great, nice, and almost there to the subject. This study explored whether psychological and physiological signals influenced each other, thereby leading to optimal flow states in participants, with the purpose of maintaining the training motivation of middle-aged and older adults. The study integrated big data that could also be used for future smart oral-medical research and analysis.

Figure 2. Development of the mobile app interface, the feedback diagram, and the game step flow chart.



Phase 2: Feasibility Testing

This study included a single-arm, unblinded evaluation of the feasibility and acceptability of the tongue app, in preparation for a planned randomized pilot trial. All participants in the feasibility study were given free access to the tongue app. Participants' use of the app was passively monitored for the pilot trial.

In the early stages, Figma version 95.7 (Figma Inc) was used to create a preliminary model, and the Wizard of Oz method was used to conduct a usability test on 5 middle-aged and older adults aged 55-70 years. After iterative improvements, the final version of the gaming app was developed. We officially started testing on October 5, 2021. All testers were either recruited from Facebook or from friends and relatives of the researchers.

A Google Form published on Facebook served as our web-based survey platform. Recruitment remained open until the prespecified sample size of 32 (7 males, 21.9%; 25 females, 78.1%) healthy middle-aged and older participants was met. We confirmed the eligibility of the test takers based on a questionnaire (open between September 30, 2021, and October 4, 2021) and ensured that participants consented to the feasibility trial. Note that there was a 100% (32/32) response rate for the baseline questionnaire and that this was the denominator used for most of the analyses.

All participants filled in the informed consent form and swallowing function test form (EAT-10). People with specific illnesses or health problems (eg, those with pre-existing dysphagia or cancer) were excluded from this study, and only settings dedicated to home or informal care for older adults were included. In this study, the application was only functional on Android phones, tablets, and computers. We aim to upload the app to the Google Play Store in the near future.

Ethical Considerations

Taipei Medical University-Joint Institutional Review Board approved this study (N202109022), which was planned, carried out, analyzed, and interpreted independently of any industrial partners. Details about procedures, potential risks, confidentiality measures, data storage protocols, and benefits were shared with all eligible participants. Signed informed consent was collected from each participant. To protect confidentiality and ensure anonymity, participant names were replaced with unique identification codes. Digital data were securely stored on encrypted and password-protected systems. Participants in this study received US $15 as a transport subsidy. The specifics of the compensation were clearly communicated during the consent process.

Data Collection

This study was based on the baseline model game experience. After answering the questionnaire items regarding demographic background, the participants began to play. During the experiment, each participant played the game for 3 minutes with a song, playing 3 times in each of 3 difficulty levels (M1: slow; M2: medium; M3: fast). Physiological signals (heart rate, low frequency HRV, high frequency HRV, LF/HF ratio, lnRMSSD,

RMSSD, NN50, PNN50, and SDNN) were collected by the Garmin HRM-PRO. After the game, participants filled out the rest of the questionnaire, which comprised the following scales: FD, FSS2, NPS, UEQ, System Usability Scale, and NASA-TLX. In the questionnaire, there were measures for the challenge level of each exercise and measures of the skill level of the participant.

Subtracting the challenge score from the skill score and dividing it by 4 resulted in the FD, a score that fell between 1 and −1. A score of 0 meant that the skill and challenge levels were balanced, which was considered to be the state of flow. If a score was between 0 and 1, the subject was classified as bored (ie, the person's skill levels were higher than the challenge level). If a score was between −1 and 0, the person was classified as anxious. We integrated the questionnaire data and physiological data, which were downloaded from Elitehrv's paid platform (version 5.5.8, Elite HRV Inc) and organized in an Excel (version 1808, Microsoft) spreadsheet.

Statistical Analysis

In this study, SPSS version 30 (IBM Corp) was used as the main analysis software, and ANOVA tests were used to analyze whether differences among individual FDs in the M1 (slow), M2 (medium), and M3 (fast) levels were significant. Paired 2-tailed sample *t* tests were used to further analyze whether the training in the 3 levels affected the learning results in terms of operability. In addition, we also investigated whether there were differences between sexes, and the Pearson correlation coefficient was used to explore the relationship between the FSS2 scores and physiological signals. Exploratory factor analysis was used to extract the two factors (operation and immersion), and cluster analysis and k-means clustering were also used to divide the population into 3 groups based on speed, before reperforming the Pearson analysis.

Results

The reliability of the FSS2 questionnaire, as measured by the Cronbach α, was 0.802. An exploratory factor analysis was conducted on questions 1 to 9 of the FSS2 questionnaire, yielding a χ^2_{36} of 448.478 (P<.001; Kaiser-Meyer-Olkin=0.757). The FSS2 questionnaire was divided into two factors that confirmed the reliability of the structure: the FSS2-01 (FSS2 items 5, 7, 8, and 9) for immersion and FSS2-02 (FSS2 items 1, 2, 3, 4, and 6) for operation. An ANOVA test found that the F values were >0.05, indicating that the M1, M2, and M3 training modes all significantly affected the FSS2-02 (P=.001), NASA-TLX (P<.001), and FD (P<.001).

Within these 3 modes, there were significant differences in load level, flow, and FD (P<.001; Table 2). A Scheffe post hoc test confirmed that there was a significant difference in the NASA-TLX score between the M1 and M3 modes and between the M2 and M3 modes. There was a significant difference in the FSS2-02 score between the M1 and M3 modes. For FD, there were significant differences between the M1 and M2 modes, as well as the M1 and M3 modes (Multimedia Appendix 1).

Table . Relationship between the 3 training modes (M1, M2, and M3) and flow outcomes.

Variable	Sum of squares	Mean square	*F* test (*df*)	*P* value[a]
NASA-TLX[b]	1116823.000	558411.500	7.887 (2, 93)	.001
FSS2-02[c]	147.896	73.948	8.542 (2, 93)	<.001
Flow distance	27513.021	13756.510	12.198 (2, 93)	<.001

[a]The α level was .01 (2-tailed).

[b]NASA-TLX: National Aeronautics and Space Administration Task Load Index.

[c]FSS2-02: Flow State Scale 2, items 1, 2, 3, 4, and 6.

In order to determine the degree of influence of the FSS2-02 score on flow between each training mode pair, paired 2-tailed sample *t* tests were used. Significant differences were found among the 3 modes, indicating that participants were in the state of operation and demonstrating that the task design of this study was effective (Table 3). However, for the FSS2-01 questionnaire, only M1 and M3 exhibited a significant difference in immersion (P=.03). This could indicate that, in the M2 mode, the ease or difficulty of tasks was biased toward the M1 or M3 modes ().

Table . Valid operations by participants in the 3 modes (M1, M2, and M3).

Mode[a] comparisons	Mean difference (SD)	*t* test (*df*)	*P* value[b]
FSS2-02[c] (operation)			
M1 to M2	–1.71875 (2.61798)	–3.714 (31)	.001[d]
M2 to M3	–1.31250 (2.57077)	–2.888 (31)	.007[d]
M1 to M3	–3.03125 (4.18511)	–4.097 (31)	<.001[d]
FSS2-01[e] (immersion)			
M1 to M2	0.40625 (2.56351)	0.896 (31)	.38[f]
M2 to M3	0.68750 (3.71950)	1.046 (31)	.30[f]
M1 to M3	1.09375 (2.64404)	2.340 (31)	.03[f]

[a]Mode: training modes slow (M1), medium (M2), and fast (M3).

[b]Significance was determined using a one-way ANOVA.

[c]FSS2-02: Flow State Scale 2, items 1, 2, 3, 4, and 6.

[d]The α level was .01 (2-tailed).

[e]FSS2-01: Flow State Scale 2, items 5, 7, 8, and 9.

[f]The α level was .05 (2-tailed).

In addition, the results of the *t* tests (n=32) showed a significant difference in heart rate between men and women in the M1 mode (t_{28}=3.697; *P*=.001) and a significant difference in load level indicated by the NASA-TLX (t_{30}=2.276; *P*=.03). For the M2 mode, only the heart rate was significantly different between men and women (t_{30}=4.791; *P*<.001). Finally, there were significant differences in flow based on the FSS2-01 (t_{28}=5.431; *P*<.001), FSS2-02 (t_{29}=3.379; *P*=.002), FD (t_{30}=2.043; *P*=.05), as well as a significant difference in heart rate (t_{30}=3.693; *P*=.001) between men and women in the M3 mode (Table 4).

Table . Relationship between sex and physiological signals in the 3 mobile game modes (M1, M2, and M3).

Measurements	*F* test (*df*)	*P* value	*t* test (*df*)	*P* value
Slow training mode (M1)				
Heart rate[a]	5.228 (30, 27.5)	.03	3.697 (28)	.001[b]
NASA-TLX[c]	1.720 (30, 7.9)	.20	2.276 (30)	.03[d]
Medium training mode (M2)				
Heart rate	1.233 (30, 7.8)	.28	4.791 (30)	<.001[b]
Fast training mode (M3)				
FSS2-01[e]	5.496 (30, 28)	.03	5.431 (28)	<.001[b]
FSS2-02[f]	5.921(30, 29)	.02	3.379 (29)	.002[b]
Flow distance	0.601 (30, 8.5)	.44	2.043 (30)	.050[d]
Heart rate	0.832 (30, 8.3)	.37	3.693 (30)	.001[b]

[a]Measured in beats per minute.

[b]The α level was .01 (2-tailed).

[c]NASA-TLX: National Aeronautics and Space Administration Task Load Index.

[d]The α level was .05 (2-tailed).

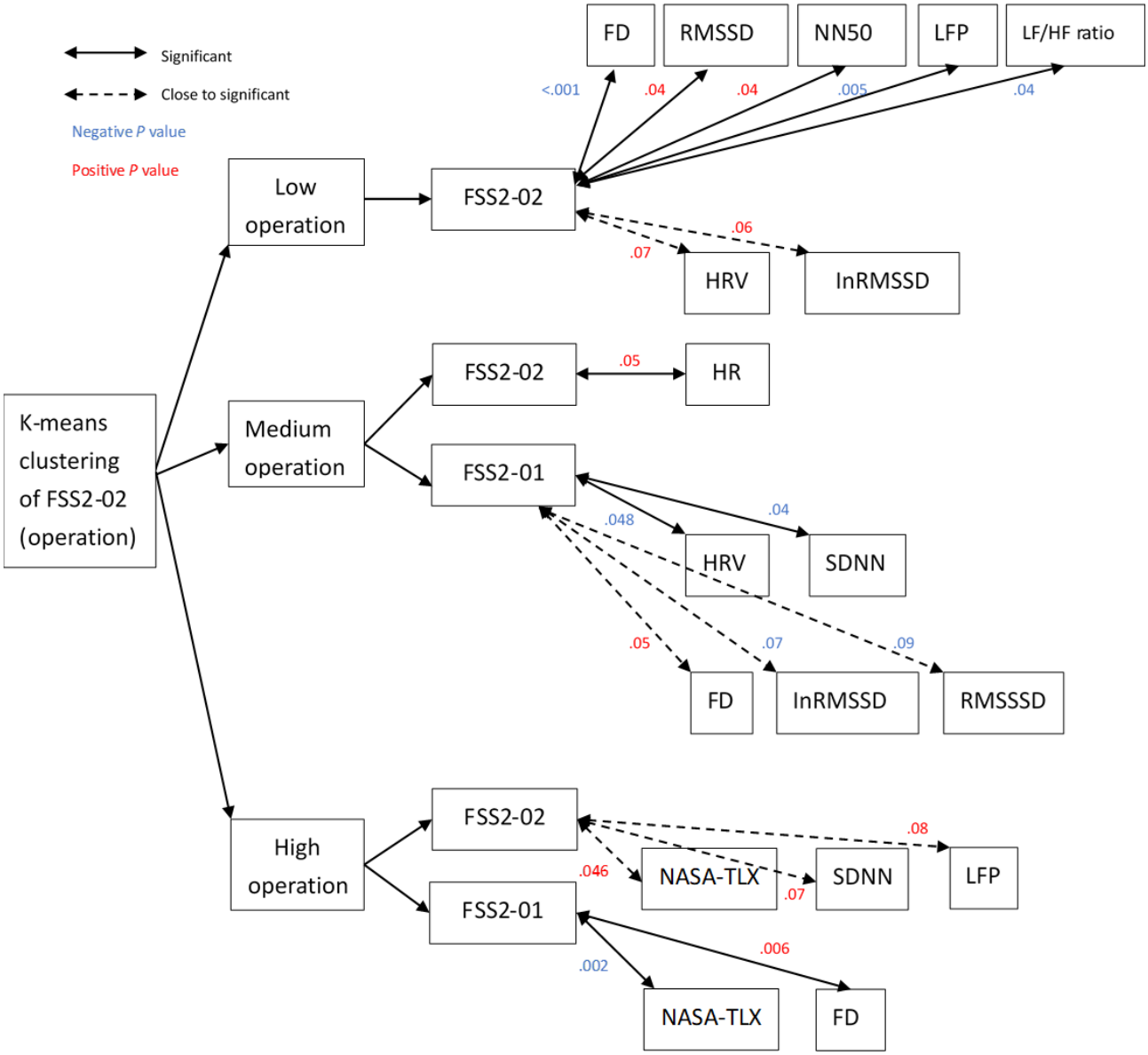
[e]FSS2-01: Flow State Scale 2, items 5, 7, 8, and 9.

[f]FSS2-02: Flow State Scale 2, items 1, 2, 3, 4, and 6.

A Pearson correlation for physiological and psychological signals was performed for each training task mode and we found that the FSS2-01 score was significantly related to age (*r*=0.39; *P*<.001), pragmatic quality (*r*=0.21; *P*=.02), NASA-TLX score (*r*=–0.30; *P*=.003), FSS2-02 score (*r*=0.32; *P*=.001), and FD (*r*=0.33; *P*=.001). The FSS2-02 score was significantly correlated with age (*r*=0.34; *P*=.001), FSS2-01 score (*r*=0.32; *P*=.001), and FD (*r*=–0.34; *P*=.001). In addition, the FSS2-02 score was nonsignificantly correlated with the LF/HF ratio (*r*=–0.20; *P*=.054).

In order to explore whether certain training groups correlated with physiological and psychological signals, we divided the data into 3 groups through k-means clustering, partitioning the FSS2-02 scores into low, medium, and high operation groups. Correlation analysis between the 3 groups and physiological signals found that the FSS2-02 score for the low operation group was significantly correlated to FD (r=–0.79; P<.001), RMSSD (r=0.46; P=.04), NN50 (r=0.46; P=.04), LFP (r=–0.60; P=.005), and LF/HF ratio (r=–0.47; P=.04). There was a low correlation between the FSS2-02 score and HRV (r=0.42; P=.07) and lnRMSSD (r=0.43; P=.06). In the medium operation group, the FSS2-02 score correlated with heart rate (r=0.41; P=.050), while the FSS2-01 score correlated with age (r=0.58; P=.003), pragmatic quality (r=0.56; P=.005), UEQ score (r=0.48; P=.02), HRV (r=–0.41; P=.048), and the SDNN (r=–0.43; P=.04) and nonsignificantly correlated to hedonic quality (r=0.37; P=.07), FD (r=0.40; P=.053), lnRMSSD (r=–0.38; P=.07), and RMSSD (r=–0.35; P=.09). In the high operation group, the FSS2-02 score was correlated with the NASA-TLX score (r=0.28; P=.046) and was nonsignificantly correlated with SDNN (r=0.07; P=.07) and LFP (r=0.24; P=.08), while the FSS2-01 score was correlated with the NASA-TLX score (r=–0.41; P=.002) and FD (r=0.38; P=.006; Figure 3).

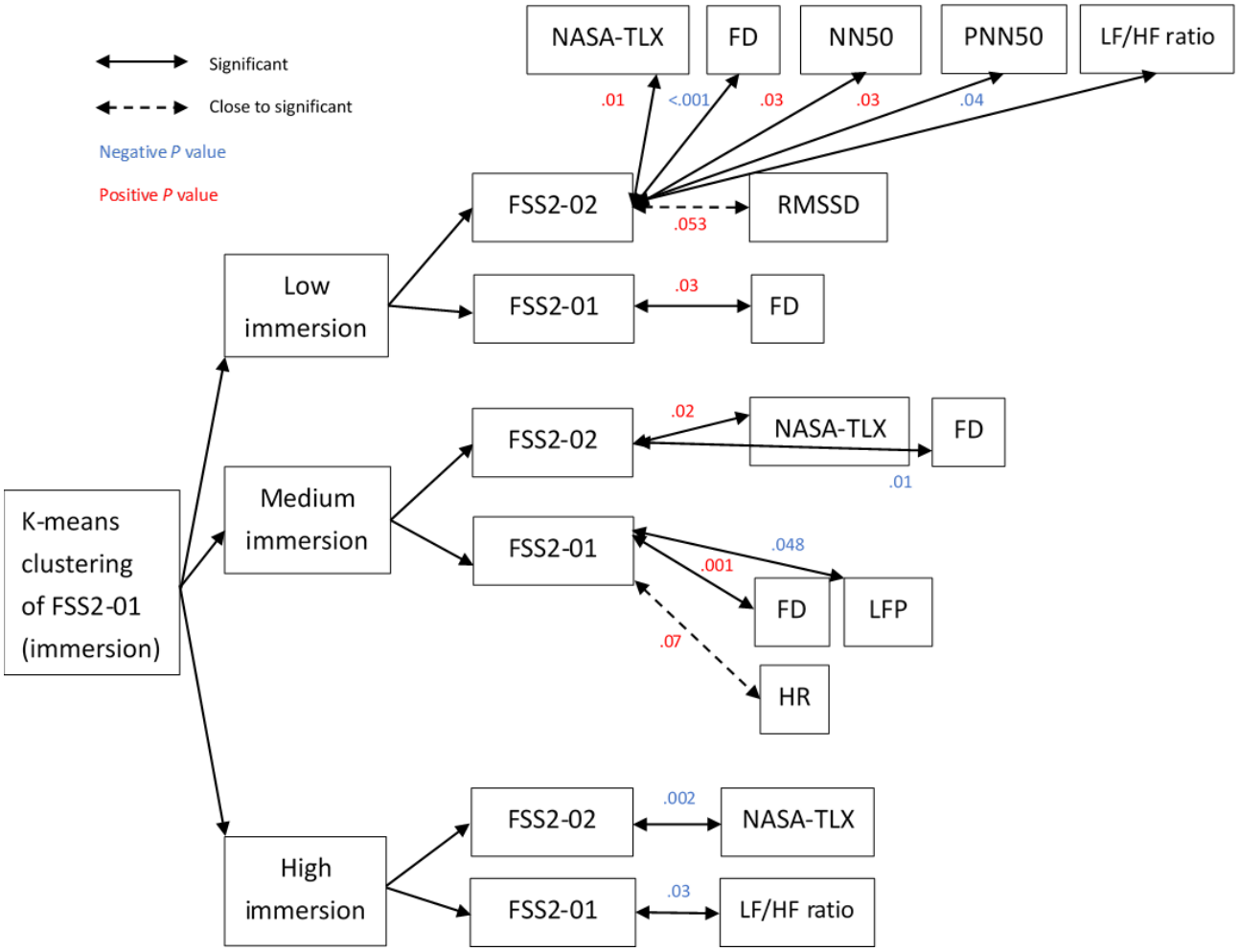
Figure 3. K-means clustering of FSS2-02 divided the relationship between mental flow and various physiological signals into 3 groups. Positive P values indicate a positive correlation, and negative P values indicate a negative correlation. FD: flow distance; FSS2-01: Flow State Scale 2, items 5, 7, 8, and 9; FSS2-02: Flow State Scale 2, items 1, 2, 3, 4, and 6; HR: heart rate; HRV: heart rate variability; LF/HF: low frequency to high frequency; LFP: low frequency power; lnRMSSD: natural logarithm of the root mean square of the successive differences; NN50: number of pairs of successive NN intervals that differ by more than 50 milliseconds; RMSSD: root mean square of the successive differences; SDNN: SD of the NN interval.



In addition, the research data for the FSS2-01 was divided into low, medium, and high immersion groups through k-means. Correlation analysis with the physiological signals found that the FSS2-02 score in the low immersion group was related to the NASA-TLX score (r=0.46; P=.009), FD (r=–0.69; P<.001), NN50 (r=0.39; P=.03), PNN50 (r=0.38; P=.03), and LF/HF ratio (r=–0.37; P=.04), while the FSS2-02 score had a low correlation with age (r=0.33; P=.07) and RMSSD (r=0.35;

P=.053), and the FSS2-01 score had a positive correlation with FD (*r*=0.39; *P*=.03). On the other hand, in the medium immersion group, the FSS2-02 score was correlated with the NASA-TLX score (*r*=0.39; *P*=.02) and FD (*r*=–0.42; *P*=.01), while the FSS2-01 score was correlated with hedonic quality (*r*=0.35; *P*=.04), UEQ score (*r*=0.36; *P*=.04), FD (*r*=0.53; *P*=.001), and LFP (*r*=–0.34; *P*=.048) and was nonsignificantly correlated with heart rate (*r*=0.31; *P*=.07). Finally, in the high immersion group, it was found that the FSS2-01 score exhibited a negative correlation with LF/HF ratio (*r*=–0.38; *P*=.03) and a low correlation with pragmatic quality (*r*=0.31; *P*=.08), and there was a negative correlation between the FSS2-02 and NASA-TLX scores (*r*=–0.51; *P*=.002; Figure 4).

Figure 4. K-means clustering of FSS2-01 divided the relationship between heart flow and various physiological signals into 3 groups. Positive *P* values indicate a positive correlation, and negative *P* values indicate a negative correlation. FD: flow distance FSS2-01: Flow State Scale 2, items 5, 7, 8, and 9; FSS2-02: Flow State Scale 2, items 1, 2, 3, 4, and 6; HR: heart rate; HRV: heart rate variability; LF/HF: low frequency to high frequency; LFP: low frequency power; NASA-TLX: National Aeronautics and Space Administration Task Load Index; NN50: number of pairs of successive NN intervals that differ by more than 50 milliseconds; PNN50: proportion of NN50 divided by the total number of NN intervals; RMSSD: root mean square of the successive differences.



Discussion

Principal Findings

We successfully identified 6 different methods for tongue training and developed a mobile game app for this purpose, aiming for users to experience flow through the training of specialized muscles (ie, the tongue). Most studies focuses on psychological and physiological signals (shown in Figure 3 and Figure 4), and this study emphasized 12 of these indicators (ie, NASA-TLX score, FD, heart rate, HRV, lnRMSSD, RMSSD, NN50, PNN50, SDNN, LFP, high frequency power, and LF/HF ratio). Among the psychological and physiological signals, flow was measured using FD, SDNN, RMSSD, NN50, HRV, and LFP. The LF/HF ratio was also used, which indicated if the findings were related to FD and if these factors generated flow. We found that our participants had effective learning operations and immersive experiences during the tasks and achieved optimal flow, confirming the effectiveness of the app. Importantly, flow generated during gameplay is known to be affected by age and sex, which in turn affects physiological signals, such as HRV [37].

In our mobile health app, interactive games were designed to train tongue muscles, which could be conducted anytime and anywhere, reducing the burden of conventional training. These games can also increase task repetition [55-57], which influences learning effectiveness [58,59]. The tasks were designed with 3 different levels of difficulty. Research has confirmed that different game designs can help participants to improve

operability and that introducing gamification into a task mechanism can intensify the balance of physiological and psychological signals [18]. When the balance between challenge and skill is achieved, flow optimization can be achieved [60]. Our findings demonstrate that the participants were immersed in training during the game, confirming the effectiveness of the tongue training app. By changing its speed and rhythm, we could modulate a user's flow experience. The tempo of the music was linked to the speed at which the tongue instruction icons moved down the smartphone screen, and training levels were generated. Thus, the M3 mode tasks were difficult and the most fast-paced. The participants had to sync the speed of the tongue training motions to the rhythm of the music. This study combined image recognition and music rhythm stimulation to explore and analyze complex physiological and psychological signals. The results show that such methods could generate an ideal flow experience.

Strengths and Weaknesses of the Study

Our research has successfully simplified complicated rehabilitation procedures, using a simple game app combined with audio effects to facilitate tongue training. To verify the effectiveness of the mobile app games, the FSS2 questionnaire for the game was divided into two groups by exploratory factor analyses: operation and immersion. An analysis of the results for the tasks performed at different speeds revealed that training outcomes were highly related to FD. This demonstrates that through this tongue training app, we can both facilitate tongue muscle rehabilitation and generate flow in users. Flow includes experiencing complete concentration, the desire to challenge oneself, and the generation of feedback reward mechanisms [61], supporting that physiological signals are affected by task stimulation [62].

The image recognition system had certain limitations. Data collection during experiments was also a time-consuming process. In our study, the participant had to wear a heart rate detector during the test, which may have caused some inconvenience and led to minor variations in heart rhythm or physiological signals. Second, research has found that there are indeed differences in flow and physiological signals between men and women, indicating differences regarding the influence of personal characteristics and environmental factors [37]. Under the same difficulty settings, results showed that there were fewer psychological signals in the M3 training mode. In the future, we can appropriately adjust the task difficulty of the M3 mode to achieve optimal training. In addition, despite the small sample size and the skewed sex ratio of the participants in this study, our image recognition system achieved a high level of accuracy, paving the way for scaling up the recruitment of participants in future experiments.

The model of this complete mobile app game was trained using a limited dataset and thus only recognized the mouths and tongues of Asian individuals. Therefore, if the mobile app was applied to non-Asian individuals, it may not perform well, leading to inaccurate experiments. Moreover, these mobile app games were only used by middle-aged and older adults, and the findings may not apply to users in other age groups. In the future, we aim to collect more diverse data to improve the accuracy and breadth of the platform.

Implications and Future Research

We expect to include the addition of a 2-player competition mode to the interface to enable not only interactions with family or friends but also to include a wider range of advanced training functions. The interface for middle-aged and older adults could be optimized with more options, such as realistic characters and diverse oral and tongue exercises, to enhance the experience of the app. The interface only allowed users to change basic settings such as age, music speed, and mode. Since this study was a pilot study, there were no experiment cases without accompanying soundtracks (ie, during the trial, there were corresponding soundtracks in all 3 modes).

In this study, the generation of a soundtrack required an internet connection. An offline training mode is planned for subsequent iterations of the app so that full training can be achieved anytime and anywhere, even in places with poor signal reception, such as rural areas, elevators, or basements. Furthermore, the soundtrack could be adjusted based on pitch or volume, or it could be muted in future experiments. In this study, our main goal was to provide either an alternative to clinical rehabilitation or a more relaxed training setting for healthy people. When used in actual clinical settings, complying with medical standards and regulations could require the demonstration of efficacy across multiple conditions. For example, the app may be further modified to include oral training. Moreover, the development of the image recognition system was susceptible to slight errors depending on variations in ambient lighting. In the future, we hope to enhance the accuracy of the image recognition system and collect more lighting data to reduce errors under different scenes and levels of light.

Conclusions

Despite the many ways to train tongue muscles, most studies have been concerned with the treatment and rehabilitation of patients with oral cavity diseases. In addition, equipment expenses or a lack of continuous professional medical services are associated with declines in patient compliance for rehabilitation. There are few gamified apps targeting health care professions and education and even fewer considering factors that may increase efficacy. Following the completion of the pilot trial and subsequent analysis, the participant cohort could be categorized into two groups based on their physiological and psychological signals: operation and immersion. Furthermore, tongue muscle training using our app could produce a superior flow experience for users. This was determined using several variables including FD, SDNN, RMSSD, NN50, HRV, LFP, and LF/HF ratio and could be repeated in different training groups, which confirmed the effectiveness of this app. Compared to strength training and full-body movement training, our method was more engaging and produced a better flow experience. We hope that the optimal flow generated by this app will encourage users to train independently and mitigate or prevent dysphagia. This study strengthens the potential for incorporating game training into mobile health.

Acknowledgments

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Data Availability

The datasets generated and/or analyzed during this study are not publicly available due to security purposes requested by the academic institution but are available from the corresponding author on reasonable request.

Authors' Contributions

KCS, KCW, KRC, and CHH conceptualized the trial. KCS, KCW, and CHH collected and analyzed the data. KCS wrote the manuscript, to which all authors gave critical feedback. All authors approved the final draft of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Multiple comparisons from Scheffe test.
[PDF File, 100 KB - games_v13i1e53045_app1.pdf]

Checklist 1
Reporting a pilot and feasibility trial checklist.
[PDF File, 285 KB - games_v13i1e53045_app2.pdf]

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Abbreviations

EAT-10: 10-item Eating Assessment Tool
FD: flow distance
FSS2: Flow State Scale 2
FSS2-01: Flow State Scale 2, items 5, 7, 8, and 9
FSS2-02: Flow State Scale 2, items 1, 2, 3, 4, and 6

HRV: heart rate variability
LF/HF: low frequency to high frequency
LFP: low frequency power
lnRMSSD: natural logarithm of the root mean square of successive differences
NASA-TLX: National Aeronautics and Space Administration Task Load Index
NN50: number of pairs of successive NN intervals that differ by more than 50 milliseconds
NPS: net promoter score
PNN50: proportion of NN50 divided by the total number of NN intervals
RMSSD: root mean square of successive differences
SDNN: SD of the NN interval
UEQ: User Experience Questionnaire

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Original Paper

Perceptions of Patients With Stroke Regarding an Immersive Virtual Reality–Based Exercise System for Upper Limb Rehabilitation: Questionnaire and Interview Study

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Abstract

Background: With substantial resources allocated to develop virtual reality (VR)–based rehabilitation exercise programs for poststroke motor rehabilitation, it is important to understand how patients with stroke perceive these technology-driven approaches, as their perceptions can determine acceptance and adherence.

Objective: This study aimed to examine the perceptions of patients with stroke regarding an immersive VR-based exercise system developed to deliver shoulder, elbow, forearm, wrist, and reaching exercises.

Methods: A questionnaire was used to assess the perceptions of 21 inpatients who had experienced stroke (mean time from stroke onset: 37.2, SD 25.9 days; Brunnstrom stage of stroke recovery for the arm: 3-5) regarding the perceived usefulness of, ease of use of, attitude toward, intrinsic motivation for, and intention to use the exercise system. The measurement items were rated on a 7-point Likert scale ranging from 1 (very strongly disagree) to 7 (very strongly agree), with higher values indicating more positive perceptions. Descriptive statistics were used to summarize the responses. Moreover, we conducted semistructured interviews that were audio recorded, transcribed, and subjected to content analysis to identify thematic patterns.

Results: The questionnaire results revealed that the patients' perceptions of the exercise system were positive (mean ratings >6). The content analysis revealed 6 positive themes from 73 statements about the exercise system: ease of use, usefulness, enjoyment, motivation, accessibility, and game design. Conversely, 15 statements reflected negative perceptions, which were clustered into 3 themes: difficulty in handling VR devices, uncomfortable experiences when using VR devices, and monotony.

Conclusions: Integrating VR technology into poststroke functional exercises holds significant promise based on patient interests. However, patient preferences and adaptability must be considered to promote the technology's success. VR-guided exercises should be user-friendly, health-promoting, engaging, and well-designed. Furthermore, addressing challenges, such as bulkiness, motion sickness, discomfort, and exercise monotony, is crucial for the widespread adoption and diffusion of this technology.

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KEYWORDS

virtual reality; stroke; perception; rehabilitation; questionnaire; interview

Introduction

Persistent upper limb impairment following stroke has a substantial impact on patients' daily activities and quality of life [1-5]. Therapeutic exercises are necessary to restore motor function and independence. Patients commonly attend face-to-face therapy sessions at clinics and perform exercises under the supervision of therapists. However, this traditional approach has limitations, including high costs, scheduling conflicts, limited access to therapy services, and the need for patients to travel to clinics [6,7].

Technologies, such as immersive virtual reality (VR), have been applied to promote the accessibility and affordability of poststroke therapeutic exercises [8-10]. The effectiveness of immersive VR-based rehabilitation programs on upper limb motor recovery has been examined in previous studies [11-13]. Besides effectiveness, it is equally important to consider patients' perceptions and acceptance of such programs because negative perceptions and nonacceptance of these technologies, which is a common challenge in practice, can lead to implementation failure, losses to stakeholders, and undesirable health care outcomes [14,15].

Several studies have examined the experiences of stroke survivors with immersive VR-based motor rehabilitation programs, evaluating various aspects such as perceived usefulness, discomfort, motivation, and intention to use these programs. Results have shown that the application of immersive VR is both feasible and acceptable among patients [13,16-18]. However, these studies primarily relied on quantitative methods, specifically rating scales, to capture the experiences of patients. This approach, while valuable, fails to uncover the underlying factors that influence these experiences, leaving critical elements unexplored [19]. To address this gap, incorporating qualitative methods, such as in-depth interviews, is essential. Qualitative research can provide rich, detailed data that reveals the complexities of patients' interactions with VR technology, their emotional responses, and the contextual factors that shape their experiences. By exploring these dimensions, researchers can identify barriers and facilitators to the formation of positive perceptions and subsequent acceptance and implementation. This will allow them to tailor interventions to meet the specific needs of patients with stroke and enhance the overall effectiveness of VR-based rehabilitation programs.

Currently, qualitative studies evaluating the experiences of stroke survivors with immersive VR-based rehabilitation programs are limited. Previous studies with small sample sizes have provided some insights but are insufficient to understand broader experiences and perceptions of such patients [20,21]. Therefore, this study aimed to conduct both quantitative and qualitative analyses of the perception of patients with stroke regarding an immersive VR-based exercise system for poststroke upper limb exercises. Through this mixed methods approach, we aim to obtain a better understanding of the factors influencing perceptions and identify areas for improvement in the design and implementation of VR-based rehabilitation programs.

Methods

Data Source

The data source was a questionnaire survey and semistructured interviews conducted as part of a proof-of-concept randomized controlled trial (RCT) [11]. The trial examined the effectiveness and safety of an immersive VR-based exercise system for poststroke upper limb exercises. The exercise system comprised 5 games (Figures 1-5): dumbbell-lifting game for shoulder flexion and abduction, fishing game for elbow flexion, sheep-whacking game for forearm pronation and supination, apple-picking game for wrist flexion and extension, and balloon-popping game for reaching exercises. The details of the 5 games are presented in Multimedia Appendix 1. A VR headset and a wireless handheld controller (HTC VIVE Pro, HTC Corporation) were used to display and interact with the virtual environments (Figure 6).

Study participants were inpatients at a public hospital in China who have had a stroke. Patients were considered eligible for the study if they were aged 19 to 75 years; had their first ever unilateral stroke, as confirmed by their computed tomography or magnetic resonance imaging records; were experiencing motor impairments in one of the upper limbs, with Brunnstrom stages of stroke recovery of the arm of 3 to 5; had an active range of motion of at least 10° in the shoulder and elbow of the affected arm; could maintain autonomous upright seating for at least 45 minutes; and had normal or corrected-to-normal vision and hearing. Patients with injuries or other health conditions restricting their upper limb mobility, unilateral spatial neglect, unstable medical conditions, a history of seizures or epilepsy, communication difficulty, mood instability, or concurrent participation in any other ongoing investigational drug studies were excluded. Physicians and physical therapists in the rehabilitation medicine department initially introduced the study to their inpatients. Patients expressing interest in participation were invited to a screening session, during which they tried the study's VR devices, and their eligibility was assessed. The researcher (JC) provided detailed explanations of the study to the patients initially determined eligible, confirmed their eligibility, and obtained their written informed consent for participation. In the RCT, participants were randomly assigned to one of the 2 study groups. The intervention group received the aforementioned exercise system and was instructed to use the system to perform upper limb exercises for 35 minutes each day, 6 days a week, for 2 weeks. The control group received commercial games downloaded from Steam (Valve Corporation) and was instructed to play them for the same duration and frequency [22]. These commercial games served as a sham VR program to conceal group assignments from participants. They were not directly aligned with the exercises provided in the exercise system and were used solely for entertainment. Multimedia Appendix 2 provides details of these commercial games. The control group used the same headset and handheld controller as the intervention group. All participants continued their prescribed stroke rehabilitation therapy in the hospital throughout the study period.

Figure 1. Dumbbell-lifting game for shoulder exercise.

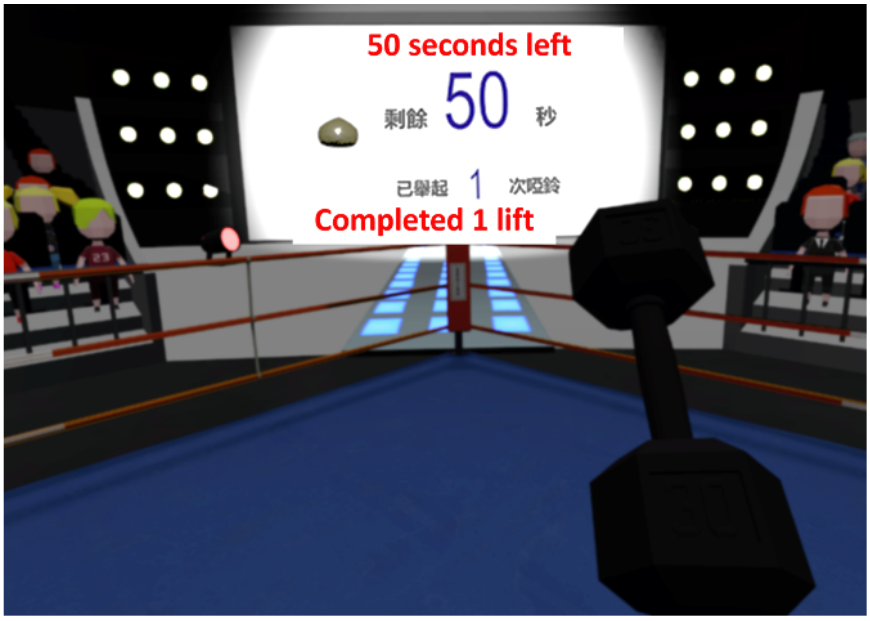


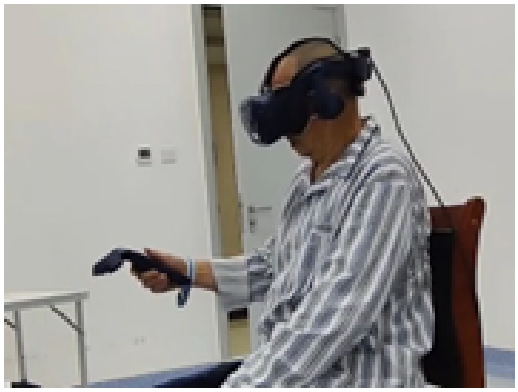
Figure 2. Fishing game for elbow exercise.

Figure 3. Sheep-whacking game for forearm exercise.

Figure 4. Apple-picking game for wrist exercise.

Figure 5. Balloon-popping game for reaching exercise.

Figure 6. A participant performing exercises using the virtual reality device.



The participants' demographic and clinical characteristics, including age, sex, education level, stroke type, time from stroke onset, Brunnstrom stage of the affected arm, and previous experience with VR, were collected at baseline. The effectiveness and safety of the immersive VR-based exercise system were measured at baseline and the 1-week and 2-week follow-up assessments. Owing to the exclusive use of the exercise system by the intervention group, perceptions of the exercise system were only evaluated in this group. A questionnaire survey and semistructured interviews were conducted during the participants' last follow-up assessments; the details are provided in the Questionnaire and Interview sections.

Ethics Approval

The RCT was approved by The University of Hong Kong–Shenzhen Hospital Human Research Ethics Committee (approval number [2021]137) and Dingzhou People's Hospital (approval number hx-2021-04) in China. It has been registered in the Chinese Clinical Trial Registry (registration number ChiCTR2100047150). All the participants provided written informed consent before participating in the RCT. No cash compensation was provided. All data used were deidentified.

Questionnaire

A questionnaire was adapted from technology acceptance models and relevant studies examining individuals' and patients' perceptions of various technologies [23-28]. It was used to assess participants' perceptions of the exercise system, including perceived usefulness, perceived ease of use, attitude, intrinsic motivation, and behavioral intention. Textbox 1 presents the measurement items. The items were rated on a 7-point Likert scale ranging from 1 (very strongly disagree) to 7 (very strongly agree), with higher values indicating more positive perceptions.

Textbox 1. Perception outcomes and measurement items.

Perceived usefulness (PU)

- PU 1: using the immersive virtual reality (VR)–based exercise system to perform upper limb exercises would improve upper limb motor function.
- PU 2: using the immersive VR-based exercise system to perform upper limb exercises would increase exercise efficiency.
- PU 3: using the immersive VR-based exercise system to perform upper limb exercises would enhance exercise effectiveness.
- PU 4: you found the immersive VR-based exercise system useful for performing upper limb exercises.

Perceived ease of use (PEOU)

- PEOU 1: learning to use the immersive VR-based exercise system was easy for you.
- PEOU 2: you found it easy to get the immersive VR-based exercise system to do what you wanted to do.
- PEOU 3: it was easy to become skillful at using the immersive VR-based exercise system.
- PEOU 4: you found the immersive VR-based exercise system easy to use.

Attitude (ATT)

- ATT 1: using the immersive VR-based exercise system to perform upper limb exercises is a good idea.
- ATT 2: using the immersive VR-based exercise system to perform upper limb exercises is a wise idea.
- ATT 3: you like the idea of using the immersive VR-based exercise system to perform upper limb exercises.
- ATT 4: using the immersive VR-based exercise system to perform upper limb exercises was a pleasant experience.

Intrinsic motivation (IM)

- IM 1: you found using the immersive VR-based exercise system to perform upper limb exercises enjoyable.
- IM 2: the actual process of using the immersive VR-based exercise system to perform upper limb exercises was pleasant.
- IM 3: you had fun using the immersive VR-based exercise system to perform upper limb exercises.

Behavioral intention (BI)

- BI 1: you intend to continue using the immersive VR-based exercise system to perform upper limb exercises.
- BI 2: You plan to continue using the immersive VR-based exercise system to perform upper limb exercises.

Interview

As the RCT was a proof-of-concept trial, individual, face-to-face, and semistructured interviews were conducted to learn more about the participants' experiences with the exercise system, allowing us to improve it further. Open-ended questions were asked regarding the exercise system's comfort, comprehensibility, usefulness, and the participants' preferences and intention to use the system. Textbox 2 presents the details of the interview questions. During the interview, a researcher (JC) reformulated and clarified questions to ensure the participants' complete comprehension. Probing questions, such as "What do you mean by that?" and "Could you be more specific?" were also asked to obtain deeper insights into the participants' responses when necessary.

Textbox 2. Interview questions.

Comfort

- Do you feel any discomfort when using the immersive virtual reality (VR)–based exercise system?
- Do virtual environments make you feel uncomfortable?
- Does the headset or the handheld controller make you feel uncomfortable?
- (Ask if the participants reported discomfort) What makes you feel uncomfortable?

Comprehensibility

- Is it easy for you to understand the exercise tasks?
- Is it easy for you to use the headset or the handheld controller?
- (Ask if the participants reported difficulties) What do you find difficult to understand or use?

Usefulness

- Do you think that the immersive VR-based exercise system is useful for your upper limb rehabilitation?
- What makes you think the immersive VR-based exercise system is useful for your rehabilitation?
- What makes you think that the immersive VR-based exercise system is useless for your rehabilitation?

Preference

- Do you like the immersive VR-based exercise system?
- What aspects of the immersive VR-based exercise system do you like?
- What aspects of the immersive VR-based exercise system do you dislike?

Intention to use

- Do you intend to use the immersive VR-based exercise system for rehabilitation in the future?
- What motivates you to use the immersive VR-based exercise system for rehabilitation?
- What fails to make you intend to use the immersive VR-based exercise system for rehabilitation?

Procedures

Written informed consent was obtained from each participant before enrollment into the RCT. Before starting, the researcher (JC) explained the objectives of the questionnaire and interview. The participants then completed the questionnaire to indicate their perceptions of the exercise system. Next, the researcher interviewed the participants. Verbal consent for audio recording was verified again before the start of the interviews. During the interviews, the participants were encouraged to express their experience with the exercise system as much as possible. The interview was audio recorded for subsequent transcription. The interviews were conducted in Chinese. The administration of the questionnaire and interview lasted approximately 20 minutes for each participant.

Data Analysis

Questionnaire

Descriptive statistics, including the mean, SD, median, and rating distribution of the measurement items, were calculated.

Interview

The interview audiotapes were transcribed verbatim by the researcher (JC). Two researchers (JC and TC) with backgrounds in human factors and health care informatics were involved in the analysis. The interview transcripts were analyzed using a qualitative content analysis approach with 3 steps [29]. Step 1: the interview transcripts were read several times before being independently analyzed by the 2 researchers. During the initial reading, the 2 researchers read through the interview transcripts while listening to the interview audiotapes to verify the accuracy of the transcripts and to gain an overall sense of the interview content. During the subsequent reading, the 2 researchers read through the interview transcripts in detail to gain a thorough understanding of the interview content. Step 2: an inductive approach was used to analyze the data because this approach allows the identification of codes and themes that answer the research question [30]. During the data analysis process, the first interview transcript was independently analyzed by the 2 researchers. Relevant statements from the interview transcript were identified, and codes were generated, which were then refined and developed into themes. The same process was repeated for each interview transcript, with the codes and themes added, revised, or developed each time. In addition, the frequencies of the statements expressed by the participants were recorded. Step 3: after all the interview transcripts were analyzed, the codes and themes were compared between the 2 researchers. In case of discrepancies, the original interview transcripts were checked, and the discrepancies were resolved through discussion between the 2 researchers until a consensus was reached.

NVivo (version 12; Lumivero) was used for content analysis, which was based on a checklist of consolidated criteria for reporting qualitative research [31].

Results

Participant Characteristics

Of the 25 intervention group participants, 3 were discharged from the hospital in advance and 1 withdrew from the study, leaving 21 participants who completed the questionnaire and interviews. The demographic and clinical characteristics of the 21 participants are presented in Table 1. The mean age was 55.3 (SD 12.9) years, and the participants were predominantly male (15/21, 71%). Two-thirds of the participants had completed their secondary school education (14/21, 67%). Two-thirds of the participants had an ischemic stroke (14/21, 67%), with a mean time from stroke onset until study enrollment of 37.2 (SD 25.9) days. More than half of the participants (13/21, 62%) were at Brunnstrom stage 3. Most participants had no experience using a VR device (20/21, 95%).

Table 1. Characteristics of the participants (N=21).

Characteristics	Values
Age (y)	
Mean (SD)	55.3 (12.9)
Median (range; IQR)	54 (28-75; 46-66.5)
Sex, n (%)	
Male	15 (71)
Female	6 (29)
Education level, n (%)	
No schooling completed	0 (0)
Some level of primary schooling	0 (0)
Primary school completed	6 (29)
Some level of secondary schooling	0 (0)
Secondary school completed	14 (67)
Diploma, advanced diploma, associate degree, or equivalent	1 (5)
Bachelor’s degree	0 (0)
Stroke type, n (%)	
Ischemic	14 (67)
Hemorrhagic	7 (33)
Time from stroke onset at enrollment (d)	
Mean (SD)	37.2 (25.9)
Median (range; IQR)	34 (7-107; 18-56)
Brunnstrom stage of the affected arm, n (%)	
3	13 (62)
4	4 (19)
5	4 (19)
Experience using a VR[a] device, n (%)	
Never	20 (95)
Rarely	1 (5)
Sometimes	0 (0)
Often	0 (0)
Always	0 (0)

[a]VR: virtual reality.

Questionnaire

Table 2 presents the distribution, mean (SD), and median of the participants' ratings for each measurement item on the questionnaire. The mean values of the overall ratings for perceived usefulness, perceived ease of use, attitude, intrinsic motivation, and behavioral intention were 6.20 (SD 0.69), 6.33 (SD 0.80), 6.25 (SD 0.74), 6.37 (SD 0.75), and 6.31 (SD 0.84), respectively. The median ratings for each measurement item were 6 or 7.

Table 2. Distribution, mean (SD), and median of the participant's responses to the measurement items (N=21).

Outcomes	Rating distribution, n (%)							Mean (SD)	Median
	1	2	3	4	5	6	7		
PU[a]									
PU 1	0 (0)	0 (0)	0 (0)	0 (0)	5 (24)	7 (33)	9 (43)	6.19 (0.81)	6
PU 2	0 (0)	0 (0)	0 (0)	0 (0)	5 (24)	8 (38)	8 (38)	6.14 (0.79)	6
PU 3	0 (0)	0 (0)	0 (0)	0 (0)	4 (19)	10 (48)	7 (33)	6.14 (0.73)	6
PU 4	0 (0)	0 (0)	0 (0)	0 (0)	2 (10)	10 (48)	9 (43)	6.33 (0.66)	6
PEOU[b]									
PEOU 1	0 (0)	0 (0)	0 (0)	0 (0)	3 (14)	6 (29)	12 (57)	6.43 (0.75)	7
PEOU 2	0 (0)	0 (0)	0 (0)	1 (5)	3 (14)	7 (33)	10 (48)	6.24 (0.89)	6
PEOU 3	0 (0)	0 (0)	0 (0)	1 (5)	2 (10)	7 (33)	11 (52)	6.33 (0.86)	7
PEOU 4	0 (0)	0 (0)	0 (0)	1 (5)	3 (14)	5 (24)	12 (57)	6.33 (0.91)	7
ATT[c]									
ATT 1	0 (0)	0 (0)	0 (0)	0 (0)	5 (24)	6 (29)	10 (48)	6.24 (0.83)	6
ATT 2	0 (0)	0 (0)	0 (0)	1 (5)	3 (14)	7 (33)	10 (48)	6.24 (0.89)	6
ATT 3	0 (0)	0 (0)	0 (0)	0 (0)	5 (24)	8 (38)	8 (38)	6.14 (0.79)	6
ATT 4	0 (0)	0 (0)	0 (0)	0 (0)	3 (14)	7 (33)	11 (52)	6.38 (0.74)	7
IM[d]									
IM 1	0 (0)	0 (0)	0 (0)	0 (0)	3 (14)	7 (33)	11 (52)	6.38 (0.74)	7
IM 2	0 (0)	0 (0)	0 (0)	0 (0)	4 (19)	6 (29)	11 (52)	6.33 (0.80)	7
IM 3	0 (0)	0 (0)	0 (0)	0 (0)	3 (14)	7 (33)	11 (52)	6.38 (0.74)	7
BI[e]									
BI 1	0 (0)	0 (0)	0 (0)	1 (5)	2 (10)	7 (33)	11 (52)	6.33 (0.86)	7
BI 2	0 (0)	0 (0)	0 (0)	1 (5)	2 (10)	8 (38)	10 (48)	6.29 (0.85)	6

[a]PU: perceived usefulness.

[b]PEOU: perceived ease of use.

[c]ATT: attitude.

[d]IM: intrinsic motivation.

[e]BI: behavioral intention.

Interviews

Overview

A total of 87.23 minutes of interview audiotapes were recorded. The interviews lasted between 2.43 and 8.30 (mean 4.15; median 3.88) minutes. The results of the content analysis were categorized into positive and negative perceptions of the exercise system. The details of the qualitative data are presented in the following sections.

Positive Perceptions of the Exercise System

Overview

A total of 73 statements derived from 21 participants were coded as positive perceptions. Of these, 25 (34%) statements were related to ease of use, 20 (27%) to benefits, 9 (12%) to enjoyment, 7 (10%) to assistance, 7 (10%) to accessibility, and 5 (7%) to game design. The findings are summarized in Table 3.

Table 3. Positive perceptions of the exercise system (N=21).

Themes, subthemes, and statements	Participants who made the statement, n
Ease of use	
Easy to understand games	
Easy to understand how to play the games	20
Easy to use VR[a] devices	
Easy to use the head-mounted display and handheld controller	5
Benefits	
Improved upper limb motor function	
Improved muscle strength	5
Improved range of motion	3
Improved stability	3
Improved overall movement performance	2
Improved flexibility	1
Improved daily living skills	
Improved self-care skills in daily life	1
Improved cognitive ability	
Improved reaction speed	2
Promoted brain thinking	1
Improved mood	
Was in a good mood	2
Enjoyment	
Had fun exercising	
Had fun during the exercise	9
Assistance	
Assisted in motor learning	
Assisted the affected upper limb in developing normal movement patterns	7
Accessibility	
Promoted access to exercise	
Provided more opportunities for exercises	7
Game design	
Virtual environments	
Well-created virtual environments	2
Feeling of immersion	
High immersion level	2
Novelty	
Novel games	1

[a]VR: virtual reality.

Ease of Use

Of the 21 participants, 20 expressed that the games were easy to understand. One of them felt that it was difficult to play the games the first time because of unfamiliarity, although it became easy after a few trials. A total of 5 participants reported that the headset and handheld controller were easy to use. Some participants stated the following:

> *[I] know how to play each [game]*. [Participant 20]
>
> *It is difficult [to play the games] the first time when you are not familiar, but after you practice a few*

times, it is not difficult, because you get to know what is going on. [Participant 1]

Picking up apples [the apple-picking game] is used to extend [the wrist]. I know it. [Participant 18]

No difficulties [in using the headset or the handheld controller]. [Participant 3]

Benefits

Some participants reported that their upper limb motor function had improved. Specifically, 5 out of 21 participants expressed that their muscle strength had increased, 3 reported that their range of motion had improved, 3 expressed that their affected upper limb became more stable, 2 expressed that their overall upper limb movement performance had improved, and 1 said that their hand became more flexible. Some examples of the participants' statements are as follows:

Muscle strength is a little better. There is no obvious [feeling] when putting the weight [on the wrist]. [It is] not tiring. [Participant 17]

[I] can get the elbow straight. [Participant 13]

Wasn't it [the arm] wobbly before? The balance does not seem good. Now it [the arm] is not wobbly like that. [Participant 18]

It [the immersive VR-based exercise system] makes your hands more flexible and softer. [Participant 1]

The joints can move to the correct location. [Participant 7]

It [the immersive VR-based exercise system] is good for arm movements, meaning your movements are more standard. [Participant 3]

One participant observed improvements in their ability to perform self-care eating activities:

I can easily pick up and hold the food now. [I needed to] break it [into small pieces] before. I was afraid that [I] could not hold it and dropped it. Now I do not need to break it [into small pieces], I can hold it and eat it directly. I can also hold the cup when brushing [my] teeth and cleaning [my] mouth. [Participant 18]

Two participants mentioned that playing games improved their reaction speed to the computer, and 1 participant expressed that playing games could promote thinking:

To the computer...I feel that [my] reaction is faster. [Participant 9]

[The immersive VR-based exercise system] can facilitate your thinking and make the brain work hard. [Participant 1]

Two participants expressed that they were in a good mood when immersed in the virtual environments.

I have been kind of stressed since I got this disease, but once I listen to that music, [my] mood turns good....I feel like I am alive again, walking into that wood and picking apples like [in] real [life], and being immersed into that environment. I feel like ... my mind broadens. [Participant 1]

[I] feel like myself...anyway, I feel as if I am still useful, I will be able to do housework like before, to do this and that. It seems like the feeling of pessimism has been reduced. [Participant 1]

Enjoyment

Of the 21 participants, 9 described their feelings of enjoyment and fun when performing VR exercises. For example, some participants stated as follows:

At least performing [exercises] with it [the immersive VR-based exercise system] is not that annoying, not that boring. [Participant 5]

You are free to play this [game]. It is also exciting. [Participant 8]

It [the immersive VR-based exercise system] is quite fun and can also train the function of the limbs. [Participant 19]

Assistance

Of the 21 participants, 7 expressed that they might not know how to perform some movements in the real world; however, the virtual objects in the games guided and helped them to learn and encouraged them to try to perform the movements. Some participants stated as follows:

You know [I] could not do that movement [elbow extension] before. I feel it [the immersive VR-based exercise system] is useful. [The elbow] could extend when [I] put the fishing rod down. [Participant 5]

[When] you would attempt to perform [the movements], it [the arm] could not move, but you would attempt to do it. [Participant 6]

For example, that apple-picking [game], together with that bird, could guide my hand to perform the movements [wrist flexion and extension]. [Participant 7]

Accessibility

Of the 21 participants, 7 reported that the exercise system provided more opportunities for exercise. Some examples of the participants' statements are as follows:

[I like using the immersive VR-based exercise system because I] can exercise. I can always exercise. [Participant 4]

[I like using the immersive VR-based exercise system because it] provides arm exercises. [Participant 13]

Game Design

Several participants expressed interest in the game design. Two out of 21 participants stated that the virtual environments were attractive, 2 stated that the games provided a sense of immersion, and 1 stated that the games were innovative. Some participants stated as follows:

[It is] just like being in a wonderland, right? It is also very clear, just like the 3D movies. I like looking around and performing the exercises. [Participant 21]

There are images, music, and sounds of the birds. It makes you feel like you are in the woods. I feel very excited. [Participant 1]

The games are novel. [Participant 17]

Negative Perceptions of the Exercise System

Overview

A total of 15 statements derived from 8 participants were identified as negative perceptions. Of those, 8 (53%) statements were related to difficulty in handling VR devices, 6 (40%) statements to uncomfortable experiences when using VR devices, and 1 (7%) statement to monotony. The findings are summarized in Table 4.

Table 4. Negative perceptions of the exercise system (N=21).

Themes, subthemes, and statements	Participants who made the statement, n
Difficulty in handling VR[a] devices	
Bulky headset	
Heavy headset	3
Sweating and stuffiness when wearing the headset	3
Cable constraint	1
Heavy handheld controller	
Heavy to hold handheld controller	1
Uncomfortable experiences when using VR devices	
Dizziness	
Feeling dizzy when using the headset	2
Fatigue	
Feeling tired during the exercise	2
Eyestrain	
Eyestrain when using the headset	1
Pain	
Pain during exercise	1
Monotony	
Boring exercise	
Repetitive movements leading to monotony	1

[a]VR: virtual reality.

Difficulty in Handling VR Devices

Of the 21 participants, 3 indicated that the headset was heavy, 3 mentioned that wearing the headset made them feel sweaty and stuffy, 1 stated that the cable connecting the headset and laptop constrained their head movement, and 1 mentioned that the handheld controller was heavy to hold. Some participants stated the following:

I feel that the headset is a little heavy. [Participant 5]

It is a little sweaty [when wearing the headset]. It is not tiring; it is stuffy. [Participant 8]

The head is being pressed. It is uncomfortable. [I] feel that it would be good if it were wireless [headset]. [Participant 5]

[If the headset is wireless], turning it [the head] around would be convenient and free. [Participant 5]

It [the handheld controller] is just heavy. The total weight is heavy. [Participant 1]

Uncomfortable Experiences When Using VR Devices

Two out of the 21 participants mentioned that wearing the headset led to dizziness, 2 reported that they experienced fatigue during the VR exercises, 1 highlighted that wearing the headset caused eyestrain, and 1 reported experiencing pain in the upper limb during the VR exercises. Some of the participants stated as follows:

[I] felt a little dizzy after taking off [the headset]. [Participant 5]

Watching [the virtual environments], the eyes are not very comfortable. [Participant 6]

[The] part [of the upper limb that] worked hard...was sore. [Participant 7]

It was a little painful when stretching. [Participant 18]

Monotony

One participant reported that repeating the same exercises every day was boring, but the participant kept doing the exercises to recover faster.

> *For my own health, [I] mean to recover faster, the exercises must be performed, right? ...It is, of course, boring, always repeating the same movement.* [Participant 18]

Discussion

Principal Findings

Overview

This study aimed to investigate the perceptions of stroke survivors regarding the use of an immersive VR-based exercise system for poststroke upper limb exercises. Quantitative and qualitative analyses were used to explore these perceptions. The questionnaire results revealed that the participants recognized the exercise system's usefulness for rehabilitation, found the exercise system easy to use, maintained a positive attitude toward the exercise system, enjoyed using the exercise system for exercises, and expressed their intention to continue using the exercise system. The interviews further uncovered the following 6 themes related to positive perceptions of the exercise system: (1) ease of use, (2) benefits, (3) enjoyment, (4) assistance, (5) accessibility, and (6) game design. Conversely, 3 themes were associated with negative perceptions: (1) difficulty in handling VR devices, (2) uncomfortable experiences when using VR devices, and (3) monotony. The interview findings may help interpret the results obtained from the questionnaire and provide further understanding of the factors influencing the patients' acceptance and use of VR-based rehabilitation programs. For example, some patients expressed interest in the highly immersive game scenarios, which might have attracted them to use the exercise system to perform exercises. In contrast, some patients expressed undesirable feelings about wearing the headset, which might have led to a negative perception regarding the exercise system and impeded its use. Moreover, our findings serve as a concrete illustration of established technology acceptance models, such as the Technology Acceptance Model and Unified Theory of Acceptance and Use of Technology model. For example, previous research has underscored perceived usefulness as a key determinant of technology acceptance by users [23,24,32,33]. Our study further elucidated that motor function, daily living skills, cognitive ability, and mood were the main aspects of usefulness valued by the participants. In the following sections, we delve into the questionnaire and interview findings in greater detail.

Perception Ratings

In contrast to previous studies reporting that individuals with limited prior technology experience are less inclined to accept the technology [8,32,34-37], our findings indicated that a lack of experience with VR may not impede patients' positive feelings about using the exercise system. The interview responses, which are discussed in the following sections, may help explain this. However, the highly positive perceptions might be a result of selection bias, meaning that participants who were satisfied with the exercise system were more likely to adhere to the VR exercises, whereas those who were unsatisfied with it could have withdrawn from the study. Therefore, the patients' perceptions of the exercise system might have been overestimated.

Ease of Use

Ease of use is a critical perceptual aspect affecting technology acceptance [23,24,32,33]. Most patients who have experienced stroke are older adults who often have limited experience with technology and may face declining physical or cognitive functions, as well as technology anxiety [38-41]. Therefore, ensuring that VR-based rehabilitation exercises are easy to use is particularly important for this demographic to promote acceptance and adoption. In this study, almost all participants reported that it was easy to understand how to play the rehabilitation exercise games and use the VR devices. Although 1 participant initially found the games difficult due to unfamiliarity, the participant quickly adapted and found the games easier after practicing several times. This may be because the games were related to daily life (eg, fishing), and there were no complicated tasks or complex operations with the handheld controller. Consequently, participants could easily become familiar with the rules of the games and the use of the VR devices without much training or practice. Another possible explanation may be that most participants were able to perform the exercises independently. Necessary assistance was provided only to ensure their safety and prevent the development of abnormal movements (eg, shrugging the shoulders) by the researcher (JC), with the guidance of physical therapists [11]. These findings suggest several specific implications for VR-based rehabilitation programs. First, the simplicity of game design, mimicking daily life activities, can significantly enhance usability for patients with stroke. Second, minimal training and practice requirements make it feasible for older adults with limited technology experience to quickly adapt to the exercises. Third, providing tailored support to prevent incorrect movements can further improve patient engagement and safety. Consequently, designing technology-based rehabilitation exercises with these considerations can foster greater acceptance, enhance patient adherence, and ultimately improve rehabilitation outcomes for stroke survivors.

Benefits

Participants perceived improved upper limb motor function and daily living skills after using the exercise system. Although this exercise system was initially designed for motor rehabilitation, participants perceived improvements in reaction speed, thinking, and mood. Such gains have rarely been reported in previous studies. One possible explanation may be that the repetitive practice led to familiarity with the exercises, thereby helping the participants increase their reaction speed. Furthermore, the setup of the games in the exercise system, such as the 1-minute countdown and real-time feedback on task performance (refer to details of the games in Figures 1-5 and Multimedia Appendix 1), might provide participants with a sense of tension and competition. This, in turn, might "facilitate your thinking and make the brain work hard," as 1 participant expressed. Another

reason may be the advantages of immersive VR; that is, wearing the headset isolated the participants from the physical world, so they could fully focus on the tasks in the games. Moreover, being able to complete the tasks in the games provided the participants with a sense of achievement, which might have elicited positive emotions. As 1 participant described, being able to play games made the participants feel "useful," and thus, "the feeling of pessimism" has been alleviated. Furthermore, the natural scenes and relaxing background music in the games might have helped relieve the participants' negative emotions due to the stroke. A participant stated as follows:

> *I have been kind of stressed since I got this disease, but once I listen to that music, [my] mood turns good... walking into that wood and picking apples like [in] real [life], and being immersed into that environment. I feel like... my mind broadens.*

The results indicate that the positive experiences associated with these games can help reduce the psychological burden of rehabilitation, making the process feel less like a chore and more like a recreational activity. These findings also suggest that the exercise system possesses the potential to influence multiple dimensions of stroke rehabilitation, which should be considered when designing and implementing such VR-based interventions.

Enjoyment

Consistent with previous studies that used video games for rehabilitation [42-46], performing exercises by playing the games in the exercise system was described as "exciting" and "fun" in this study. These findings suggest that the exercise system offers an enjoyable possibility for performing upper limb exercises. The enjoyment factor has specific implications for VR-based rehabilitation programs. First, enjoyable exercises can increase patient motivation and adherence and can consequently lead to more consistent participation in the rehabilitation regimen. This is particularly important for stroke survivors, as sustained engagement is crucial for recovery. Second, incorporating enjoyable elements into the exercise design can help alleviate technology anxiety, making patients more willing to try and continue using the system. Motivational and enjoyable elements can include reward systems that provide a sense of accomplishment, features that facilitate social interaction, and real-time positive feedback and encouragement.

Assistance

Some participants expressed that the virtual objects in the games guide and encourage them to perform movements that they might not be able to perform in the real world. For example, 1 participant said, "That apple-picking [game], together with that bird, could guide my hand to perform the movements." The rationale behind this effect may be that learning a motor task is more effective when learners' attention is focused on achieving specific goals (ie, focusing on external cues) rather than focusing on performing specific movements (ie, focusing internally on the movements themselves) [47-49]. For example, the apple-picking game was designed for wrist flexion and extension exercises. It required the participants to extend their wrists to pick a red apple and flex their wrists to drop it. Picking up and dropping the apple (ie, external focus) was relatively easy for the participants to understand because the instructions were specific and the goal was clear. However, if the participants were told to contract and relax muscles in the wrist and forearm (ie, internal focus), it would have been too abstract to understand and execute the movements. These findings suggest that the objects in virtual environments should be carefully designed because they play a vital role in helping patients learn movements and perform therapeutic tasks.

Accessibility

The participants reported that the exercise system provided extra opportunities to perform rehabilitation exercises, reflecting their need for exercises in addition to conventional rehabilitation therapy. A possible explanation may be that the needs for rehabilitation in patients who have experienced stroke, may not always be fulfilled because of constraints on professional and institutional resources in public hospitals [50,51]. For example, the patients in this study usually had to wait several days before getting an appointment with a physical therapist. The patients could only receive 30 minutes of physical therapy with the guidance of therapists every day during hospitalization [11], which was less than the treatment duration suggested in previous research [52,53].

Game Design

The games in the exercise system were characterized as "novel"; the virtual scenes and auditory components within the games offered the participants a highly immersive experience, described as "being in a wonderland." These findings suggest that the virtual environment design and the VR device type might significantly impact user experience, which should be carefully considered when designing VR-based interventions. The implications of these findings are multifaceted. First, the novelty and immersive nature of the virtual environment can greatly enhance user engagement and enjoyment, making the rehabilitation process more appealing to patients. This implies that designers should focus on creating visually rich and interactive environments that capture patients' attention and interest. Second, the type of VR device used can affect the level of immersion and comfort. High-quality VR devices that offer clear visuals, realistic audio, and ergonomic design can prevent discomfort and enhance the overall experience. This suggests that investment in advanced VR hardware could be beneficial. Third, the positive descriptions of the experience indicate that carefully crafted virtual environments can provide a significant psychological boost to patients. Feeling as though they are "in a wonderland" can distract patients from the monotony of repetitive exercises, making the rehabilitation process feel less burdensome and more enjoyable. Fourth, these findings suggest that regular updates and new content should be incorporated to maintain novelty and engagement levels. Stale or repetitive content could undermine the benefits of the initial immersive experience, so ongoing development and refreshing content are crucial.

Difficulty in Handling VR Devices

Negative perceptions were mainly related to using the headset and handheld controller. Wearing the headset was heavy, making participants feel sweaty and stuffy, the cable used to connect

the headset to the laptop sometimes limited the free movement of the participants' heads, and the handheld controllers were heavy for some participants. This is due to the technical limitations of current VR technology. A large headset is necessary to support a high-resolution display, and a physical cable is needed to support the transmission of massive amounts of real-time data at a high speed and low latency. A better user experience with an immersive VR device relies on advances in hardware and software. For example, the development of retina displays can reduce the size of a headset and improve its wearable comfort, and advances in wireless transmission technology can facilitate the development of wireless VR devices to promote users' freedom of movement in virtual environments [54,55].

Uncomfortable Experiences When Using VR Devices

A few participants experienced mild and short-lived discomfort with the VR exercise system, such as dizziness and eyestrain, as observed by the researcher. These findings indicate that the exercise system overall was well tolerated by the participants. Nevertheless, factors that may be associated with the side effects of immersive VR should be further identified and minimized in the design and development of immersive VR-based interventions for patients. The implications of these side effects are crucial for the safe implementation of VR-based rehabilitation programs. First, identifying the root causes of discomfort, such as prolonged use, visual strain from screen resolution, or motion sickness due to discrepancies in visual and vestibular input, is essential. Addressing these issues could involve optimizing session durations, improving screen technology, and ensuring smooth and realistic motion tracking. Second, providing clear guidelines and training for patients on how to use the VR system correctly can help minimize discomfort. Educating users on taking regular breaks, adjusting headset fit, and recognizing early signs of discomfort can enhance their overall experience. Third, personalizing the VR experience based on individual tolerance levels can further mitigate adverse effects. Implementing customizable settings that allow patients to adjust brightness, contrast, and motion sensitivity can help tailor the experience to their comfort. Fourth, continuous monitoring and feedback mechanisms can be integrated into the VR system to track patient responses in real time. This would allow for immediate adjustments and support, ensuring that the therapy remains both effective and comfortable.

Monotony

Although the upper limb exercises were designed as games, repetitive practice can become boring and monotonous for some individuals, potentially lowering their motivation to adhere to the exercise system [56]. This finding underscores the need for further exploration of strategies to sustain patients' interest in VR-based interventions in the long term. Several strategies can be considered. First, incorporating a variety of game scenarios and levels can keep the exercises fresh and engaging, thereby preventing boredom. For instance, rotating through different themes, such as sports, adventure, and daily activities, can maintain patients' interest. Second, designing exercises with progressively challenging tasks can provide a sense of achievement and keep patients motivated. Third, personalizing exercise routines to match the individual's progress and preferences can make the sessions more enjoyable and relevant. Fourth, integrating social elements, such as multiplayer modes or community challenges, can enhance the fun aspect and encourage patients to stay committed to their rehabilitation.

Implications for Practice

This study offers the following implications for practice. First, the immersive VR-based exercise system was initially accepted by patients because it offered increased exercise opportunities and was easy to use, enjoyable, and beneficial for motor rehabilitation. Thus, health care technology developers, public health decision makers, and health care providers can consider the possibility of integrating such VR-based interventions to complement conventional therapeutic exercises. The aforementioned characteristics should also be addressed to increase the likelihood of system acceptance. Second, therapeutic games can function as an appealing approach to encourage patients to engage in exercises. The preferences demonstrated by patients toward the games within the exercise system, including well-designed virtual environments and a high level of immersion, offer valuable insights for future refinement of VR-based exercise systems. Consequently, this can enhance the user experience and foster the acceptance of such systems. Third, considering patients may have limited prior technology experience, exercise systems must prioritize ease of use. To achieve this, integrating usability inspections and tests throughout the developmental phase is recommended. This approach ensures that the newly developed systems align with users' needs and expectations, ultimately making them usable and useful [57-62]. Fourth, it is important to recognize that patients may encounter discomfort during VR exercises. Although this aspect was highlighted by patients only a few times, health care professionals must remain vigilant about the potential risks of VR technology in the use of VR-based exercise systems. During the design phase, the types of VR devices to be used should be carefully chosen or evaluated, considering the patients' abilities. In addition, elements within virtual scenes that might induce discomfort, such as poor environmental illuminance and highly realistic graphics, should be avoided. During the implementation phase, health care providers should meticulously assess patients' susceptibility to side effects related to VR-based therapy. Education can play a vital role in minimizing the risk of discomfort (eg, advising patients to avoid rapid head movements in virtual environments), and individualized therapy plans should be tailored to each patient's unique needs and circumstances.

Implications for Research

This study's findings provide implications for future research. First, possible reasons for the participants' withdrawal from the study should be further examined, as these may shed light on factors that impede patients' acceptance of and adherence to the intervention. Such information would help improve the design and implementation of VR-based interventions, improve patients' experiences with and acceptance of such interventions, and increase their benefits for patients. Further studies are warranted to collect information using approaches such as interviews with patients and heuristic evaluation by experts

[63]. Second, fewer statements related to negative perceptions of the exercise system were identified than those related to positive perceptions. One possibility for this finding may be that the respondents were inclined to be agreeable and positive to avoid the disapprobation of the interviewers [64,65]. Future studies should consider the impact of response bias on the validity of the results, detect such biases when administering questionnaires and conducting interviews, and deal with the bias during data analysis. Third, the participants used the immersive VR-based exercise system for up to 2 weeks. However, poststroke motor rehabilitation is often a long-term process, and patients' experiences with the exercise system may change with time. Further research is needed to examine patients' perceptions of such VR-based interventions in the long term. For example, it has been suggested that >15 hours of total intervention are needed to produce improvements in upper limb motor function [66]. Further studies should accumulate patients' experiences with such VR-based interventions at different time points. Fourth, the implementation of VR-based interventions requires the involvement of health care providers and caregivers, whose attitude toward such interventions can also influence patients' acceptance of and adherence to VR-based therapy [24,32,33]. Therefore, research examining the opinions of health care providers and caregivers regarding VR-based interventions is warranted.

Limitations

This study has several limitations. First, the participants included in the study were predominantly male individuals (15/21, 71%), were in the subacute stage of stroke (≤6 months after stroke onset), and had limited experience using VR devices. Therefore, further research is needed to assess the generalizability of the findings to other user groups. Second, some withdrawals from the study may have been caused by dissatisfaction with the VR-based exercise system, which might have led to an overestimation of the participants' perceptions. In addition, the participants' reasons for withdrawal were not recorded, resulting in their barriers to accepting and adhering to VR exercises and the usability issues of the exercise system being unknown. Third, participants' perceptions of the exercise system were based on a relatively short period of use. Long-term perceptions of the system should be investigated in future studies. Fourth, some interviews were brief. Consistent with challenges documented in relevant studies [67,68], some of our participants exhibited limited communication and articulation. This limitation could be attributed to reduced sensitivity to perceptions and increased susceptibility to fatigue following brain injuries. For future studies, it may be beneficial to explore other strategies that could improve overall understanding, such as engaging caregivers and family members who can represent patients' experiences to provide complementary information; using group discussions to enhance participation, expression, and recall; and establishing user-friendly communication methods (eg, avoiding highly technical terms) [67-69].

Conclusions

Integrating VR to support poststroke functioning improvement exercises appears promising and acceptable based on patient interests. However, individual preferences and adaptability must be considered to achieve optimal outcomes, as some patients may find VR challenging. VR-guided exercise approaches of this nature should be simple to use, promote improvement in health conditions, foster a sense of fun, facilitate exercise access, and be well-designed in terms of VR exercise content. In addition, these approaches must address challenges such as bulky VR equipment, motion sickness, discomfort, and exercise monotony. Overall, assessing and addressing both favorable and unfavorable patient concerns should be done early in the development process, as this is critical for diffusion and adoption.

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Data Availability

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

Authors' Contributions

JC and CKO designed the study. ZL and EHKY supported participant recruitment and experiment implementation. JC conducted data collection. JC and TC performed data analysis. JC drafted the manuscript. CKO reviewed and significantly revised the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Games developed and used by the intervention group in the randomized controlled trial.
[DOCX File , 23 KB - games_v13i1e49847_app1.docx]

Multimedia Appendix 2
Commercial games used by the control group in the randomized controlled trial.
[DOCX File , 19 KB - games_v13i1e49847_app2.docx]

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Abbreviations

RCT: randomized controlled trial
VR: virtual reality

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