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Viewpoint

Extended Reality for Enhanced Telehealth During and Beyond COVID-19: Viewpoint

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Abstract

The COVID-19 pandemic caused widespread challenges and revealed vulnerabilities across global health care systems. In response, many health care providers turned to telehealth solutions, which have been widely embraced and are likely to become standard for modern care. Immersive extended reality (XR) technologies have the potential to enhance telehealth with greater acceptability, engagement, and presence. However, numerous technical, logistic, and clinical barriers remain to the incorporation of XR technology into telehealth practice. COVID-19 may accelerate the union of XR and telehealth as researchers explore novel solutions to close social distances. In this viewpoint, we highlight research demonstrations of XR telehealth during the COVID-19 pandemic and discuss future directions to make XR the next evolution of remote health care.

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KEYWORDS

extended reality; virtual reality; augmented reality; mixed reality; telehealth; telemedicine; COVID-19; telepresence

Introduction

In-person health care became limited during the COVID-19 pandemic. Social distancing, travel restrictions, and lockdowns forced many to perform and receive health care remotely via telecommunication (ie, telehealth) [1]. Telehealth emerged as a widely effective and accepted solution to support continuity of care throughout the ongoing pandemic [2-4]. Consensus among providers, patients, and policymakers indicates that the shift to telehealth will likely continue even after the pandemic ends [5-7]. To maintain current uptake and support delivery of the best possible care in the future, telehealth needs to supplement and transcend traditional models of in-person care.

As the health care industry adapts to telehealth, aspects of in-person treatment must be optimized for remote care (eg, conversational flow, physical evaluation, therapeutic presence). Some patients report reluctance to self-advocate during typical telehealth sessions because of poor eye contact and audio interference if more than one person speaks at a time [8].

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Providers may find it difficult to build rapport and express empathy with patients via telehealth due to limited visibility of body language and the unavailability of physical presence [9]. Both providers and patients can encounter distractions as telehealth is conducted from within their homes [10]. Although telehealth appears set to become the new norm, novel approaches are needed to optimize patient outcomes by restoring critical aspects of in-person health care for remote formats and expanding clinical options to deliver health services at a distance.

Technologies that evoke presence—the perception, feeling, and interaction with simulations as if they were real [11]—can meaningfully impact the practice and outcomes of telehealth. Immersion into fully simulated virtual reality (VR) [12], simulated objects or overlays superimposed onto users' real sight in augmented reality (AR) [13], or direct interaction between simulations and the physical world in mixed reality (MR) [14] each afford new ways to support, extend, and enhance health care practice in the shift to remote delivery. These VR,

AR, and MR technologies—collectively referred to as extended reality (XR)—have been demonstrated for inpatient and outpatient psychiatric, medical, and rehabilitative applications with equal or greater effectiveness than their non-XR standard treatments [13,15-17]. However, research on XR as an extension of remote health care is comparatively recent and has yet to be synthesized.

The need to explore XR for telehealth has never been greater than in the fallout of COVID-19. Postponement of regular and preventive medical care, the psychological and developmental impacts of the extended pandemic, and escalating reports of provider burnout are harrowing signs on the health care horizon [18-26]. Research on the combination of XR and telehealth embodies recent events, addresses current limitations of conventional telehealth, and paves the path for the health care of tomorrow. We believe that XR telehealth research performed since the onset of COVID-19 will set the tone for research and innovations in the coming years. In this viewpoint, we provide a narrative review of current XR telehealth research and highlight future directions to address remaining barriers.

XR for Telehealth Before COVID-19

The potential for reality-altering technologies in remote health care has been heralded since the earliest days of VR. Early VR required complex and costly computing hardware that kept the technology localized, for use by a single individual, and prohibitively expensive until the proliferation of the internet and affordable computing hardware [27,28]. Once the internet became widely available in the mid-1990s, surgical applications of VR and AR expanded to include multiuser supervision by remote experts, and detailed simulations to plan and practice surgical procedures [29-31]. Growing interest in interactive therapy drove MR technologies for at-home telerehabilitation, sometimes using off-the-shelf video game console hardware [32,33]. XR gradually matured with consumer-oriented hardware and software packages that led to interdisciplinary developments such as online VR for psychiatric treatments and sophisticated medical training simulations [34,35]. However, costs and technical complexity remained barriers to the wide deployment of XR for telehealth [36].

Trends in home computing and entertainment made user-friendly, robust, and polished XR equipment available for personal ownership in the 2010s, which facilitated the rapid growth in XR telehealth research and development [37]. Since then, XR telehealth has expanded to a wide variety of remote health care applications in AR telesurgery and telesupervision, MR training and simulations, VR telemental health, and telemonitoring of fully remote interventions and specialized medical equipment with VR/AR [13,38,39]. Similar growth occurred in consumer markets with reported use of entertainment VR apps and video games for therapeutic purposes such as mental wellness, identity exploration, healthy aging, and social anxiety [40-42].

Advances in internet infrastructure, computer technology, and portable consumer entertainment gradually decreased costs and increased consumer interest in XR devices. Increasing commercial availability of these devices and continued

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innovative research placed XR telehealth on a mainstream trajectory in 2019 [43].

XR for Telehealth During COVID-19

Resource Constraints and the Rise of Telehealth

In early 2020, the World Health Organization declared the COVID-19 pandemic and promoted social distancing to limit the spread [44]. Soon after, mass consumption of personal protective equipment (PPE) such as N95 face masks, medical-grade sanitizers, and disposable gloves led to global supply shortages for both health care workers and the general population [45]. The health care industry's primary response to COVID-19 and PPE shortages was a rapid and widespread shift to remote services [4,46]. By June 2020, in-person health care visits were down by 30% while telehealth visits increased by up to 2013% [47]. This shift was even more pronounced for mental health services, which saw 70% fewer patients in person while telehealth sessions increased by up to 6558% [48,49].

XR telehealth was reported to be an effective solution that enhanced safety and reduced PPE consumption in COVID-19 health care settings. Two frontline case studies showed how medical specialists, unable to travel during quarantine, used AR to provide remote consultation and ventilator management for COVID-positive patients [50,51]. Intelligent AR information displays enhanced the workflows of frontline hospital staff to increase clinical efficiency, improve remote team communications, reduce COVID exposure by 51.5%, and decrease PPE consumption by 83% [52]. VR simulation systems for trauma and emergency medicine offered effective and high-fidelity alternatives to traditional supervision with less need to consume PPE for on-site medical training [53]. XR telehealth alternatives were also demonstrated for patient therapy. A VR group-singing intervention as respiratory therapy for spinal cord injury was found to be feasible, acceptable, enjoyable, and reported as less socially inhibited than the in-person prospects of the same intervention [54]. General population users in another feasibility study favored telemental health in VR over the standard webcam format [55]. Multiuser VR in analog telehealth conditions was found to be an ideal environment to conduct evidence-based cognitive behavioral therapy (CBT) in a space that felt immersive, expressive, private, anonymous, and free from judgment [56]. Overall, this published research shows that XR technologies complemented telehealth solutions to support frontline health care workers and maintain social distancing for critical evidence-based treatments during COVID-19.

Access to Medical and Mental Health Care

In addition to social distancing, local and state governments imposed travel restrictions to limit the transmission of COVID-19 and reduce strain on health care systems [57]. However, these restrictions entailed collateral costs to the public's health. Reduced public transportation disproportionately impacted lower-income and ethnic groups in urban areas, and further destabilized access to health care in rural regions with few local specialists [58-60]. Extended pandemic conditions also increased the global risk of psychological distress, impacted

people's daily habits and life plans, and subjected vulnerable populations to prolonged social isolation [57,61].

Barriers to health care access intensified during the pandemic and XR telehealth emerged as a responsive option. XR telehealth had a particularly significant impact to increase the immediacy of care and access among medically and geographically isolated populations who required continual rehabilitation services [62,63]. In addition to providing immersive and accessible care, XR telehealth connected people in virtual spaces to combat social isolation and maintain health-promoting social relationships over distances [64]. For example, location-based AR video games provided a protective effect for social, physical, and mental health during the pandemic [65-69]. Experts also promoted XR telehealth developments as a potential solution to address the downstream developmental impacts of the prolonged pandemic upon children and adolescents who eagerly take to new technologies [25,70].

Burnout and Contagion Exposure Among Health Care Workers

The psychological distress of COVID-19 was particularly burdensome for health care workers. Sudden increases in workload, overcrowding, medical supply shortages, exposure to the virus, and the suffering of patients led to extreme physical and emotional strain upon frontline and hospital staff [22,71-73]. Health care workers were seven times more likely to exhibit severe COVID-19 symptoms than other workers due to their frequent and extreme exposure to contagion environments [74]. It is estimated that more than 3500 US frontline health care workers have died from COVID-19 contracted during their health care service [75]. Burnout among health care workers proved to be another contagion that spread within hospital wards with cascading staff turnover, compassion fatigue, and secondary traumatic stress [76,77]. Experts anticipate severe downstream impacts upon health care workers, and urge for evidence-based therapeutic interventions responsive to the impacts of COVID-19 and for methods to reduce health care workers' exposure to the virus [78-81].

CBT for mindfulness is known to alleviate burnout and improve overall mental wellness among health care workers [71,82-84]. XR virtual visits have emerged as a promising technology for stress reduction using CBT and other evidence-based telemental health approaches [85,86]. With the advent of telehealth, VR and AR for COVID-related stress and trauma therapies have been promoted for distribution among frontline health care workers [51,87,88]. Although these studies are ongoing, VR telehealth for posttraumatic stress among survivors of COVID-19 has shown promising effects [89,90], and it is reasonable to expect these effects to generalize to providers from these same environments and traumatic experiences [91]. In addition to targeting burnout among health care workers, XR has been used to innovate health care workflows with remote, intelligent, and burnout-reducing solutions. A preliminary application of AR telesurgical consultations allowed remote specialists to provide real-time expertise for COVID-positive patients without travel or exposure risks, paving a way for large-scale future implementation [50]. Interconnected AR systems improved infection control, increased access to

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specialist remote supervision, reduced time spent in contagion environments, and enhanced clinical workflows in frontline health care environments [51,52].

Economic and Professional Pressures on Health Care Providers

The accumulated effects of social distancing, chronic resource shortages, travel restrictions, hospital surges, and pandemic stress created instability for current and future health care providers. By August 2020, more than 16,000 private practices had permanently closed with 41% of their peers facing the same fate with unsustainable loss of staff, patients, and income [20]. The subsequent low viability of for-profit clinics exacerbated concerns with reduced health care support [92]. This new fragility in health care networks was particularly straining for already underserved rural regions and ethnic populations [93,94]. Prolonged pandemic conditions further inhibited traditional pathways to hands-on health care experience and clinical supervision, which delayed professional development of the next generation of health care providers [95-97]. Governments, hospitals, and health care providers rallied to support public health during COVID-19, but extended pandemic conditions created a clear need for remote health solutions to sustain health care practice, improve access to health care, and provide quality health care education.

Many aspects of health care and education were ready for XR and telehealth before the pandemic but remained underutilized due to equipment costs, unresponsive legislation, and limited health insurance coverage [98,99]. COVID-19 produced the conditions necessary to accelerate change, and now provides ample opportunity for those who embrace telehealth and complementary technologies. XR telehealth allowed providers to deliver services into patients' own homes and naturalistic environments, which has long been a limitation of traditional clinical treatment [100]. Low-cost, off-the-shelf hardware and royalty-free software for therapy and rehabilitation made XR telehealth an economically feasible solution [101,102]. XR telehealth training and education also rose in response to COVID-19. The realistic, interactive capabilities of XR were broadly promoted as a solution to reach and educate patients and trainees over distances [103]. Simulations in VR and AR were common, safe, and repeatable alternatives to risky on-site in-person medical student training [104-106]. A cohort of medical-surgical students set to graduate during COVID-19 rated VR training as realistic for 77% of clinical assessments, 81% of treatment options, and 94% of diagnostics. After exposure to the virtual training, 84% of the cohort reported interest in the future use of VR for medical training and 90% overall satisfaction with virtual learning [107]. The rise of telehealth provided options for health care providers to sustain their practice when in-person visits became unfeasible. As part of telehealth, XR also proved to be a critical solution to provide health services and education amid pandemic conditions.

XR Telehealth After COVID-19

General Prospects

The impact of COVID-19 on the health care industry was sudden, severe, and broad. Longitudinal data are necessary to evaluate XR telehealth as an alternative to traditional in-person treatment and training. Nevertheless, XR telehealth served as a critical solution to the emergent conditions of COVID-19, maintenance of health care systems, and preparation of future providers. Telehealth is likely to become a staple of health care practice, as the majority of patients and more than 90% of providers intend to continue remote care beyond the resolution of COVID-19 [108-113]. Telehealth on its own is broadly effective and accepted but still leaves some patients and providers dissatisfied with their interactions with providers, specifically in their ability to feel present and build therapeutic relationships [114-116]. This lack of communicative nuance creates a vagueness in non-XR telehealth interactions that can be interpreted as awkward or even malicious [117]. Continued research and development of XR for telehealth can address some of these barriers to enhance therapeutic relationships, expand clinician capacity, and empower patients toward optimal health outcomes.

XR Can Facilitate Telepresence to Strengthen Teletherapeutic Relationships

Therapeutic alliance is one of the best predictors of treatment success and health outcomes [118-120]. Therapeutic alliance is broadly defined by the relationship between the provider and patient, fostered through mutual agreement of clinical goals and the strategies to achieve those goals [121]. Non-XR telehealth is effective, accepted, and sustainable, but can make it difficult to replicate the communicative nuances and rapport building of in-person health care [122,123]. Health care providers who seem rigid, distant, or distracted (ie, typical attributes of non-XR telehealth [124,125]) produce poorer therapeutic alliances [126], which lead to higher chances of dropout, dissatisfaction, and negative health outcomes [127-129]. As a result, a small but important minority of providers believe that their patients do not enjoy telehealth as much as in-person care [116,130].

Preliminary evidence shows that XR can enhance remote interactions to strengthen therapist-patient relationships. Patients who received interactive CBT using VR avatars reported feeling less judged by their physical appearance, that the VR space was somewhere they could be honest and private with their therapist, and that the interaction felt more casual than an in-person clinic visit [56]. Likewise, physicians reported building rapid trust with their patients while jointly viewing patient body scans in VR and AR [131]. VR has also been promoted over non-VR alternatives for benefits such as more comfortable treatment, higher engagement, greater satisfaction, more consistent practice, greater skill transfer, and facilitation of nonverbal communication that improves therapist-client contact [132].

XR facilitates presence, when one perceives that the virtual environment is real [11]; embodiment, when one perceives a virtual body as one's own real body [16]; and telepresence, when one perceives that they are inhabiting another place with

virtual others [133]. Each of these aspects can aid in the establishment, improvement, and maintenance of therapeutic alliances in telehealth. Miloff and colleagues [134] developed an automated AR hologram embedded in VR exposure therapy and demonstrated that therapeutic alliance measures generalized to the virtual therapist. Although patients reported positive perceptions of this audio-only VR therapist, visually and behaviorally realistic VR therapists have been shown to evoke greater perceived presence [135]. Realistic XR avatars and XR interactions tend to evoke stronger physical and emotional closeness and greater confidence in the credibility of the therapist [135-137], which are key factors that influence an alliance with a virtual health care provider. However, XR telehealth is a nascent field, and more research is needed to understand how the two technologies interact to cultivate therapeutic alliances and impact health outcomes.

XR With Telehealth Can Expand the Reach of Clinicians and Researchers

XR technologies were used frequently for health care education and training prior to COVID-19 [138-140], and this practice is expected to become increasingly common as traditional on-site medical education remains limited under the pandemic [86,104]. Simulation training in XR provides highly realistic experiences that deeply immerse learners in clinically realistic scenarios to facilitate skill acquisition and skill transfer for real application [141]. XR simulations can also provide repeatable exposure to important but improbable clinic scenarios, to prepare for states of emergency, and to access otherwise impossible views of medical procedure [103,142]. Remote XR simulations were used to facilitate skill development, prevent contagion spread, and rapidly disseminate COVID-relevant medical education during the pandemic [52,104,105]. Although the relationship between XR simulation training and clinical outcomes remains unclear [138,143-145], further exploration of remote XR training can help health care workers acquire, develop, and maintain cutting-edge skills with limited access to facilities or clinical populations. XR simulations stand to benefit from technologies to enhance realism and transfer of skills such as remote supervision, haptic feedback, anatomical replicas responsive to MR, and artificial intelligence to provide the most flexible and clinically beneficial education of future health care providers [146].

Health care is complex, fluctuating, and high-stakes work that often necessitates coordination of schedules, tasks, and information between multiple providers and teams. Unfortunately, hospitals are notoriously inefficient and error-prone due to a historic lack of human factors considerations in workflows, communications, equipment, user interfaces, and physical environments [147-150]. XR can play an important role in connected collaborative health care. Telesurgery with AR is a prominent example of how the marriage of XR and telehealth can improve health care work environments with surgeons receiving notes from expert consultants directly on their real-time view of the patient, seeing a proctor's hands directing incisions, and delivering the expertise of medical specialists to regions with few or no local specialists [13,14,50,151]. The benefits of XR telesurgery have recently been demonstrated in nonsurgical medical teams for live

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distanced collaboration for inpatient unit care and coordination [51,152,153]. XR technologies enable immersive learning environments and pervasive sensor-display interfaces in the field. Telehealth enables real-time remote specialist consultation and expert supervision. The combination of XR and telehealth represents a system of potential force multipliers that can support, improve, and extend the capabilities of health care practitioners.

XR telehealth has increased patient access to health care, but this relationship has rich bidirectional potential to explore; clinicians and researchers can use XR telehealth to gain better access to patients and participants. Persky [154] described how controlled programmatic XR experiences could merge with remote clinical trials to minimize researcher and participant travel burdens; streamline and automate data collection; and critically improve engagement, retention, and procedural integrity. The recent popularity of consumer XR entertainment devices such as Facebook Oculus Quest 2, Sony PlayStation VR, and smartphone-based Google Cardboard can function as recruitment, enrollment, and data collection solutions with access to participants in their naturalistic settings. The use of fictionalized XR avatars to represent researcher and participant bodies can provide complete control over social manipulations and single- and double-blind study logistics [155]. Complicated data displays, technical instructions, and study processes such as informed consent are also easy for participants and researchers to visualize and interactively explore together in XR [156-158]. It will be critical to study XR for telehealth as a solution to extend historically localized research practices with mobility deployment to the general public and outreach for remote, underserved populations [159].

XR Can Empower Patients to Seek Health Care and Improve Outcomes

Patients are empowered when they are treated as active collaborators in understanding and making decisions about their health care, rather than as passive subjects merely compliant with "doctors' orders" [160]. Telehealth has already improved patients' access to health care by removing geographical barriers (eg, travel costs and arrangements); however, remaining social and behavioral barriers to patient empowerment may be addressed with humanizing and engaging XR technologies.

There are widespread cultural stigmas that inhibit health-seeking behavior [161,162]. For example, men tend to avoid medical and mental health care to the point of early death and preventable decline in quality of life [163-165]. Other stigmas of diagnosis, gender, sexuality, ethnicity, body image, criminal history, and others similarly compromise health care utilization and outcomes [166-170]. Telehealth provides a beneficial distance that can make patients with stigmatized conditions feel confident and comfortable seeking services from their own homes [171-173]. XR can further enhance telehealth to include temporary, therapeutic distance from stigmatized bodies or identities. Avatars are 3D computer-generated models used in virtual environments to represent agents (eg, patients, providers, computer-controlled characters) [174]. The simulated nature of XR avatars makes them uniquely flexible for personalized health care approaches and interventions. One's avatar can resemble

their physical likeness in XR therapies faithful to what they would be like during an in-person health care visit [142]. Alternatively, patients may build a fictionalized avatar to provide more comfortable degree of anonymity, extend а embodiment-oriented therapies, and as a clinical enhancement for telehealth providers' web-side manner [175,176]. Matsangidou and colleagues [56] recently demonstrated the many benefits of fictionalized avatars in VR treatment for both therapists and patients. Therapists tasked patients to build their own avatars, which provided useful clinical insights as to how the patient viewed themselves (ie, avatar appearance compared to real body). Patients attributed a wide variety of subjective benefits to the use of VR avatars, the most important of which were corroborated by therapists who noticed that avatars occasioned remarkable patient openness and trust. Interestingly, the therapists were also depicted with VR avatars in the form of simplistic cubes that were reported to enhance patients' willingness to discuss difficult topics and engage in other mental health exercises. Telehealth allows patients to access health care with no need to travel, and XR can further enable access to care with no need for concern they will be judged. It will be important to explore avatars in XR telehealth as a solution for stigmas of visible medical conditions (eg, skin disease and burns) [177,178], criminal history or potential (eg, prevention of offense related to sexual preference) [179,180], and provide unprecedented opportunities for mental health and wellness [86,181,182].

The presence of and embodiment facilitated by avatars in responsive XR environments can result in simulated experiences that feel more real than physical reality (ie, hyperpresence) [183]. This hyperpresence may have tremendous clinical potential for remote health care. For example, patient motivation tends to be low for at-home rehabilitation due to the gap between unpleasant exercise and long-term health outcomes [184-186]. XR can boost the salience of physical rehabilitation with fictional but proactive feedback, similar to those in modern entertainment video games. Exaggerated body tracking in XR showed participants' virtual bodies as stretching further and running faster than their real bodies, which significantly improved performance, enjoyment, and motivation for unsupervised rehabilitation-oriented exercises [187,188]. Hyperpresence in XR can also enable treatment contexts that in-person care and telehealth cannot. Traditional mental health treatments for internal stimuli (eg, emotional states or auditory hallucinations) rely on guided imagination that can alternatively be visualized and engaged with directly in XR [189,190]. Further, counterfactual hyperpresence can make health care more approachable for the shy or therapies that can be socially awkward. Group singing is an effective and cost-efficient intervention to promote respiratory health, but participants report lack of confidence when singing in front of others [191]. The same group-singing intervention in remote VR made participants feel socially uninhibited owing to their manifestation as anonymous and nonhuman VR avatars [54]. Hyperpresence is an emerging concept that merits investigation as a potential path for XR to enhance telehealth patient engagement, retention, and comfort. XR is currently used to alter patients' sense of where they are and what they are doing but can also enhance patients' sense of who they are in the future of telehealth [192].

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Remaining Barriers and Steps Forward

Telehealth revolutionized health care to meet patient needs at a distance. Although the majority of telehealth adoption was due to the pandemic, it is clear that telehealth will continue to expand beyond the resolution of COVID-19. We believe that XR is the next evolution for remote care built upon decades of foundational research and innovative demonstrations published in response to COVID-19. Toward that future, however, the barriers to XR are broadly similar to those of telehealth. Both technologies involve costly investments in equipment and training, can be abandoned after investment because of poor usability, and rely on broadband internet access that limits access on the basis of socioeconomic status and geographic location [151,193-195]. To realize the telepresent and empathetic future of XR telehealth, key barriers to mainstream adoption of both technologies must be addressed.

XR technologies involve complex electronic sensors, displays, and networks, which make costs a constant prohibitive factor. In 2000, a clinically sufficient VR headset with necessary computers and proprietary software could cost approximately US \$17,000 (adjusted for 2021 inflation) [34]. However, high-end VR setups can be purchased today for use in one's own home for about US \$3000 total with a growing variety of free-to-use and open-source software [196]. Low-end XR (eg, Google Cardboard VR, Holokit AR) costs as little as US \$15-\$50, involves the use of smartphones many people already own, and has been applied with clinically significant treatment success [102,197]. Costs are anticipated to continue decreasing as consumer XR hardware becomes more established [198]. Concerns over costs can be further addressed with formal cost-benefit analyses of comparative treatment costs and impacts on quality of life.

Commercially produced XR hardware removes many barriers for health care providers interested in the technology, but this reliance on proprietary devices and software can be a double-edged sword for telehealth. Privacy is an ongoing concern with increasingly interconnected health care technologies [199]. This issue is particularly tricky with XR, as few devices exist on consumer markets that are compliant with regulatory health policies and the constantly evolving ways people use XR [40,200,201]. Although XR telehealth can feel private, the reality is that many XR devices and applications needlessly collect identifiable information and share user data with third parties. Certain XR devices such as Oculus Quest 2 are inoperable without data logging, and the manufacturer explicitly discourages its use with protected health information [202]. The recent rapid uptake of telehealth and XR continues to highlight the need for privacy and policy focused on health care end users [203]. Health care researchers, clinicians, consumers, and XR developers will need to organize and openly communicate to promote transparent and responsive privacy measures.

As a relatively new area of research, XR telehealth has a growing number of ethical concerns to address. First, the contexts in which XR telehealth are or are not appropriate have not been well established. XR telehealth may not benefit all

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health conditions or contexts equally. Treatment of high-risk conditions (eg, suicidality) still necessitates in-person responsiveness, while XR remains inaccessible to some (eg, those with chronic neurological conditions) or is unlikely to help others (eg, those with acute delirium). Second, practice competency is unclear with emerging telehealth and XR technologies. The broad foundational principles of competency are expected to be maintained as the public settles into widespread utilization of telehealth [204,205]. However, few telehealth practitioners are also experienced in software and hardware development. This current reality leaves most decisions about XR telehealth features and functions out of the hands of health care providers, making interdisciplinary collaborations a vital need into the future [206]. Third, the unique uses of XR for telehealth carry equal potential for misuse. Immersion, presence, copresence, and embodiment can facilitate remote health care, but it is not yet known how to best utilize these components or when one component should be emphasized over others. Modification of experiential states needs to be transparent and responsible in proportion to the potential risks [207]. Organizations for health care research and practice will need to establish and discuss ethical guidelines for XR telehealth. This is particularly important in light of reports that some are using nonmedical technology resources (eg, apps, games, websites) in lieu of qualified health care and the growing availability of self-help resources with little or no medical oversight [208,209].

In current and coming years, XR content offerings may be the greatest barrier for deployment via telehealth. There are currently about 60 million regular VR users and 91 million regular users of AR in the United States [210]. Major technology companies aim to make XR ubiquitous in the near future, which may make telehealth a more appealing use case for XR [211]. Although there is a growing variety of commercial XR telehealth options, the vast majority of XR consumption is for entertainment and industrial application [212]. XR for telemental health is promising, but uptake has been slow due to lack of usability or easy integration into existing clinical workflows [14,195,213]. It will be vital for researchers, clinicians, and developers to collaboratively assure that telehealth is a priority market in the design of XR hardware and software [214]. Furthermore, there are currently few sources of reputable, evidence-based, comprehensive information for telehealth providers to learn about and make treatment decisions with XR. Scholarly, clinical, and patient advocacy organizations should formally curate XR hardware and software to help navigate emerging treatment options for telehealth providers and patients.

The research literature on XR for telehealth is new, vast, and accelerating. The wide variety of XR hardware and software, study designs and populations, metrics and outcome variables, and vocabularies can be difficult to navigate and synthesize. The parameters of what constitutes VR, AR, and MR are still being explored, leaving overlap and obscurity in terms for practice and literature searches [215,216]. A consistent finding in XR narrative, systematic, and meta-analytic reviews is the variability in approaches that prevent formal comparison between studies [14,143,217]. Toward that end, Birckhead and colleagues [218] have provided recommendations to guide

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progressive and programmatic lines of XR research. Other good practices in this field of research include pretraining to orient participants to XR and minimize error, repeated exposure to detect and control for novelty confounds, and on-demand technical support during XR studies [54,219,220]. Failures with XR telehealth are equally important to publish as successes to accumulate details relevant to application and sustainability. Consistency of language, replicability, long-term effectiveness, and best practices for implementing XR telehealth must be disseminated to establish a comprehensive and conceptually systematic literature.

Conclusion

Studies published during the COVID-19 pandemic showed that XR for telehealth helped health care providers stay safe during

treatment of COVID-19 patients, improved the way health care was delivered to patients remotely, helped sustain a healthy frontline health care workforce, and supported the professional development of current and future providers. Toward the future of telehealth, we argue that XR can enhance interactive nuances and treatment options for telehealth patients, function as a force multiplier for health researchers and clinicians, and provide new options for at-risk patient populations. Cost, privacy, ethical practice, actionable practice guidelines, and improvements to research approaches must be addressed to fully realize the potential benefits of XR for telehealth. Despite these barriers, XR technologies have unique potential to enhance, extend, and expand the future of telehealth in and beyond the COVID-19 pandemic.

Conflicts of Interest

BW is a shareholder and all other authors are employees of Doxy.me, LLC, a commercial telemedicine company. The authors declare no other conflicts of interest.

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Abbreviations

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AR: augmented reality **CBT:** cognitive behavioral therapy

https://games.jmir.org/2021/3/e26520

MR: mixed reality PPE: personal protective equipment VR: virtual reality XR: extended reality

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Original Paper

Feasibility and Effects of Virtual Reality Motor-Cognitive Training in Community-Dwelling Older People With Cognitive Frailty: Pilot Randomized Controlled Trial

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Abstract

Background: Cognitive frailty refers to the coexistence of physical frailty and cognitive impairment, and is associated with many adverse health outcomes. Although cognitive frailty is prevalent in older people, motor-cognitive training is effective at enhancing cognitive and physical function. We proposed a virtual reality (VR) simultaneous motor-cognitive training program, which allowed older people to perform daily activities in a virtual space mimicking real environments.

Objective: We aimed to (1) explore the feasibility of offering VR simultaneous motor-cognitive training to older people with cognitive frailty and (2) compare its effects with an existing motor-cognitive training program in the community on the cognitive function and physical function of older people with cognitive frailty.

Methods: A two-arm (1:1), assessor-blinded, parallel design, randomized controlled trial was employed. The eligibility criteria for participants were: (1) aged \geq 60 years, (2) community dwelling, and (3) with cognitive frailty. Those in the intervention group received cognitive training (ie, cognitive games) and motor training (ie, cycling on an ergometer) simultaneously on a VR platform, mimicking the daily living activities of older people. Those in the control group received cognitive training (ie, cognitive games) on tablet computers and motor training (ie, cycling on the ergometer) sequentially on a non-VR platform. Both groups received a 30-minute session twice a week for 8 weeks. Feasibility was measured by adherence, adverse outcomes, and successful learning. The outcomes were cognitive function, physical frailty level, and walking speed.

Results: Seventeen participants were recruited and randomized to either the control group (n=8) or intervention group (n=9). At baseline, the median age was 74.0 years (IQR 9.5) and the median Montreal Cognitive Assessment score was 20.0 (IQR 4.0). No significant between-group differences were found in baseline characteristics except in the number of chronic illnesses (P=.04). At postintervention, the intervention group (Z=-2.67, P=.01) showed a significantly larger improvement in cognitive function than the control group (Z=-1.19, P=.24). The reduction in physical frailty in the intervention group (Z=-1.73, P=.08) was similar to that in the control group (Z=-1.89, P=.06). Improvement in walking speed based on the Timed Up-and-Go test was moderate in the intervention group (Z=-0.16, P=.11) and greater in the control group (Z=-2.52, P=.01). The recruitment rate was acceptable (17/33, 52%). Both groups had a 100% attendance rate. The intervention group had a higher completion rate than the control group. Training was terminated for one participant (1/9, 11%) due to minimal VR sickness (Virtual Reality Sickness Questionnaire

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score=18.3/100). Two participants (2/8, 25%) in the control group withdrew due to moderate leg pain. No injuries were observed in either group.

Conclusions: This study provides preliminary evidence that the VR simultaneous motor-cognitive training is effective at enhancing the cognitive function of older people with cognitive frailty. The effect size on frailty was close to reaching a level of significance and was similar to that observed in the control group. VR training is feasible and safe for older people with cognitive frailty.

Trial Registration: ClinicalTrials.gov NCT04467216; https://clinicaltrials.gov/ct2/show/NCT04467216

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KEYWORDS

virtual reality; motor-cognitive training; cognitive frailty; game; feasibility; VR; training; older adults; frail; pilot study; randomized controlled trial

Introduction

Background

Cognitive frailty refers to a clinical syndrome where physical frailty and mild cognitive impairment (MCI) coexist, and excludes concurrent dementia [1,2]. Cognitive frailty is associated with a higher risk of developing dementia, depression, malnutrition, and dependency [3,4], and is a common clinical syndrome among community-dwelling older people with a prevalence rate ranging from 4.4% to 19.9% [5-7]. Nevertheless, it is a reversible condition, particularly when treated at an earlier stage [8]. Therefore, cognitive frailty is regarded as a novel target for the prevention of elderly dependency and is a potential target for the secondary prevention of dementia [9,10].

Motor-cognitive training refers to a combination of physical exercise and cognitive training, and can be classified into two categories: (1) sequential motor-cognitive training (ie, motor and cognitive trainings are conducted separately) and (2) simultaneous motor-cognitive training (ie, motor and cognitive trainings are conducted concurrently) [11]. Evidence shows that physical exercise (eg, brisk walking) and cognitive training are two components of training that are effective at yielding clinical benefits for older people with cognitive frailty in terms of their cognitive function, physical frailty, and physical performance [12-14]. A systematic review showed that either simultaneous or sequential motor-cognitive training is more effective at promoting cognitive function than a single physical or single cognitive exercise [15].

The Guided Plasticity Facilitation framework postulates that simultaneous motor-cognitive training might lead to greater improvements in cognitive function through enhanced neuroplasticity [11]. The explanation for this is that when a task demands simultaneous cognitive and physical functioning, superadditive synergistic effects emerge from the facilitation effects of physical exercises and the guidance effects of cognitive exercises. As a result, synaptogenesis and neurogenesis could be fostered, leading to improved cognitive function. Studies have shown that motor-cognitive training is effective at improving physical performance (eg, walking speed), brain functional network as demonstrated by a resting-state functional magnetic resonance imaging (fMRI) scan, and cognitive function (eg, executive control, paired-associates learning) [16-18]. However, these studies compared the effects of motor-cognitive training with those of a passive control or single-component control (ie, either physical exercise or cognitive training). Clinical evidence showing that simultaneous motor-cognitive training is more effective than the sequential counterpart is lacking. Furthermore, no studies have been performed specifically on older people with cognitive frailty.

Virtual reality (VR) systems immerse users in a virtual environment by replacing the visual and aural environments to achieve a sense of presence so that users perceive themselves as being part of the virtual environment [19]. VR has been used in training because it is capable of simulating real-life scenarios in a controlled, safe, and ecologically valid setting [20]. A VR system can serve as a platform from which to launch cognitive and motor training programs. As a result, the effects of training are theoretically more easily translated in real-life environments. Moreover, adding gaming elements to the training to yield therapeutic effects (ie, serious games) could increase the motivation of participants to engage in the training [21]. A systematic review indicates that VR has been used for the rehabilitation of people with various neurological disorders (eg, stroke, cerebral palsy, spinal cord injuries), and that it is effective at improving the participants' cognitive function, motor function, and community participation [22]. Another systematic review has shown that game-based VR interventions are potentially effective at improving the motor function and quality of life of people after stroke [23]. That said, various barriers to the use of VR in neurorehabilitation have also been reported, including the complex technical setup, simulation sickness, and the suitability of the design and its development for a population [24]. The generalizability of the training effects of the VR rehabilitation in different populations is unclear. Evidence is lacking on the effects and feasibility of a simultaneous motor-cognitive training program launched on a VR system for community-dwelling older people with cognitive frailty.

Objectives

Based on this background, the aims of this study were to (1) explore the feasibility of VR simultaneous motor-cognitive training for older people with cognitive frailty; and (2) examine the effects of a VR simultaneous motor-cognitive training program compared with those of a non-VR sequential motor-cognitive training program in the community on the cognitive function, frailty, and physical function of older people with cognitive frailty.

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Methods

Trial Design

This pilot study was designed as a single-blinded, single-centered, parallel-group randomized controlled trial (RCT). Therefore, we followed the reporting format of the CONSORT (Consolidated Standards of Reporting Trials) 2010 guideline [25]. The trial was registered with ClinicalTrials.gov (identifier number NCT0446726).

Participants

Recruitment

The participants were recruited at an elderly community center in Hong Kong. The center provides social and recreational services for those 60 years of age or over. The staff of the center invited participants through a poster advertisement and telephone calls. Trained research assistants subsequently screened the potential participants according to the following eligibility criteria.

Inclusion Criteria

The inclusion criteria were (1) age ≥ 60 years; (2) community-dwelling, defined as living at home and not having stayed in a long-term care facility (eg, a nursing home) in the past 12 months; and (3) cognitive frailty, defined as the coexistence of MCI and physical frailty without being severe enough to have dementia. MCI was measured according to (1) a Montreal Cognitive Assessment (MoCA) score ≤ 25 [26] and a Clinical Dementia Rating of 0.5 [27]. Frailty status was measured on a scale from prefrail to frail, using the Fried Frailty Phenotype (FFP) scale, which assesses five components of frailty, namely handgrip strength, walking speed, physical activity level, exhaustion, and weight loss with an FFP score of ≥ 1 [28].

Exclusion Criteria

Participants were excluded if they had (1) a diagnosis of dementia, according to the subject's medical record; (2) probable dementia, as defined by a MoCA score ≤ 18 [26]; or (3) restricted mobility, as defined by a Modified Functional Ambulatory Classification below Category 7 (ie, outdoor walker) [29]. This criterion was used because the subject might be unable to complete the motor-training exercises.

Interventions

Design

There were two interventions employed in this study: the VR partially simultaneous motor-cognitive training (ie, the experimental group) and the non-VR sequential motor-cognitive training (ie, the control group). Both interventions were provided complementarily to eligible participants. There were no interventions that were provided in addition to the targeted

intervention. However, the research team did not forbid participants from taking part in other usual activities that they had been participating in regularly. The staff at the elder center would call the participants to remind them to attend if they were not present on time. We rescheduled the intervention for participants no later than 1 week if they missed an appointment.

Experimental Group

The intervention provided many tasks taxing participants' motor and cognitive functions simultaneously through a training system developed by the research team. In the training, some tasks demanded motor and cognitive functions simultaneously, while other tasks demanded cognitive functions only. This design did not demand all tasks to tax motor and cognitive function simultaneously, as shown in Table 1. This approach could better reflect reality because not all tasks in daily living performed by older people demand motor and cognitive functions simultaneously. Nevertheless, to ensure an adequate amount of motor-cognitive training, the majority of the tasks demanded motor-cognitive functions simultaneously (6/8, 75%). The training system included an immersive VR platform with a head-mounted VR display with a pair of headphones and wireless handheld controllers (HTC VIVE Focus Plus), under-desk ergometer with adjustable cycling resistance (DeskCycle 2), motion sensor, wrist-worn heart rate sensor (Polar OH1), and video game developed by the team (see Multimedia Appendix 1)

Cognitive training was delivered through a serious video game codeveloped by a team of health care academics specializing in the care of older people with cognitive impairment and in designing VR applications. The team engaged a technical company to produce the game. The video game included training in eight daily living tasks commonly performed by older people in Hong Kong. As shown in Table 1, these eight tasks were arranged in eight progressive stages. They included orientation, finding a bus stop, reporting lost items, finding a supermarket, grocery shopping, cooking, finding a travel hotspot, and bird watching. These tasks tax cognitive functions such as visuospatial (eg, wayfinding), calculation (eg, settling payment), memory (eg, recalling items while grocery shopping), reaction time (eg, flipping eggs when cooking), and attention (eg, getting off a bus). Each week featured tasks involving two levels of difficulty in terms of cognitive demands (eg, more distractors, a higher complexity of items to be memorized, a shorter time for reaction). If the participant could complete the lower level in the first session in the week, they could proceed to the higher level in the second session of the same week. Motor training was provided by cycling on an ergometer, which allows cycling resistance adjustments to be made to increase the effort of cycling. The training system requires the participants to travel in the virtual world of the game through cycling on the ergometer while simultaneously participating in the cognitively demanding daily-living tasks.



Table 1. Description of the contents of the intervention.

Kwan et al

Week	Name	Description	Demanding functions
1	Orientation	Participants were instructed to learn all of the commands in the game (eg, movement control, item selection) through a standardized tutorial package	N/A ^a
2	Finding a bus stop	Participants were asked to find a bus stop on a given route in a city; visuospatial function and attention were required	SMC ^b
3	Reporting lost items	Participants were asked to report to police some items that were lost in the street; problem-solving and visuospatial function were required	SMC
4	Finding a supermarket	Participants were asked to find a particular supermarket in the city; visuospatial function and attention were required	SMC
5	Grocery shopping	Participants were asked to shop in a supermarket for a list of food items, which they were told at the beginning of the game; memory and attention were required	SMC
6	Cooking	Participants were asked to flip eggs at a specific time interval; mental processing speed was required	C ^c
7	Finding a travel hotspot	Participants were asked to find a travel hotspot in a park; visuospatial function and at- tention were required	SMC
8	Bird watching	Participants were given a list of birds and asked to identify those that they had been shown at the beginning of the game as being present in a park; attention and memory were required	SMC

^aN/A: not applicable.

^bSMC: simultaneous motor-cognitive training.

^cC: cognitive training.

Tailoring of the training was allowed. The level of difficulty, cycling resistance, and target cycling distance could be adjusted according to the participant's preference and previous cycling performance. The settings were determined at the beginning of each training session. Both the interventionist and participant mutually agreed on the settings before each session of training started.

A similar pilot RCT employed VR motor-cognitive training for older people with MCI used a dosage of two 30-minute sessions per week for a total of 6 weeks [30]. Improvements on cognitive function and walking speed were noted but the effects on cognitive function were small. To assure that an adequate intervention dose is delivered for the desired effect while balancing the tolerance of VR by older people, our pilot study increased the total intervention dose from 6 to 8 weeks while keeping the twice-weekly sessions at 30 minutes each. The intervention lasted for 8 weeks with 2 sessions per week. Each training session lasted for 30 minutes. One new stage was added per week. Participants started the training from stage 1 every time and passed the stages cumulatively. For example, they participated in stage 1 only in week 1; by week 3, they would have completed stages 1, 2, and 3. The aim of this design was to ensure that the participants had sufficient time to learn through repeated practice, while at the same time exploring new stages to sustain their motivation through a sense of fun.

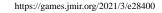
The training sessions were held in an elderly community center. To complete the training, the participants mostly followed the auditory and written instructions provided by the VR system. A trained research assistant provided one-to-one standby assistance to the participants throughout the training period to solve any technical problems the participants might encounter.

Control Group

The intervention for the control group involved providing motor and cognitive training sequentially on a non-VR platform. Materials included a tablet computer (Microsoft Surface Pro 7) and an under-desk ergometer (DeskCycle 2). Cognitive training was provided by a series of cognitive games performed on a tablet computer. The cognitive games included (1) Card Pairs (ie, attention), (2) Mind Game Double Memory (ie, memory), (3) Flashcard Maths (ie, calculation), and (4) Mind Game Double Connect the dots (ie, visuospatial); see Multimedia Appendix 2. Participants were asked to cycle on the ergometer to complete the motor training. The four games were all planned by level of difficulty according to the demand on the cognitive load (eg, more distractors, a higher complexity of items to be memorized, a shorter time for reaction). The motor and cognitive training were provided sequentially (ie, cognitive training followed by motor training).

The intervention lasted for 8 weeks with 2 sessions per week. The dose was comparable to that in the intervention group. Each training session lasted for 30 minutes, which included tablet-based cognitive training for 15 minutes followed by motor training for 15 minutes. Two cognitive games were offered to the participants in each session. The participants continued the game levels from the previous session. During the cycling segment of the session, the participants were not allowed to do anything other than cycling (eg, watch TV, browse on their smartphone).

The training segments in the control group were also held in the elderly community center. The participants mostly followed the written instructions provided in the cognitive games. The participants were only provided with an ergometer and were encouraged to practice cycling at their preferred pace and level of resistance. A trained research assistant provided one-to-one



standby assistance to the participants throughout the training period to solve any technical problems they might encounter.

Outcomes

Main Variables of Interest

We collected two types of data: demographic and outcome data. Demographic data were collected at baseline (T0) and outcome data were collected at both baseline (T0) and the week after completion of the intervention (T1). The data were collected face to face by trained research assistants.

The demographic data included age, gender, BMI, marital status, level of education, and number of chronic illnesses as defined by a confirmed medical diagnosis documented in the participants' medical records according to the diseases listed on the Charlson Comorbidity Index [31].

The outcome variables included global cognitive function, physical frailty level, walking speed, and feasibility.

Cognitive Function

Cognitive function was measured using the MoCA [26], which contains 30 dichotomous items. A correct answer for one item is accorded a score of 1 point. Total scores range from 0 to 30, with a higher score indicating better cognitive function. The test has been found to have good validity in detecting MCI (sensitivity=0.90, specificity=1.00) [26].

Frailty

Frailty was measured using the FFP [28], which quantifies the phenotypes of frailty according to five components (ie, weight loss, exhaustion, low physical activity, slow walking speed, and weakness) using physical performance tests and questionnaires following the Fried guideline. FFP scores range from 0 to 5, with 1 point assigned for the presence of one component. A higher FFP score indicates a higher frailty level. Scores of 0, 1-2, or 3-5 are respectively classified as robust, prefrail, or frail.

Walking Speed

Walking speed was measured by the Timed Up-and-Go (TUG) test [32], which quantifies the total time needed for participants to stand up, walk 3 meters, turn around, walk back to the chair, and sit down. Community-dwelling older people between 65 and 85 years of age are expected to be able to perform the TUG task within 12 seconds [33]. The TUG test has been reported to have moderate reliability in community-dwelling populations (intraclass correlation coefficient=0.56) [34] and has also been employed to identify slow walking speed in older people with frailty [35].

Feasibility

Feasibility was measured by adherence, adverse outcomes, and successful learning. Adherence was measured by the intervention attendance rate of completers (ie, those who did not withdraw from the study), the intervention completion rate (ie, the number of completers divided by the number of participants at baseline), as well as by the level of engagement in ergometer cycling (ie, the distance cycled and energy consumed in cycling as measured by the ergometer) over the intervention period. Adverse outcomes were measured using

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the Virtual Reality Sickness Questionnaire (VRSO) [36] because simulator sickness is the most frequently reported adverse event in VR-based training [37]. The VRSQ consists of nine commonly observed simulator sickness symptoms, including general discomfort, fatigue, eye strain, difficulty focusing, headache, fullness of head, blurred vision, dizziness, and vertigo. The severity of each symptom is rated using a 4-point Likert scale (ie, 0=never, 3=very). The total score was computed by the summation of all item scores and was then converted to a percentage score. A higher score indicates higher severity in VR sickness. The VRSQ was validated as a reliable tool (Cronbach α =.847-.886) [36]. The participants of both groups were asked an open-ended question (ie, "What uncomfortable symptoms did you experience during and after the training?") immediately after the intervention to identify other possible adverse outcomes. Successful learning was measured by the trend in completion time over time. A progressive reduction in completion time indicates successful learning, because it implies that the participants have learned to be more proficient in completing the cognitive tasks after repeated training.

Sample Size

We did not estimate the sample size because we did not intend to test the effects for statistical significance. We planned to recruit a small sample of 15-20 participants for pilot testing.

Randomization

A simple randomization method was adopted. A list of randomized numbers of either 1 or 0 (ie, 1=intervention group, 0=control group) was generated by an independent research assistant using Microsoft Excel. After subjects were screened for eligibility, a list of eligible participants was produced by the subject recruitment team. One author (LS) assigned the eligible participants to either the intervention or control group according to the list of randomized numbers. To ensure concealment, the list was kept by an independent research assistant who did not participate in the subject recruitment process. The randomized group allocation was performed after the data of all participants had been collected at baseline.

Blinding

The outcome assessor was blinded to the group labels. However, it was not possible to blind the interventionists and participants in this study.

Statistical Methods

The clinical profiles of the participants are described by the demographic data, reported according to the level of measurement. Continuous variables are reported as the median with IQR because of the small sample size. Categorical variables are reported as frequency and percentage. Differences in the demographic data of the groups were tested using either the Mann-Whitney U test or χ^2 test according to the level of measurement.

For objective 1, we report the recruitment, attendance, and completion rates, and any adverse outcomes according to frequency and percentage. The VRSQ score in the intervention group is reported as the median and range.

For objective 2, we employed the Wilcoxon signed-rank test [38] to examine the within-group effects (ie, the difference in the outcomes observed between T0 and T1). We adopted this nonparametric test because the sample size was small. We also report the *Z*-score to represent the within-group effect size. The level of significance was judged at a threshold of .05. Intention-to-treat analysis was employed.

Ethical Considerations

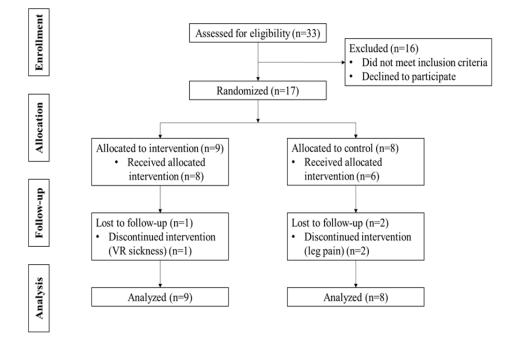
The study was approved by the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University (reference number HSEARS20200113003). Informed consent was obtained from all participants. To ensure safety, after the completion of every training session, the participants were required to sit at the elderly center for at least 10 minutes in case they were feeling any effects of VR sickness as assessed by the VRSQ (ie, any symptoms were rated as "3=very") and that would affect their mobility. Otherwise, they would be sent to a clinic/hospital for medical treatment. If major injuries (eg, falls, severe VR sickness) occur, the study on the participant would be terminated. Participants were only allowed to leave if no adverse symptoms were reported. This study did not provide any forms of reimbursement to participants because this was considered to potentially confound the level of acceptance of the intervention.

Figure 1. Participant flowchart. VR: virtual reality.

Results

Participant Flow

As shown in Figure 1, we assessed 33 subjects for eligibility and 16 were excluded because they did not meet the eligibility criteria (n=15) or did not consent to participate (n=1). The recruitment rate was acceptable (17/33, 52%). We randomly allocated 17 participants to the two groups (intervention group n=9, control group n=8). The research team terminated the training of 1 participant (11.1%) in the intervention group because they reported repeatedly experiencing mild VR sickness (VRSQ=18.3/100). Although the participant still wanted to continue with the training, the research team decided against this to ensure a high level of safety. In the control group, 6 participants completed the intervention. Two participants withdrew because they reported experiencing a moderate level of leg pain and were unable to participate in the cycling. All participants completed the outcome assessment at T1 and the data of all participants were employed in the data analysis. There were no missing data. The trial from recruitment to completion of follow-up was performed during the period from September to November 2020.



Baseline Data

As shown in Table 2, most of the participants were female, widowed, had attained a primary level of education, had no VR experience, and had no chronic illnesses. The median age was 74 years, the median BMI was 22.9, the median MoCA score

was 20.0, the median TUG time was 15.0 seconds, and the median grip strength was 14.0 kg. There were no significant differences between groups, except for the number of chronic illnesses (P=.04), with the participants in the control group reporting more chronic illnesses than those in the intervention group.



Table 2. Clinical profile at baseline.

Variables	All (N=17)	Intervention (n=9)	Control (n=8)	P value
Gender, n (%)		,		.93
Male	2 (12)	1 (11)	1 (13)	
Female	15 (88)	8 (89)	7 (88)	
Age (years), median (IQR)	74.0 (9.5)	73.0 (7.5)	77.5 (15.3)	.29
BMI, mean (SD)	22.9 (4.2)	24.4 (6.3)	22.2 (2.6)	.53
Marital status, n (%)				.46
Single	0 (0)	0 (0)	0 (0)	
Married	8 (47)	5 (56)	3 (38)	
Widowed	9 (53)	4 (44)	5 (62)	
Level of education, n (%)				.48
Secondary or above	5 (29)	2 (22)	3 (38)	
Primary	9 (53)	6 (67)	3 (38)	
No formal education	3 (18)	1 (11)	2 (25)	
VR ^a experience, n (%)				N/A ^b
Yes	0 (0)	0 (0)	0 (0)	
No	17 (100)	9 (100)	8 (100)	
Number of chronic illnesses, n (%)				.04
0	12 (71)	8 (89)	4 (50)	
1-2	4 (24)	0 (0)	4 (50)	
3 or above	1 (6)	1 (11)	0 (0)	
Outcomes, median (IQR)				
Cognition: MoCA ^c	20.0 (4.0)	20.0 (4.0)	20.5 (4.5)	.62
Walking speed: TUG ^d (seconds)	15.0 (4.7)	14.0 (4.2)	15.5 (6.0)	.92
Frailty: FFP ^e	2.0 (1.5)	2.0 (1.0)	2.0 (1.8)	.24
Muscle strength: GS ^f (kg)	14.0 (6.0)	14.7 (8.0)	14.0 (4.6)	.89

^aVR: virtual reality.

^bN/A: not applicable.

^cMoCA: Montreal Cognitive Assessment.

^dTUG: Timed Up-and-Go test.

^eFFP: Fried Frailty Phenotype.

^fGS: grip strength.

Outcomes

Objective 1: Feasibility

With regard to adherence, the attendance rate for completers was 100% in both groups. The completion rate of the intervention group (8/9, 89%) was higher than that of the control group (6/8, 75%). As shown in Figure 2, the cycling distance of the control group (median 58.3 km, IQR 34.67) was greater than that of the intervention group (median 30.1 km, IQR 9.9), as measured by the ergometer. According to the ergometer, the cycling energy of the control group (median 1420 kcal, IQR 834) was higher than that of the intervention group (median 595 kcal, IQR 140). There was no significant difference between groups concerning total cycling distance (Z=–1.44, P=.15),

XSL•FO RenderX whereas the difference in total cycling calories between the two groups was significant (Z=-1.93, *P*=.004).

The difference in cycling amount between the intervention and control groups was due to the difference in the design of the trainings. In the intervention group, participants only cycled as required by the tasks (eg, traveling in the virtual city for grocery shopping and finding a bus stop). When they participated in other tasks without movement (eg, cooking and getting off the bus at the right stop), simultaneous cycling was not needed. In the control group, cycling was unpaired with any other task. Most of the participants cycled continuously. Therefore, cycling-related energy expenditure between groups was significantly different. However, the difference in cycling distance between groups was not statistically significant. A

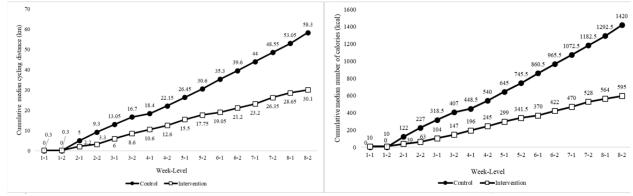
factor that could account for the significant between-group difference in cycling energy expenditure was the participants' individual adjustments to the cycling resistance. In a given cycling distance, the increase in cycling resistance requires a higher level of energy. As the cycling resistance of the control group surpassed that of the intervention group overall, their between-group difference in cycling-related energy expenditure became significant.

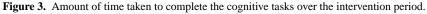
With regard to adverse outcomes, the vast majority of participants never experienced any symptoms of VR sickness. Overall, those who did feel such symptoms experienced mild symptoms, as detected by a median VRSQ score in the intervention group (n=9) of 4.63 (IQR 18.33). In the control

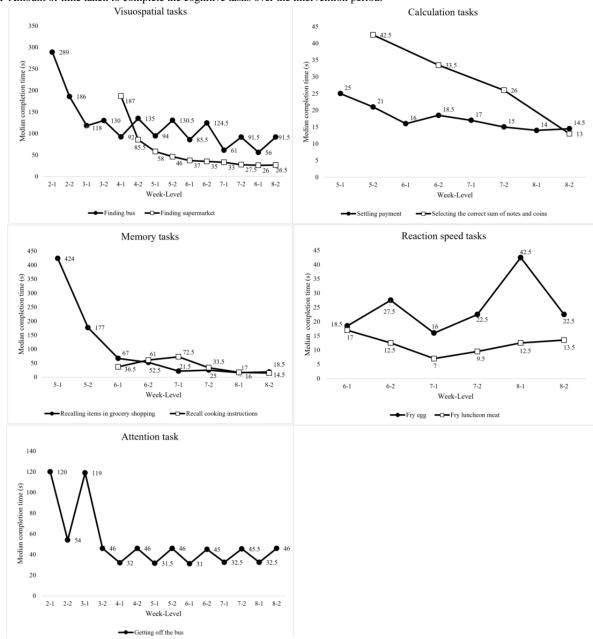
group, two participants withdrew because they reported a moderate level of pain in the joints and muscles of their lower limbs. In the postintervention interview, they reported that the pain was exacerbated by the cycling, so that they were unable to continue the cycling training. No other symptoms causing discomfort were reported by the participants.

Successful learning among the participants was observed, as shown in Figure 3. During the intervention period, there was a gradual reduction in the time taken to complete all of the cognitive tasks as logged by the VR training system in week 2 (ie, visuospatial and attention tasks), week 4 (ie, visuospatial task), week 5 (ie, memory, attention, and calculation tasks), and week 6 (ie, reaction speed).

Figure 2. Comparison of the amount (left) and effort (right) of cycling exerted by the two groups over time.







Objective 2: Intervention Effects

As shown in Table 3, the improvement in cognitive function in the intervention group was larger than that in the control group. The within-group effect of cognitive function was significant in the intervention group (P=.008) but not in the control group. After completion of the intervention, the reduction in frailty in

the intervention group was similar to that in the control group. The within-group effects in both groups were close to reaching statistical significance. The improvement in walking speed as measured by the TUG test was greater in the control group than in the intervention group. The within-group effect was significant in the control group (P=.01) but not in the intervention group.



Table 3. Effects of the interventions by group.

Outcomes	Intervention (n=9)				Control (n=8)			
	Pre, median (IQR)	Post, median (IQR)	Ζ	P value	Pre, median (IQR)	Post, median (IQR)	Ζ	P value
Cognition: MoCA ^a	20.0 (3.5)	24.0 (5.0)	-2.67	.008	20.5 (4.5)	22.5 (4.5)	-1.19	.24
Walking speed: TUG ^b	14.0 (4.2)	10.5 (4.2)	-1.60	.11	15.5 (6.0)	10.8 (6.1)	-2.52	.01
Frailty: FFP ^c	2.0 (1.0)	1.0 (1.0)	-1.73	.08	2.0 (1.8)	1.0 (1.0)	-1.89	.06
Muscle strength: GS ^d	14.7 (8.0)	15.7 (4.7)	-1.24	.38	14.0 (4.6)	15.3 (5.4)	-1.35	.18

^aMoCA: Montreal Cognitive Assessment.

^bTUG: Timed Up-and-Go test.

^cFFP: Fried Frailty Phenotype.

^dGS: grip strength.

Discussion

Principal Findings

To the best of our knowledge, this is the first trial comparing the effects of a VR simultaneous motor-cognitive training program with those of a non-VR sequential motor-cognitive training program on older people with cognitive frailty. There are three key findings of this study. First, VR simultaneous motor-cognitive training is feasible (ie, good adherence and successful learning) and safe (ie, minimal adverse effects) for older people with cognitive frailty. Second, the preliminary findings of the VR simultaneous motor-cognitive training program suggest that it could be an effective method to enhance cognitive function in older people with cognitive frailty. Third, cycling-related energy expenditure is associated with greater improvement in walking speed, but could also lead to a higher dropout rate due to pain in the lower limbs.

A recent systematic review with a meta-analysis showed that older participants experienced a lower level of simulator sickness than younger participants when they used head-mounted displays for virtual application-based purposes [39]. However, the contents of the VR programs (eg, watching 360° videos, video game playing, and scenic viewing) in the studies varied greatly. The content of a program could play an important role in the severity of the simulator sickness symptoms experienced by participants. This study showed that VR simulator sickness was not a concern for many older people with cognitive frailty. Yet, for unknown reasons, some older people did experience prolonged VR sickness. To ensure safety, we recommend that potential participants first undergo a trial with VR; if VR sickness is observed and the severity is a concern, they should be excluded from participating in VR training. Even older people who did not experience any symptoms of VR sickness should be asked to stay behind for a short period after training. Only if they are observed to experience no symptoms of VR sickness in posttraining supervised walking should they be advised that it is safe to leave the community center.

Cognitive and exercise training stimulate similar neurobiological processes that produce a synergistic response through increasing

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cerebral blood flow, inducing angiogenesis in the cortex and cerebellum; however, the neurophysiological mechanism underlying the cognitive improvement is not fully understood [40]. This study provides preliminary evidence that simultaneous motor-cognitive training could produce a synergistic response on global cognitive function. This finding also concurs with the conclusion of a systematic review that simultaneous training was the most efficacious method for cognition, followed by sequential combinations [41]. Future studies should replicate this study with a tighter control (eg, a comparable training time, a comparable VR platform) and a larger sample size to examine if a synergistic response would indeed produce a stronger effect. Biomarkers (eg, fMRI) should also be added in future studies to confirm the underlying neurobiological mechanisms.

Walking speed is not only a marker of cognitive frailty but is also negatively associated with survival, physical function, and the risk of falls in older people [42-44]. An improvement in walking speed is an important modifiable health marker in older people. Physical activity promotes walking speed and, as a result, reduces the risk of disability and mortality in older people [2]. While physical activity could improve physical performance (eg, walking speed), it could also induce pain in older people, although the findings on this point in the literature are unclear. Physical activity beyond one's level of physical endurance could cause exercise-induced pain through acute inflammation, whereas chronic pain could be alleviated by regular physical activity as explained by the exercise-induced analgesia model [45]. Older people with cognitive frailty might not regularly engage in physical activity or have low endurance. Should they suddenly increase the amount of their physical activity, they could experience exercise-induced pain or an exacerbation of their chronic pain. Although more physical activity could result in a significant improvement in walking speed, this study recommends that any increase in physical activity be steady to balance the risk of possible exercise-induced pain. The control group's engagement in continuous cycling might have caused the participants to cycle more than usual but might have also led to more leg pain and a higher withdrawal rate from the study than might otherwise have been the case. It is possible that VR simultaneous motor-cognitive training with meaningful targets

for increases in physical activity as directed by the cognitive games could minimize the risk of exercise-induced pain.

Limitations

The limitations of this study are mostly related to its small sample size. First, the small sample size limited confidence in the effects that were observed. In particular, the effect sizes of the intervention on walking speed and frailty were close to statistical significance. Moreover, frailty is known to be associated with several chronic illnesses [46]. However, 70% of our sample reported no chronic illnesses. Caution should be exercised when generalizing findings to this population because this sample comprised older people with relatively fewer chronic illnesses in addition to MCI and frailty. Second, because of the small sample size, we used a nonparametric statistical test to examine only the within-group effect without testing the interaction effect between group and time. The cognitive improvement in the intervention group as measured by the MoCA could have been the result of repeated learning [47]. Third, although this study attempted to control many factors (eg, simultaneity), there were still many factors that could not be controlled to make the intervention and control groups more comparable. These factors included the cognitive training platforms (ie, 3D VR versus 2D tablet computer) and cognitive

training time (ie, 15 minutes vs 30 minutes). Further studies should control for these factors more tightly to provide a stronger conclusion that simultaneous motor-cognitive training is more effective than sequential motor-cognitive training. Fourth, the study was only performed in one elderly center; thus, the mild symptoms of VR sickness observed in this group of older people should be interpreted with caution because this finding likely cannot be generalized to other settings.

Conclusion

Preliminary evidence shows that VR simultaneous motor-cognitive training is effective at enhancing the cognitive function of older people with cognitive frailty. The effect size on frailty was close to reaching a level of statistical significance and was similar to that observed in the control group. The VR simultaneous motor-cognitive training program is feasible and can be safely applied to older people with cognitive frailty, although VR sickness was observed in a small number of participants. Future training sessions should exclude those who exhibit VR sickness at the eligibility screening phase and provide for adequate posttraining observations. Future studies should replicate this study by employing a larger sample so that its effects can be more confidently evaluated.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1 Setup of the VR motor-cognitive training. [PDF File (Adobe PDF File), 218 KB - games_v9i3e28400_app1.pdf]

Multimedia Appendix 2 Screenshots of the VR games used in intervention. [PDF File (Adobe PDF File), 547 KB - games v9i3e28400 app2.pdf]

Multimedia Appendix 3 CONSORT-eHEALTH checklist (V 1.6.1). [PDF File (Adobe PDF File), 830 KB - games v9i3e28400 app3.pdf]

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Abbreviations

FFP: Fried Frailty Phenotype
fMRI: functional magnetic resonance imaging
MCI: mild cognitive impairment
MoCA: Montreal Cognitive Assessment
RCT: randomized controlled trial
TUG: Timed Up-and-Go
VR: virtual reality
VRSQ: Virtual Reality Sickness Questionnaire

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Original Paper

A Virtual Reality Game (The Secret Trail of Moon) for Treating Attention-Deficit/Hyperactivity Disorder: Development and Usability Study

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Abstract

Background: Attention-deficit/hyperactivity disorder (ADHD) affects between 4% and 8% of children worldwide. The treatment of choice is multimodal treatment. Multimodal interventions for ADHD may be improved by incorporating new treatments, such as treatment via serious video games. *The Secret Trail of Moon* (TSTM) is a virtual reality serious video game that was designed for cognitive training related to core ADHD symptoms and executive dysfunction.

Objective: We aimed to describe the development and usability of TSTM.

Methods: The usability study included 37 children and adolescents who tested TSTM during the early usability stage (preinclusion) of a randomized controlled clinical trial for testing the effectiveness of TSTM. Chi-square tests were performed to compare patients with ADHD (ADHD combined subtype vs inattentive subtype) and to compare frequent and infrequent video game players in the second study. We used SPSS version 20 for Macintosh (IBM Corporation).

Results: A total of 31/37 (86%) and 30/37 (83%) of participants liked playing TSTM and wanted to continue playing TSTM, respectively. Further, 5/37 (14%) of participants reported that they experienced either perceived dizziness or virtual reality motion sickness. We found no statistically significant differences after comparing the ADHD combined subtype to the inattentive subtype and frequent video game players to infrequent video game players.

Conclusions: Serious video games, such as TSTM, may complement the current multimodal approach for treating ADHD.

Trial Registration: ClinicalTrials.gov NCT04355065; https://clinicaltrials.gov/ct2/show/NCT04355065

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KEYWORDS

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attention-deficit/hyperactivity disorder; chess; virtual reality; serious video game; psychotherapy; cognitive training; usability; new technologies; transfer; randomized controlled trial

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Introduction

Background

Attention-deficit/hyperactivity disorder (ADHD) is the most common neurodevelopmental disorder of childhood and adolescence; it affects 4% to 8% of children worldwide [1]. Apart from the core ADHD symptoms (inattention, hyperactivity, and impulsivity), patients with ADHD frequently present with poor social skills, problems in planning, and the inability to complete tasks on time [2]. The prognosis of ADHD is complicated by comorbidities, and impairments may intensify during adolescence or adulthood [2,3]. The treatment of ADHD is multimodal and can include the use of medication, psychoeducation, and psychological intervention [4]. Unfortunately, the current multimodal approach for ADHD treatment has some shortcomings [5]. For instance, motivation is critical for people with ADHD, and they sometimes lack the motivation to engage in treatment [6]. Furthermore, psychotherapies can be expensive [7] and have high rates of treatment discontinuation [8,9]. As such, the incorporation of new treatments that promote high levels of motivation may be a good strategy for improving ADHD outcomes and prognoses.

Some recent proposals include the use of board games, such as chess [10]; neurofeedback [11,12]; virtual reality (VR) [13]; or serious video games [14]. All of these new approaches have the potential to keep people with ADHD motivated and engaged during therapy. Indeed, serious video games can be very stimulating and provide immediate reinforcement [15]. In addition, they present some advantages, such as [15] (1) the precise control of variables, (2) easy data collection that allows for the evaluation of a patient's progress, (3) the provision of immediate feedback to the user, and (4) a more attractive presentation (ie, a video game format). It is not surprising that various serious video games have recently been developed to treat ADHD [15-17]. However, it is also important to mention some disadvantages. For instance, a major problem for people with ADHD is their vulnerability to some addictions, particularly the addiction to video games. Children and adolescents with ADHD are more likely to present with internet gaming disorder [18]. Thus, when developing a serious video game for treating ADHD, it is necessary to find a balance between obtaining a good level of user satisfaction and avoiding increasing the risk of becoming addicted to this video game. Independent of the factors that influence addiction in the design of a serious video game, researchers can control the patients who enter into a study, since addiction is linked with adverse childhood experiences

[19,20] and game addiction is specifically linked with ADHD severity level [21].

Another problem is the lack of evidence regarding the transfer of improvements and benefits. In other words, it is not known whether improvements in video game performance would translate into improvements in other cognitive tasks in a subject's daily life. For instance, regular chess use has been demonstrated to transfer benefits to the educational domain (eg, by improving mathematics performance) [22]. However, evidence about a potential transfer to the health domain is lacking. The challenge of cognitive training and transfer was addressed by Rabipour and Raz [23]. These authors recommended the potential use of brain training to ameliorate the undesired symptoms of ADHD. They also raised the question of the transfer "of practiced skills to other untrained cognitive domains." Furthermore, high-quality evidence that supports the massive use of video games to treat ADHD is scarce. Indeed, there is just 1 video game that has recently been approved by the Food and Drug Administration for decreasing the severity of ADHD [24].

The development of any serious video game requires a series of stages [15,25,26]—(1) defining the learning goals (theoretical background and initial design); (2) creating prototypes (proof of concept); and (3) testing usability and clinical effectiveness (in this order). A recent example is *Plan-It Commander*—a serious game that was developed for children with ADHD [15]. They initially defined the learning goals and created a prototype to test the game's usability and user satisfaction [15]. Afterward, they tested its clinical effectiveness in a randomized controlled trial [16]. They found that girls as well as boys with higher levels of conduct problems were the subgroups that benefited the most from playing the video game [27].

In addition to the development stages reported above, we present the third step (usability) of the development of *The Secret Trail* of *Moon* (TSTM)—a serious video game that was specifically created to train patients with ADHD and increase various cognitive abilities. This usability study allowed us to (1) obtain initial feedback from patients with ADHD; (2) detect bugs and integrate improvements; and (3) confirm that the use of our VR video game was attractive, was intuitive, and did not generate severe adverse effects in users.

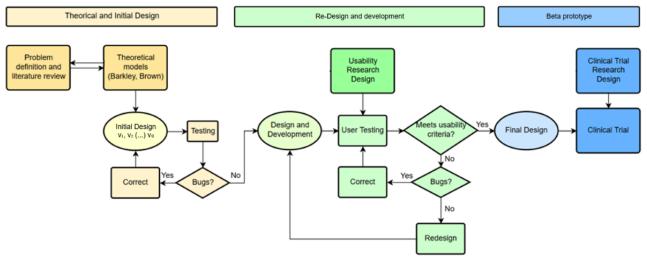
Deconstructing TSTM: Theoretical Background, Design, Development, and Description

Development Stages

The development stages of TSTM are shown in Figure 1.



Figure 1. Design and development stages of the user-centered design study.



Theoretical Background

Information about the first stage of TSTM development can be found elsewhere [28]. The main characteristics of TSTM are summarized in Table 1. These characteristics were influenced by work that was conducted by others [29].

TSTM is the result of interdisciplinary collaboration among health care professionals, researchers, serious video game consultants, and a single educational and therapeutic game development company. This collaboration made it possible to integrate several theoretical models of ADHD with clinical experience, the use of chess and VR by patients with ADHD, and other playful elements of video games that increase players' motivation for engaging in therapy [30].

TSTM is theoretically driven by (1) both the Barkley [2] and Brown [21] models of ADHD and executive dysfunction and (2) our personal clinical experience of using chess with patients with ADHD [10]. The original Barkley model was based on the work of other researchers, such as Bronowski and Fuster [31,32]. This model focuses mainly on the hyperactive-impulsive ADHD subtype (type 2). The primary premise of the Barkley ADHD model is a deficit in behavioral inhibition. This deficit in inhibition is related to problems in the following four executive neuropsychological functions: (1) working (nonverbal) memory; (2) the self-regulation of affect-motivation and arousal; (3) the internalization of speech (verbal working memory); and (4) reconstitution, which is understood as the ability to manipulate verbal and nonverbal mental representations (behavioral analysis and synthesis) [2].

The Brown ADHD model postulates that the core deficit depends on executive dysfunction. In the Brown model, ADHD is considered to involve 6 major deficits in activation, focus, effort (motivation), emotion, memory, and action. In the Brown model, similar to the Barkley model, executive dysfunction is core to ADHD. However, both models have some differences [21]. The Barkley model focuses on the combined type of ADHD and emphasizes the relevance of behavioral inhibition. In contrast, in the Brown model, behavioral inhibition is just 1 of the 6 defective executive functions [2,21].

The TSTM prototype that was used in this usability study had 5 minigames; each minigame targeted specific cognitive abilities (Table 2) and particularly focused on inhibitory control, selective attention, cognitive flexibility, or processing speed [2,33]. The minigames were embedded into a VR forest context in order to provide a more immersive and motivating experience [28]. Furthermore, as stressed by Rabipour and Raz [23], "regular interaction with nature appears to facilitate improvements in cognitive function and behavioral control." A minigame was defined as "a small, isolated game within the larger game environment that integrates unique game elements offering tools to improve strategic behavior" [15].

After an initial design of TSTM was produced, we iteratively tested modified versions in order to detect and correct all bugs [34]. Furthermore, we integrated all suggestions that were made by different users who tested the initial version. Accordingly, we included several modifications that allowed us to create a redesigned video game (redesign stage) [34]. We gathered further information on usability criteria, such as effectiveness, efficiency, user satisfaction, and the adverse consequences of use, and fixed some extra bugs. Thanks to this, we constructed the first functional prototype.

In conclusion, TSTM is a serious video game that is defined as either a game that was designed for a primary purpose other than entertainment [35] or a "computer-based [game] designed for training purposes" [36]. We also used gamification [37,38] to introduce chess and to teach the basic rules of chess to participants who did not know how to play the game.



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Table 1. Brief description of The Secret Trail of Moon (TSTM) characteristics (based on Baranowski [30]).

TSTM Characteristics	Description
General characteristics	
Health topics	Attention-deficit/hyperactivity disorder (ADHD) and attention-deficit disorder (ADD)
Targeted age groups	Individuals aged 12-22 years
Other targeted group characteristics	Exclusion criteria: epilepsy and dizziness (severe)
Short description of the game idea	A VR ^a serious video game aimed at cognitive training related to various cognitive abilities and core ADHD symptoms
Target players	Individual
Guiding knowledge, behavior change theory models, or conceptual frame- works	The Thomas Brown model of executive functions and the Barkley Behavioral Inhibition Model
Intended health behavior changes	Improvements in attention-deficit/hyperactivity disorder symptomatology
Knowledge elements to be learned	Cognitive abilities
Behavior change procedures or thera- peutic procedures used	Feedback and monitoring, the achievement of goals and planning, the shaping of knowledge, repetition, natural consequences, rewards, and regulation and identity techniques
Clinical or parental support needed	Clinical support
Data are shared with parent or clinician	Yes
Type of game	Adventure and puzzles
Story	
Synopsis	A kid appears suddenly in a cave and is greeted by a curious black fox that talks. While traveling together, they eventually meet a scurrying raccoon, and together they form the MOON ^b team. Through their adventures in the woods, they will learn about an impending war between two animal factions that want to fill the power vacuum that the King of the Forest—Cernuous—left when he vanished. Wanting to unite all animals again, they set out on a quest to find Cernuous and put an end to the war that threatens the coexistence and nature of the forest itself.
How the story relates to targeted behav- ior change	This is a VR adventure experience that is augmented by some specifically designed mechanics. The main goal of the game is to find the King of the Forest throughout several chapters by following the main storyline of the MOON team while resolving problems (game mechanics) in the forest.
Game components	
Player's game goals and objectives	Cognitive training by using game mechanics
Rules	Restricted cognitive training (25 minutes per session and per day) and exploring the forest (10 minutes)
Game mechanics	<i>Smasher</i> (minigame for sustained attention and impulse control), <i>Enigma</i> (minigame for working memory), <i>Kuburi</i> (minigame for visuospatial ability), <i>Teka Teki</i> (minigame for planning), and chess (minigame for reasoning)
Procedures to generalize or transfer outside of the game	Help enhance metacognitive thinking strategies through game play, clinical support, and VR immersion
Virtual environment	
Setting	In the forest, there are ruins of ancient civilizations that praised chess.
Avatar	
Characteristics	The MOON ^b team consists of the player as well as Movi (raccoon) and One (fox), who will help and accompany the player throughout the game.
Abilities	Characters will help regulate behavior and be a role model for the player
Game platform(s) needed to play the game	PlayStation 4 VR (Sony Group Corporation)
Sensors used	PlayStation 4 VR sensor (Sony Group Corporation)
Estimated play time	6-8 hours

^aVR: virtual reality. ^bMOON: Movi and One.

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Table 2. Description of each minigame.

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Minigame	Target	Description
Smasher	 Sustained attention (based on the Brown model of attention-deficit/hyperactivity disorder) Inhibitory control 	Within this minigame, participants must break a rock that is blocking their way by following the appropriate set of chess pieces.
Enigma	Working memoryCognitive flexibility	Participants must memorize the associations among differ- ent elements. Afterward, they must match the association as quickly as possible.
Kuburi	 Visuospatial ability According to the classic Baddeley model (1992), the visuospatial agenda is part of working mem- ory. 	Participants must create a drawing by using the face and orienting some cubes.
	• Cognitive flexibility	
Teka Teki	• Planning game	Participants can obtain a key if they can help the fox follow her path to the lock. However, the path is obstructed by different blocks. The number of possible movements will decrease, thus increasing the difficulty.
Chess	ReasoningPlanningMath calculations	Participants must learn the basic rules of chess (ie, the movement of pieces, value of pieces, most relevant moves, etc). The level of difficulty progressively increases.

Study 1 (Market Study)

Methods

Sample and Procedure

The objective of our market study was to determine whether brain training via a serious video game, such as TSTM, would be of interest to mental health and education professionals. A survey that included the characteristics of TSTM and general questions about the game was designed. We used the Google Forms platform to disseminate Spanish and English versions of the survey through professional networks [39]. A total of 57 people responded, but 1 person was excluded, as he was neither a health worker or an education worker (he was a programmer). The local Committee of Medical Ethics did not require official review for study 1.

Statistical Analyses

We only analyzed the percentage of responses. No statistical test was needed.

Results

The survey was completed by 56 mental health (mostly psychologists and neuropsychologists) and education professionals (teachers, pedagogues, counselors, etc), of which 71% (40/56) either treat and educate or have treated and educated people with ADHD. A total of 91% (51/56) and 87% (49/56) of the professionals thought that a serious video game such as TSTM could be useful and stated that they would use it as a therapy and educational tool, respectively (Table 3).

Table 3. Results of our market survey study (study 1).

Factors and questions	Yes, n (%)
Potential use: "Do you think a scientifically validated tool with these features which can help you in ADHD treatment could be useful?"	51 (91)
Practical use: "Would you use it in therapy session?"	49 (87)
Profile adaptation: "Do you think it is relevant to be able to adapt the tool to various ADHD profiles? (Inattentive, hyperactive)"	54 (96)
Adaptive settings: "Would you like to be able to modify variables according your patient needs? (Distracters, number of elements to memorize)"	55 (98)
Enjoyable immersion: "Would you like the game to tell a story (script, plot, characters) in order to facilitate immersion?"	44 (75)

Discussion

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Responses about the characteristics of TSTM helped us to prioritize some development goals Some of the recommendations that were made were in line with literature that stressed the relevance of using attractive graphics or minigame mechanics with an increasing difficulty curve [15,40].

Study 2 (Usability Study)

Methods

Sample and Procedure

The second study included the first 40 consecutive patients with ADHD who were offered inclusion into a randomized controlled

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clinical trial (RCT) for testing the effectiveness of either TSTM or web-based chess [41]. This RCT study was a prospective, unicentric, randomized nonequality trial for patients with ADHD. All participants underwent drug titration (up to the optimum drug dose) and were determined to be clinically stable before the baseline evaluation. Patients were randomized into the following three groups: TSTM group (cognitive training via TSTM), the therapeutic chess group (web-based cognitive training via chess), and the control group (patients were called every week, but no cognitive intervention was used) [42]. The allocation ratio was equal in all 3 groups (35 participants per branch).

The patients included in this early usability stage tested the initial version of TSTM between December 6, 2019, and February 22, 2020, at preinclusion. In order to provide all available information before entering into the RCT, patients were offered the opportunity to test TSTM at preinclusion. Of the first 40 patients, 3 were excluded from the statistical analyses either because they did not complete the test or because the data provided were incomplete. The remaining 37 patients tested TSTM and eventually entered the study. However, not all patients were allocated to TSTM group, as randomization took place during the inclusion visit (day 0), and the data presented in this paper were recorded at preinclusion.

The inclusion criteria were (1) an age of 12-22 years, (2) competency in the Spanish language, and (3) written informed consent. The exclusion criterion was epilepsy, since the use of VR is not recommended for individuals with epilepsy, as per the official recommendations of PlayStation VR [43]. Ethical approval was obtained from the local Committee of Medical Ethics at Puerta de Hierro University Hospital – Majadahonda (Madrid, Spain; research project code: PI 187/19; approved on

December 1, 2019). Written informed consent was obtained from participants and at least 1 parent.

The materials used for this study included the video game itself (TSTM), VR glasses, PlayStation 4 controllers (Sony Group Corporation), test kit consoles, monitoring screens, and headphones. The VR software runs on a PlayStation 4 (Sony Group Corporation) test device, which allows for the tracking of movement through the camera (eg, position, head movement, speed, etc).

Demographics, previous VR experience, and vision problems were noted by using an ad hoc questionnaire. The testing time was always monitored by a professional looking through a screen (Figure 2).

Initially, participants attended a single session in which they tested the TSTM experience. Patients with ADHD were given the opportunity to test a single minigame. After passing the tutorial of the minigame to be tested, a higher level of difficulty was tested. Patients could test each minigame for as long as they liked (ie, only for the duration of that session). After testing a single minigame, patients rated their opinion about the minigame by using an ad hoc questionnaire, which included (1) 5 general questions about the TSTM experience and (2) 2 questions about possible adverse effects. Based on previous studies [44-46], we included information about perceived dizziness and motion sickness, which were rated by using a 3-point Likert scale and 2 questions about patients' feelings before and after testing TSTM. Standard questionnaires were used as a reference [47] by adapting them to the characteristics of our video game and using language adapted for children. We arbitrarily determined that a user satisfaction rate of 75% would indicate a good level of acceptance by users.

Figure 2. Picture of the principal investigator (HBF) facing The Secret Trail of Moon.



Statistical Analyses

Participants were divided into the ADHD combined and inattentive subtypes because some authors consider these subtypes to be different disorders and believe that they should be treated separately. Thus, we feared that the different subtypes of ADHD would impact our usability measures. A descriptive analysis was performed by using the mean proportions (%) of participants' ratings for categorical variables and means and SDs for numerical variables. Chi-square tests were performed to compare patients with ADHD (ADHD combined subtype vs inattentive subtype) and to compare frequent and infrequent video game players. We used SPSS version 20 for Macintosh (IBM Corporation).

Results

Sociodemographic Characteristics

Table 4 displays the basic demographic and clinical characteristics of participants. The testing time for the video game lasted between 10 and 40 minutes (mean 21.31 minutes, SD 6.77 minutes). Most participants were male (25/37, 68%), were right-handed (29/37, 78%), never repeated a school year (26/37, 70%), and were diagnosed with at least 1 comorbid mental disorder (28/37, 76%). Further, 38% (14/37) of participants wore glasses, 59% (22/37) had previously used VR, and 70% (26/37) played video games regularly. We found no statistically significant differences between the combined and inattentive subtypes of ADHD.

able 4. Demographics of the attention-deficit/hyperactivity disorder (ADHD) and attention-deficit disorder (ADD) subtypes (N=37).
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Demographic characteristics	All subtypes (N=37)	Participants with ADHD (combined subtype; 21/37, 57%)	Participants with ADD (inattentive subtype; 16/37, 43%)	P value
Age (years), mean (SD) ^a	13.78 (2.28)	13.38 (2.156)	14.31 (2.387)	.222
Intelligence quotient, mean (SD) ^b	106.42 (17.91)	104.07 (16.69)	108.76 (19.44)	.525
Gender, n (%)				
Male	25 (68)	14 (67)	11 (69)	1
Repeated at least 1 school year, n (%)	11 (30)	7 (33)	4 (25)	.723
Handedness, n (%)				.595
Right-handed participants	29 (78)	16 (76)	13 (81)	
Left-handed participants	1 (3)	1 (5)	0 (0)	
Ambidextrous participants	5 (14)	2 (9)	3 (19)	
Comorbidity with at least 1 mental disorder (yes), n (%)	28 (76)	16 (76)	12 (75)	1
Wears glasses, n (%)	14 (38)	9 (43)	5 (31)	.432
Previous use of virtual reality, n (%)	22 (59)	12 (57)	10 (63)	1
Regularly plays video games, n (%)	26 (70)	16 (76)	10 (63)	.203

^aData were collected from 37 participants.

^bData were collected from 26 participants.

Usability Results

Figure 3 displays the proportion of children and adolescents who liked each minigame. All minigames were based on the opinions of the participants, and percentages ranged from 80% (chess: 4/5) to 100% (*Kuburi*: 22/22; *Teka Teki*: 23/23). With regard to the results for comprehensibility, the ease of play, and the ease of control of the PlayStation 4 controller, all proportions surpassed 60% (22/36). All minigames were easy to play, and only *Teka Teki* had an easy-to-play percentage of below 80% (22/36, 61%). *Teka Teki* was the only minigame in which the participants pointed out that it was difficult to achieve improvement after repeating the minigame. We found no

statistically significant differences after comparing the ADHD combined subtype to the inattentive subtype and frequent video game players to infrequent video game players.

Table 5 displays the percentages of children and adolescents who had positive opinions, which were based on the two highest scores ("much" or "very much"). With regard to the discomfort of VR glasses and motion sickness, we considered any level of discomfort to be a negative opinion, even if it was just "a little bit" of discomfort. Most children and adolescents provided very positive responses to all questions. Furthermore, 5 out of 36 (13.1%) children and adolescents reported the discomfort of VR glasses and motion sickness, and just 1 (3%) reported this clearly.

Figure 3. Specific questions about each game's mechanics (*Smasher, Kuburi, Enigma, Teka Teki*, and *chess*). The questions were as follows: (1) "Was the minigame fun" (factor: fun), (2) "Did you find it easy to understand the instructions" (factor: comprehensible), (3) "Did you find the minigame easy to play" (factor: easy to play), (4) "Did you find the controller easy to use" (factor: proper control), (5) "Do you understand the game better as the level increases" (factor: improvement after repeating), (6) "Did you think visual graphics were beautiful" (factor: enjoyable graphics), and (7) "Did you find it short" (factor: too short)?

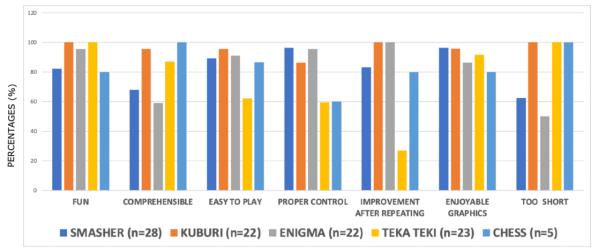


Table 5.	The satisfaction of patients wi	h attention-deficit/hyperactivity disorder	r after testing The Secret	Trail of Moon (TSTM).
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Factors and questions (responses)	Positive experience (n=36 ^a), n (%)
Satisfying experience: "Did you like the experience?" (much or very much)	31 (86)
Desire to repeat: "Would you repeat it?" (much or very much)	30 (83)
Enjoyable graphics: "Did you find it beautiful?" (much or very much)	30 (83)
Enjoyable music and sound: Did you like the music and sound?" (much or very much)	27 (75)
Easy to understand: "Did you find it easy to understand the game?" (much or very much)	28 (78)
Perceived dizziness: "Did you feel dizzy when playing the video game?" (much or very much)	5 (14)
VR motion sickness: "Did you become motion sick while playing the video game?"	5 (14)
Feelings before testing TSTM: "How do you feel?" (good or very good)	26 (73)
Feelings after testing TSTM: "How do you feel?" (good or very good)	36 (100)

^aInformation regarding satisfaction was not recorded for 1 patient out of the 37 included in the second study.

Discussion

Our study expands on current knowledge concerning the development of serious video games for treating patients with ADHD [15-17,25-28,33,48]. Before serious video games are incorporated into the multimodal treatment of ADHD, they must demonstrate clinical usefulness and have tolerable side effects [15,25,26,28].

Our results suggest that TSTM was fun, was understandable, was easy to play, was intuitive, was easy to master, used enjoyable graphics, and was of adequate duration for most participants. However, there were some interesting differences between each minigame that may suggest that certain components of TSTM need more improvement. The most enjoyable minigames (*Teka Teki* and *Kuburi*) were the most dynamic and interactive minigames. The areas for improvement in *Smasher* appear to be making it a little bit easier to understand and extending the play time. *Kuburi* was the minigame with the highest usability ratings across all parameters. *Enigma* was the minigame that was the most difficult for users to comprehend. Thus, we may have made the graphics too attractive or enhanced

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minigame mechanics with an increasing difficulty curve [15,40]. *Teka Teki* was the most difficult minigame to play and the only minigame in which participants found it difficult to achieve improvement after repeating the minigame. As such, this minigame may need some improvement, such as using a less stringent difficulty curve and thus preventing a potential decline in initial motivation [15,40]. As for chess, we obtained the opinions of just 5 patients. Therefore, there is too little information to extract any meaningful data on the game.

Compared to a similar study, our study yielded better satisfaction percentages than those reported by the users of *Plan-It Commander* [15]. For instance, compared to the 72% of participants who reported feeling good or very good before testing *Plan-It Commander*, 100% (36/36) of our participants reported feeling good or very good after testing TSTM. Furthermore, our results are comparable to those reported in the *Plan-It Commander* study with regard to players' motivation to play the game again and their opinions of the game [15]. Finally, a small proportion of participants (5/36, 14%) reported experiencing either perceived dizziness or motion sickness, which was clinically meaningful in just 1 child (1/36, 3%).

Wearing glasses was not related to either of the two side effects. Both perceived dizziness and motion sickness are the potential side effects of VR that are the most frequently reported in literature [44-46].

Our usability study presents the following limitations. First, not all of the participants tested the same versions of each minigame during the usability phase, although the changes made were kept at a minimum. We used the preinclusion period of the RCT to fix the bugs detected by participants, and we made some improvements based on their ongoing suggestions in an iterative, continuous way. Thus, the data reported in this paper were the data collected during the preinclusion period. However, after the preinclusion period, all included participants in the RCT eventually tested the same TSTM version. Second, our questionnaire was not validated but was based on questionnaires that were used in similar studies [15]. Finally, we based TSTM development on 2 predominant theoretical models of ADHD. However, there are other ADHD models that integrate cognitive and affective science data and may be interesting to consider when constructing a therapeutic video game for treating ADHD [30,49].

Conclusion and Future Directions

Serious video games and VR are new technologies that can be used as therapeutic tools for the treatment of mental disorders [24,50]. Compared to traditional treatments, serious video games have many advantages [48,50], such as helping individuals maintain their commitment to therapy [2,13,14]. Furthermore, VR has already proven its therapeutic utility for some mental disorders [47,51,52], but such evidence for ADHD is limited [53]. Moreover, there is an increasing number of studies that have reported encouraging results about the use of serious video games and gamified versions of different tests for treating and diagnosing ADHD populations, respectively [15-17,54-56]. Thus, in a recent clinical trial that included 857 children with ADHD, the researchers reported that the patients who were randomized to a serious video game (Akili interactive) intervention group improved more than those who were randomized to the digital control intervention group and experienced fewer adverse events [24]. In another study that compared a serious game intervention (Plan-It Commander) group to a treatment-as-usual crossover group (the intervention was used as an adjunct treatment for children with ADHD), the 10-week serious game intervention proved to be a more effective strategy [16]. However, the creation, development, and empirical testing of a serious video game are not easy tasks [29,57]; the game must be proven to be safe, and its use is not easy to implement in real settings.

TSTM—a VR serious video game that was designed for patients with ADHD—was fun, was intuitive, and displayed a favorable profile of side effects that were in line with those reported in literature [44-46]. Additionally, TSTM may have the potential to be used as an add-on cognitive training tool for medically treated patients with ADHD.

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Conflicts of Interest

In the last 24 months, HBF received lecture fees from Shire. He is a member of the Advisory Board of ITA Mental Health [59]. The remaining authors do not have any conflicts of interest regarding the publication of this manuscript.

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder RCT: randomized controlled clinical trial TSTM: The Secret Trail of Moon VR: virtual reality

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Original Paper

The Effect of a Serious Health Game on Children's Eating Behavior: Cluster-Randomized Controlled Trial

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Abstract

Background: Currently, children's dietary intake patterns do not meet prescribed dietary guidelines. Consequently, childhood obesity is one of the most serious health concerns. Therefore, innovative methods need to be developed and tested in order to effectively improve the dietary intake of children. Teaching children how to cope with the overwhelming number of unhealthy food cues could be conducted effectively by serious health games.

Objective: The main aim of this study was to examine the effect of a serious health computer game on young children's eating behavior and attitudes toward healthy and unhealthy foods.

Methods: A cluster-randomized controlled trial with a between-group design was conducted (n=157; 8-12 years), wherein children played a game that promoted a healthy lifestyle or attended regular classes and did not play a game (control). The game was designed in collaboration with researchers and pilot-tested among a group of children repeatedly before conducting the experiment. After 1 week of playing, attitudes toward food snacks and actual intake (children could eat *ad libitum* from fruits or energy-dense snacks) was assessed.

Results: The results showed that playing a serious health game did not have an effect on attitude toward fruits or energy-dense snacks or on the intake of fruits or less energy-dense snacks. Additional Bayesian analyses supported these findings.

Conclusions: Serious health games are increasingly considered to be a potential effective intervention when it comes to behavior change. The results of the current study stress the importance of tailoring serious health games in order to be effective, because no effect was found on attitude or eating behavior.

Trial Registration: ClinicalTrials.gov NCT05025995; https://tinyurl.com/mdd7wrjd

(JMIR Serious Games 2021;9(3):e23050) doi:10.2196/23050

KEYWORDS

children; eating behavior; food-cues; serious health game; health intervention

Introduction

Background

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Developing healthy eating patterns during childhood and adolescence is essential for healthy growth and development [1]. Research shows that eating behaviors established during youth continue during adulthood and play a major role in developing long-term health and chronic disease risks [2-4].

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Moreover, currently, the dietary intake patterns of children and adolescents do not meet prescribed dietary standards [5,6]. As a consequence, overweight and obesity in children have greatly increased over the last three decades and are one of the most serious health concerns [7,8].

Multiple factors influence eating behaviors and food choices among children. One major contributor is food cue exposure, which can lead to actual food intake by activating both physiologic and psychological responses [9-11]. Research has

shown that food cues embedded in advertising play a contributing role in this process [9-12]. Advertising in which food cues are depicted has a direct effect on preferences by creating familiar and positive associations with the brand and food products [13]. For example, food companies aim to mobilize, enhance, and even create food preferences among consumers. Messages in advertisements for snacks and high caloric food products are formulated in a way to exploit preferences for sweetness and energy density [13].

Currently, people live in a media-saturated environment, in which advertisements and food cues are omnipresent [11]. As a result, people are constantly exposed to food cues and, in particular, food cues for highly energy-dense snacks [9,10,14,15]. Due to priming-exposure to these food cues, physiological and psychological responses are automatically activated [9,10,16], making it hard for children to inhibit their responses and resist consuming palatable food [9,17]. This effect applies especially to young children because their inhibition system is still developing [9,15].

Some studies have shown that teaching children how to cope with the overwhelming number of unhealthy food cues using serious health games might be an interesting technique [18-20]. Fun elements in games attract, capture, and maintain attention, which suggests that games have the capacity to enhance exposure to health-stimulating messages [18]. Games can teach children to solve problems, gather information, analyze risks, and provide various insights in an enjoyable and educational way [20]. Games that aim to conduct this are labeled as serious health games [21,22].

Theory

A serious health game is a rule-based system with variable outcomes, which can be altered by the performance of the player [23]. Within these rules, the player has to overcome a physical or mental challenge to reach the goal of the game [22]. Due to this control, the player becomes emotionally connected to the outcome and consequences of their own actions and decisions, giving them the feeling of being transported in the game [21]. This state of mind is called *flow*, which can lead to arousal, physical responses, enjoyment, involvement, persuasion, and memory.

The enjoyable state that players experience during playing these games can be transferred to the implicit messages that are integrated in the gaming environment [22]. That is why games are labeled as *lean-forward media* in contrast to traditional *lean-back media*, such as radio and television [24]. Consequently, serious games are considered to be highly effective in catching and retaining the attention of children; this makes games an ideal platform for communicating implicit eating behavior associations, and thereby, improving their intake [18,22].

Given the enormous amount of daily food choices, eating behavior mainly consists of automatic choices, which are highly vulnerable to situational, contextual, and implicit factors [25-27]. Several studies confirm that embedded health messages in media have the power to alter attitudes and behaviors [28-30]. Therefore, implicitly altering the attitudes and decisions with

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regard to food snacks in serious health games is of interest as an intervention technique [18].

The main objective of this study was to test the effectiveness of a serious health game that was specifically developed to improve eating behavior among children. The game was designed by a professional game designer based on game learning theories for enhancing playing motivation, attention, and retention of the message by manipulating game characteristics, to increase the children's playing experience [31]. In every step of the development, the game was pilot-tested among the target age group (6-12 years) for difficulty, understanding, user-friendliness, attitude toward the game, and clarity of instructions.

Hypotheses

The integration of food choices in videogames can transfer negative implicit associations with unhealthy food products and eating behavior, and healthy implicit associations with healthy food products and eating behavior [22]. Based on these findings, we expected that children who played the serious health game would have more positive attitudes toward fruits than those of the children who did not play the serious game (hypothesis 1a) and would have more negative attitudes toward energy-dense snacks than those of the children who did not play the serious game (hypothesis 1b). We also expected that children who played the serious health game would eat more fruit (hypothesis 2a), less energy-dense snacks (hypothesis 2b), and more in general (hypothesis 2c) than the children who did not play the serious health game, because of the effects of the food cues.

Methods

Experimental Design

We used a between-group design with 2 conditions. Children were randomly assigned to 1 of the 2 conditions; children who played a serious game and children who did not play a serious game. Attitudes toward foods in the game and actual food intake were assessed as the dependent variables.

Serious Health Game: Garfield vs Hotdog

A serious health game, called Garfield versus Hotdog, was used. This game was designed by a professional game designer to increase the knowledge and awareness of children aged between 6 to 12 years about healthy food products and healthy eating habits. The game was designed in collaboration with scientific researchers based on a behavior change technique theoretical framework [32]. In addition, the game was pilot-tested among a group of children within the age of 6 and 12 years, repeatedly, in accordance with cocreation methodology. In the game, Garfield the Cat must make several cities healthy again. To make a city healthy again, the player has to play 7 different mini-games; every game has its own implicit message embedded. In general, based on the behavior change techniques taxonomy [32], most games contained mixed techniques to provide information about the link between behavior and health, provide direct information on consequences of an action, prompt intention formation, provide general encouragement through compliments and rewards, set graded tasks, provide instructions, model and demonstrate the behavior in the game, use prompt

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specific goal setting, prompt review of behavioral goals through the feedback if a participant is playing the game well, and provide feedback on the performance.

The first minigame teaches children how to recognize healthy and unhealthy food products. The player directs Garfield to collect healthy foods, which increase the score; collecting unhealthy foods will decrease the score. A specific score is needed to play the next level. The goal of the second minigame is to enhance self-control. The player is taught that it is better to prepare one's own meal than it is to eat at restaurants-Garfield can only finish the level when a specific score is reached, which can be achieved if Garfield prepares his own meals. If Garfield consumes his meal at restaurants, it is more difficult to complete the level. The goal of the third minigame is to teach children that a regular and balanced diet is important, by providing points if the participant directs Garfield to do this. The fourth minigame educates children that exercising and playing outside is healthy and fun. The fifth minigame introduces the idea that a regular diet helps Garfield stay healthy, by modifying his weight and body according the choices of the participant. When the participant directs Garfield to eat regular diets, he will stay healthy and fit and fast, otherwise he will become heavier and slower. The sixth minigame aims to teach children how to recognize and protect themselves against marketing techniques used to sell unhealthy foods, by providing specific feedback on decisions children make after being exposed to advertising while playing the game and making food decisions for Garfield. The seventh minigame encourages children to drink more water on a daily basis instead of sugary sodas; Garfield's weight increases and he becomes slower when the participant directs Garfield to drink sugary sodas. Every minigame teaches children a different healthy eating behavior, that is transferred and internalized during game play.

Procedure

The committee for ethical concerns of the Behavioural Science Institute at the Radboud University, the Netherlands, approved this study (ECG/CW-MB/13.03). We obtained written consent from the administrators of 2 schools, chosen based on convenience sampling, and we sent the parents of children who attended these schools letters with detailed information about the study. We instructed them to inform us if they did not want their child to participate in the experiment or if their child was allergic to one of the test foods. Children who were allergic to the test food did not participate in the experiment. In total, approximately 91% of the children participated. We emphasized to the parents and the children beforehand that all data would remain confidential and children could cease participation at any time.

A between-group design was conducted with 2 conditions (control vs intervention group). Classes were randomly assigned by flipping a coin. In the control group, the experimenter explained to the class that the children would be participating in an experiment, without mentioning serious health games. After this explanation, children were tested individually in order to overcome peer influences. In the experimental condition, the experimenter presented the game to the class and explained how to download it at home and how to play it on a tablet. The children were asked to download the game and play it at home for a week. Children who were not allowed to participate in the study received a different task from the teacher to conduct outside the classroom.

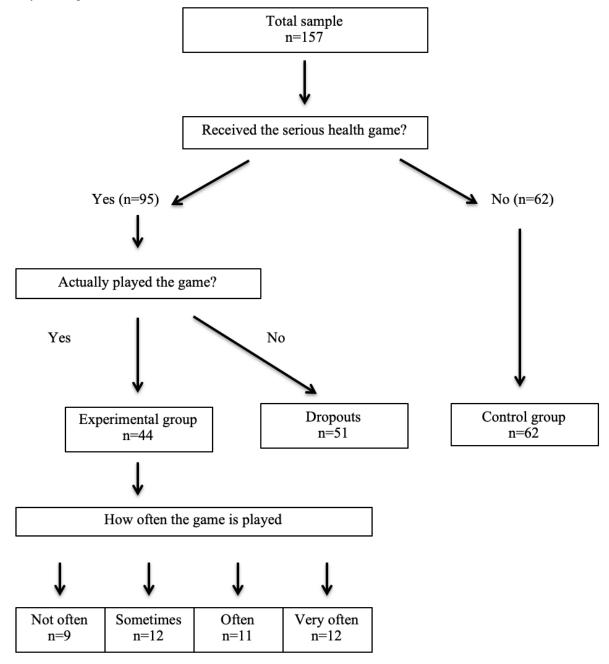
After 1 week, children from the intervention group were tested. Children were tested individually at school during their regular school hours. The experimental setting which was a quiet and separate classroom. This room contained a table with a computer, 4 bowls with 4 different food products, and a line puzzle. When the child was seated, the researcher explained that the child should make the line puzzle and was free to eat *ad libitum*. The 4 bowls contained pieces of bananas, pieces of mandarins, jelly candy (cola bottles), and milk chocolate candy shells.

The researcher explained that the goal was to solve the puzzle. After the participant started solving the puzzle, the researcher left the room for approximately 5 minutes. This was done to allow the child to make food choices autonomously. After 5 minutes the experimenter returned to the room. The participant's weight and height were measured to determine BMI, and together, the researcher and child filled out a questionnaire that assessed sex, age, school year, and the attitude toward the 4 food products on the table. Additionally, the children in the experimental group were asked to what extent they liked the game, how frequently they played the game, and the perceived level of difficulty of the game. Children who received the link to download the game but did not actually play the game were considered to have dropped outs (n=51) and their data were not included in analyses; therefore, the experimental group consisted only of children who had actually played the game (Figure 1).

After filling out the questionnaires, the child returned to their classroom and the next child was tested. After each child, the 4 bowls were weighed and refilled so the next participant did not notice how much the previous participant had eaten.



Figure 1. Study flow diagram.



Measures

Attitude Toward Food Products

To measure attitude toward the fruit and energy-dense snacks in the experiment, we used a questionnaire, which has been used in previous studies [33,34]. For each food product, we asked 6 questions to measure the attitude toward food products. The 4 possible answers varied from "I totally do not like this product" to "I like this product very much." Together, these 6 questions are reliable for each food product: banana (Cronbach α =.822), mandarin (Cronbach α =.875), candy bottles (Cronbach α =.869), and chocolate candy shells (Cronbach α =.869).

Food and Caloric Intake

To measure food intake, we measured the individual weight of each bowl of food. Children could eat the food products *ad*

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libitum during the experiment. We used a professional balance scale (precision 0.1 g). Before each child entered the room, we measured the amount of food in each bowl and weighed the bowl again after the child had completed the experiment. Therefore, we were able to calculate food intake using the nutritional values of each product [34].

Individual Characteristics

Age, gender, and grade were assessed using a questionnaire. We used a measuring tape to measure height (to the nearest 0.5 cm) and a professional balance scale was used to estimate weight (to the nearest 0.1 kg; children did not wear a jacket or shoes during weighing) in order to calculate BMI. We categorized children's weights as underweight, normal weight, overweight, or obese using international cut-off scores [35]. Children with underweight or normal weight were allocated to the low BMI

group and overweight and obese children were allocated to the high BMI group.

Perceived Difficulty and Attitude Toward the Game

Participants attitudes toward the game were assessed using 7 questions about gameplay (difficulty) and attitude toward the game (like, fun, nice, boring, stupid, annoying), with answer options that ranged from "Not at all" (1) to "Very much" (4).

Statistical Analysis

Before testing the hypotheses, we used analysis of variance to verify whether sex, BMI, and age differed between groups (no significant differences were found—sex: P=.73; BMI: P=.29;

 Table 1. Group characteristics (n=106).

age: P=.29; Table 1), and Pearson correlations between the variables were calculated. The attitude toward food products and intake of specific foods were positively correlated (banana: r=0.17, P=.02; mandarin: r=0.24, P=.001; jelly candy: r=0.44, P<.001; chocolate: r=0.40, P=.008). Attitude toward unhealthy food products were negatively correlated with age (jelly candy: r=-0.21, P=.02; chocolate: r=-0.20, P=.001) and BMI (jelly candy: r=-0.14, P=.02; chocolate: r=-0.22, P=.01). For this reason, we included age and BMI as covariates in our analyses. In addition, we computed residual scores and tested them for Mahalanobis distance, Cook distance, and leverage scores; we found no indication of outliers.

Characteristic	No game (n=62)	Game (n=44)	P value
Sex, n (%)			.73
Воу	32 (51)	22 (50)	
Girl	30 (49)	22 (50)	
BMI ^a	18.0 (2.6)	17.5 (3.1)	.29
Age (years), mean (SD)	10.1 (1.2)	10.5 (1.5)	.29
Attitude (rating), mean (SD)			
Banana	18.3 (3.7)	19.0 (3.5)	.17
Mandarin	18.4 (3.8)	17.6 (5.5)	.63
Jelly candy	20.6 (3.5)	20.8 (3.5)	.42
Chocolate	20.5 (3.9)	20.5 (3.7)	.91
Intake (grams), mean (SD)			
Banana	6.7 (15.9)	8.6 (19.2)	.39
Mandarin	2.1 (7.4)	2.0 (3.4)	.99
Jelly candy	41.5 (48.8)	41.9 (55.0)	.40
Chocolate	19.3 (28.1)	17.3 (37.7)	.87

^aBMI: body mass index.

Multivariate analysis of covariance (MANCOVA) was used to test the effect of the game on attitudes toward the fruits and energy-dense snacks, with BMI and age as covariates, and to test the effect of the game on the intake of fruits and energy-dense snacks, with BMI and age as covariates. Univariate analysis of covariance (ANCOVA) was conducted to examine the effect of the health game on general intake, controlling for BMI and age. Moreover, to further test for the (non)existence of the main effects of the experimental condition, multiple Bayesian ANCOVAs were performed with JASP software (version 0.7, Jasp project). Evidence for each model in these analyses is evaluated against the null model, which is represented by the BF_{10} value. $BF_{10}>3$ is interpreted as substantial support for the alternative hypothesis, and BF_{10} <0.33 is substantial support for the null hypothesis. BF₁₀=0.33-3 suggest that the data are insensitive [36]. The data that support the findings of this study are available from the corresponding author upon reasonable request.

Results

General

The total sample consisted of 172 children (grades 5, 6, 7, and 8; age: mean 10.2 years, SD 1.4) from 2 Dutch primary schools. From the total number of children, 15 were excluded because their parents did not give consent for them to participate in the study. In addition, 41 children did not play the game and were excluded from the analyses. Therefore, we used a sample that consisted of 106 children (girls: 49/106, 46.4%). Of the children in the sample, 6.3% (7/106) were underweight, 74.8% (79/106) were normal weight, 14.4% (15/106) were overweight, and 4.5% (5/106) were obese. In total, 18.9% of the children (20/106) were overweight or obese, which is higher than the current national percentage of overweight and obese children in the Netherlands (12.2%). This is probably due to the fact that primary schools that were willing to participate have a relatively higher percentage of children with overweight.

Hypothesis 1

Based on MANCOVA with BMI and age as covariates, no differences in attitude toward healthy foods (P=.44) or unhealthy foods (P=.60) were found. Age was significantly related to attitude toward jelly candy ($F_{1,105}$ =3.971, P=.049) and milk chocolate candy shells ($F_{1,105}$ =7.098, P=.009) but not attitudes toward bananas (P=.16) and mandarins (P=.91), while BMI showed no significant relationship with attitudes toward food products (healthy foods, P=.15; unhealthy foods, P=.18).

Bayesian ANCOVA findings were consistent with these results and supported evidence against the effect of the serious health game on attitude toward the fruits (BF_{10} =0.208) and energy-dense products (BF_{10} =0.210). These results refute hypothesis 1a and hypothesis 1b. No moderation effects between condition and age on attitudes toward the food products were found, and the frequency of playing time did not influence effect of the game (ie, the interaction was not significant *P*=.528).

Hypothesis 2

MANCOVA, with BMI and age as covariates, revealed no differences in actual consumption (P=.38). Age seemed to be a significant covariate ($F_{1,105}$ =5.062, P=.03) of intake of jelly candy, while BMI was not significantly related to intake for any food products (bananas, P=.91, mandarin, P=.76, jelly candy, P=.52, milk chocolate candy shells, P=.82). Older children ate more jelly candies than younger children.

ANCOVA, controlling for age and BMI, showed no significant effect of the game on general intake (P=.38). Bayesian ANCOVA was consistent with these results and supported evidence against the effect of the serious health game on intake of fruits (BF₁₀=0.210) and energy-dense products (BF₁₀=0.209), and on the general intake (BF₁₀=0.209). These results refute hypothesis 2a, hypothesis 2b and hypothesis 2c. No moderation effects between condition and age on actual intake were found, and the frequency of playing time did not influence effect of the game (ie, the interaction was not significant).

Discussion

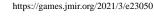
Although previous studies [18-20] have shown that serious health games can be a potential effective intervention technique for teaching children how to cope with the overwhelming number of unhealthy food cues, it has not yet been determined to what extent healthy food cues embedded in a serious health game stimulate actual healthy food intake for children. In a meta-analysis, DeSmet et al [31] found that health games have a small effect on healthy lifestyles. To the best of our knowledge, our study is the first to determine the effectiveness of a serious health game on the actual food intake of children, using a professionally designed game that aimed to improve children's dietary intake. We expected to find an effect of playing a serious health game on the attitude toward fruits and energy-dense snacks (hypothesis 1). We also expected to find a positive effect of playing a serious health game on the actual intake of fruits and a negative effect on energy-dense snacks (hypothesis 2).

The results showed that the children who played the serious health game did not have a more positive attitude toward fruits and did not have a more negative attitude toward energy-dense snacks than children who had not played the game. Hypothesis 1a and hypothesis 1b were rejected. To examine the effect of the serious health game on the actual food intake we measured food intake of children who played the game and children who did not play the game. We did not find any differences in actual food intake between these 2 groups. This finding was applicable to all 4 food products, and intake in general. Children who played the game did not eat more healthy foods or less unhealthy foods than children who did not play the game. Hypothesis 2a, hypothesis 2b, and hypothesis 2c were rejected.

Serious health games have the capacity to enhance exposure to health-stimulating messages [18-20], but an unresolved issue is the extent to which this exposure alters real attitudes and, eventually, eating behaviors. Serious health games are designed to attract the players' attention and simultaneously impart implicit attitudes about health behavior [37]. Eating behavior mainly consist of automatic choices which are highly vulnerable to situational, contextual and implicit factors [26]. Although the serious health game consisted of multiple implicit and explicit health messages that were directly associated with the food products that we used during the experiment, it could not stimulate healthier food choices in the children.

Games have the power to transport players into the virtual world in which they are playing at that moment. This so-called telepresence or flow, is a state of mind that gives players the feeling of getting lost in the story of the game [38]. The enjoyable state which players experience during playing games transfers to the implicit messages that are integrated in the gaming environment, which could lead to positive evaluations of these messages [22]. Therefore telepresence can lead to better product knowledge, brand attitudes, buying intentions and less counter arguing [39,40]. To reach telepresence or flow, a game has to be challenging enough and meet its player's abilities and capacities [41-43]. This works in both ways. If a game is too easy, it is not challenging enough to get lost in the game; therefore, the player will not reach the state of telepresence. When a game is too difficult, players will quit playing, preventing them from reaching the favorable state of mind. Thus, if researchers want to intervene in children's eating habits using games, they have to ensure players reach this state of mind. Only then can players' attitudes and behaviors be altered. While individual tailored games could be a theoretical solution to overcome this problem [31,44], actual practical implications make this extremely difficult because serious health games need to be developed for a large group of players to be cost-effective.

Serious health games communicate healthy messages to the player with the goal to alter the players' attitudes and behaviors. Some serious health games are not challenging enough to give players the feeling of getting lost in the story of the game which is essential in transferring implicit and explicit beliefs to the player [18]. They therefore do not have the power to alter the players' attitudes and behaviors and need to be better adapted to children's capabilities and skills.



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The first strength of this study is that, until now, no studies have focused specifically on serious games and actual eating behavior of children. Although games are popular among children and have potential for being an effective intervention technique, minimal scientific research has been conducted on this type of media in combination with eating behaviors. Second, this study tested the effects of a serious health game in their own private environment and time, thereby increasing the ecological validity of the study. Children received a hyperlink to download the game on their tablet at home so they could play it at free will without the effects of an experimenter during playtime. We did this to increase ecological validity of the study.

One limitation of this study is that many of the children who were allocated to the experimental condition did not play the game (over half of the children). In addition, children who played the game did not play the game very often. Nonetheless, this can be considered an important finding; the adoption and frequency of playing the serious health game is an important element of its effectiveness. Second, children could only play the game for 1 week. A longer duration might have led to different results on the effectiveness of serious games on eating behavior, although the results showed that only a small group of the children played the game often or very often. Normally the game, which we provided for free during this study, has to be bought online in an app store. Given that, when children or parents have to pay, the adoption level will be even lower, it is important to investigate the adoption of serious games that aim to improve eating behavior or children. A third limitation is that we only assessed the intake of 4 different foods, whereas normally children can select many different foods as a snack. Nonetheless, these are popular food fruits [45] and candies [46] in the Netherlands among the target group. Future research might focus on whether devaluation of the unhealthy foods and more positive evaluation of healthier foods through serious health games helps children to overcome the undesired effects of food cue exposure.

In conclusion, this study did not find an effect of serious health games aiming to improve eating behavior among children. The findings further provide evidence that the adoption, the frequency of play time, and the play experience of the serious health game are important. It is important to obtain greater insight into the link between reactivity to food cues and executive control abilities in children. Unhealthy food cues that trigger eating behavior are omnipresent, and children are susceptible to these food cues [9]. In order to improve the dietary intake of children, effective intervention techniques are important.

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Conflicts of Interest

None declared.

Editorial Notice

This randomized study was only retrospectively registered. This is because, as explained by the authors, they did not expect registration to be required. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials because the risk of bias appears low. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

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Abbreviations

ANCOVA: analysis of covariance BMI: body mass index MANCOVA: multivariate analysis of covariance

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Original Paper

The Impact of a Gameful Breathing Training Visualization on Intrinsic Experiential Value, Perceived Effectiveness, and Engagement Intentions: Between-Subject Online Experiment

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Abstract

Background: Slow-paced breathing has been shown to be positively associated with psychological and physiological health. In practice, however, there is little long-term engagement with breathing training, as shown by the usage statistics of breathing training apps. New research suggests that gameful smartphone-delivered breathing training may address this challenge.

Objective: This study assesses the impact of breathing training, guided by a gameful visualization, on perceived experiential and instrumental values and the intention to engage in such training.

Methods: A between-subject online experiment with 170 participants was conducted, and one-way multiple analysis of variance and two-tailed *t* test analyses were used to test for any difference in intrinsic experiential value, perceived effectiveness, and the intention to engage in either a breathing training with a gameful or a nongameful guidance visualization. Moreover, prior experience in gaming and meditation practices were assessed as moderator variables for a preliminary analysis.

Results: The intrinsic experiential value for the gameful visualization was found to be significantly higher compared to the nongameful visualization (P=.001), but there was no difference in either perceived effectiveness (P=.50) or the intention to engage (P=.44). The preliminary analysis of the influence of meditation and gaming experience on the outcomes indicates that people with more meditation experience yielded higher intrinsic experiential values from using the gameful visualization than people with no or little meditation experience (P=.03). This analysis did not find any additional evidence of gaming time or meditation experience impacting the outcomes.

Conclusions: The gameful visualization was found to increase the intrinsic experiential value of the breathing training without decreasing the perceived effectiveness. However, there were no differences in intentions to engage in both breathing training conditions. Furthermore, gaming and meditation experiences seem to have no or only a small positive moderating effect on the relationship between the gameful visualization and the intrinsic experiential value. Future longitudinal field studies are required to assess the impact of gameful breathing training on actual behavior, that is, long-term engagement and outcomes.

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KEYWORDS

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breathing training; serious game; digital health; mobile health; mHealth; mobile phone; experiential value; instrumental value; online experiment

Introduction

Background

Slow-paced breathing training has been positively associated with psychological and physiological well-being. It has the potential to help ease the burden of mental illnesses [1] and chronic diseases [2], such as hypertension [3,4], type 2 diabetes [5], and chronic pain [6]. Slow-paced breathing has been shown to influence heart rate variability and cardiac vagal tone positively. The latter corresponds to the activity of the parasympathetic nervous system [7]. Therefore, often the main goal of slow-paced breathing training is to induce relaxation.

The use of smartphones and apps is increasing as they support users' daily activities [8,9]. For example, smartphone apps can support health and medical actions [9]. Moreover, persuasive technologies and digital interventions are showing promise in influencing personal and health behavior changes [10,11].

This increase in the use of digital technologies and the positive effects of breathing training have led to the development of various applications that support breathing training [12-14]. Usually, such breathing training applications consist of an animation that guides users to breathe at a rate of 6 breaths per minute. The users usually breathe following a specific breathing pattern; for example, 5 seconds inhalation and 5 seconds exhalation [15].

While adapting to such healthy behaviors can help prevent the onset of many diseases [16], behavior changes are challenging to sustain long-term [17]. It has been shown that breathing training apps have very low long-term adherence, even though the number of installations is high [18].

One approach to addressing low long-term adherence might be to approach intrinsic motivation through gamification [19]. Gamification adds game elements to nongame tasks to make them more engaging and enjoyable. This approach is motivated by the notion that playing a game is generally considered an enjoyable experience [20]. Therefore, the combination of technology to influence human behavior [21] and gamification in the health care context [22] offers a promising benefit for people, especially regarding health behavior change and long-term usage.

It is thus not surprising that experiential values, such as fulfillment, enjoyment, meaningfulness, or playfulness, have received growing recognition in recent years [23,24]. Liu et al [25] introduced the term meaningful engagement as the main goal of gamification. It constitutes the experiential and instrumental values of a gamified system. In terms of breathing training, the instrumental value is the effectiveness of the training in inducing the desired effects, such as relaxation. Meaningful engagement can be the deciding factor for the continued use of a system [26]. However, it must be ensured that an increase in experiential values does not reduce the effects regarding relaxation [25]. For example, a previous study [19] collected breathing rate recordings and heart rate variability-derived measures to ensure that gameful breathing training does not impair the effectiveness of breathing training. While the study found that gameful breathing training is as

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effective as normal breathing training, it did not investigate whether there was an experiential gain in gameful breathing training. Chittaro et al [12] researched the effectiveness of different nongame breathing training guidance based on visualizations and audio. The authors found that some types of guidance are more effective than others. However, they did not investigate gameful visualizations, and they did not report the experiential values of these different visualizations. Furthermore, whether participants would have the intention to engage in such breathing training in their everyday life, guided by these different visualizations, remains unknown.

Objectives

In this study, we compare gameful and standard slow-paced breathing training visualizations regarding the intrinsic dimension of the experiential value. This perceived intrinsic value serves as a concept to evaluate the effectiveness of the visual components of the gameful design. As a basis for the gameful breathing training, we used Breeze (Centre for Digital Health Interventions), which was first introduced by Shih et al [27]. Additionally, perceived effectiveness was measured to ensure that the gameful design elements do not weaken the instrumental aspect of the task. Furthermore, we measured the intention to engage, that is, the intention to perform the breathing training regularly. Intention to engage was used as a surrogate to study potential long-term engagement.

Moreover, the study investigated the impact of gaming time and meditation experience on the main outcome, namely the intrinsic dimension of the experiential value. However, the analysis was not powered for this latter analysis.

Consequently, this study aimed to compare gameful and nongameful breathing training visualizations regarding different perceived aspects and thus pursued the following objectives:

- 1. To compare intrinsic values.
- 2. To compare perceived effectiveness.
- 3. To compare the intention to engage as a preliminary forecast of long-term engagement.
- 4. To preliminarily assess the influence of gaming time and meditation experience on the intrinsic value, perceived effectiveness, and intention to engage.

Methods

Study Design

The study compared Breeze (Figure 1), a gameful breathing training visualization, to a standard breathing training visualization, hereafter referred to as Circle (Figure 2). The standard breathing training visualization was adapted from previous studies [15,19,27]. The videos used to instruct and guide the participants before and during breathing training can be found in Multimedia Appendices 1-4. Both breathing training visualizations guide the user to breathe at a rate of six breathing minute. We employed cycles per а 4-3-3 (inhalation-exhalation-pause) pattern in both visualizations. It is a slight variation from the 4-2-4 breathing pattern from Russel et al [15]. The increase of the exhalation phase was motivated by feedback from testers that felt that the exhalation phase was too short.

The anonymized study was conducted from June 2020 to July 2020 and followed a between-subject design amid the independent variable visualization versions, Breeze or Circle.

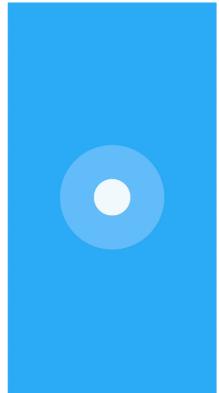
The study was reviewed and approved by the ethics committee of the Swiss Federal Institute of Technology Zurich (ID: 2020-N-82).

Figure 1. Breeze, the developed gameful breathing training visualization.





Figure 2. Circle, the standard breathing training visualization.



Main Outcomes

The intrinsic dimension of the experiential value induced by Breeze and Circle formed the major outcome of the study. The intrinsic dimension consists of the subdimensions' aesthetics and playfulness. To measure the intrinsic experiential value, referred to as intrinsic value in this study, we adapted items from the validated value landscape suggested by Mathwick et al [28] that have also been used in the mobile gaming context [29]. However, solely the intrinsic value was included, as the extrinsic values, consumer return on investment, and service excellence are made for goods on the market. Consequently, no price and no sales processes are in place for Breeze or Circle, nor do they include a service component.

Liu et al [25] suggested that meaningful engagement consists of experiential values and instrumental values. An earlier study [19] had collected breathing rate recording and heart rate variability-derived measures to ensure that the instrumental values are maintained when using Breeze. Therefore, this study focused mainly on the second category—the experiential value to evaluate experiential outcomes.

Besides the experiential value, the instrumental value, consisting of perceived effectiveness (including perceived relaxation) suggested by Chittaro et al [12], was investigated to ensure that the desired effects are achieved. Moreover, intention to use, referred to as intention to engage in this study, was adopted from Shih et al [27] and included to ensure comparability to this earlier study.

Consequently, the following main hypotheses were formulated:

H1: Intrinsic experiential value differs between conditions.

- 2. H2: Perceived effectiveness does not differ between conditions.
- 3. H3: Intention to engage differs between conditions.

The study also investigated the effects of the visualizations on the subdimensions' aesthetics and playfulness of the intrinsic experiential value to gain more insight, resulting in the following hypotheses:

- 1. H4.1: Aesthetics differs between conditions.
- 2. H4.2: Playfulness differs between conditions.

The main hypotheses, H1, H2, and H3, were tested using two-tailed independent t tests.

A multiple analysis of variance (MANOVA) with subsequent univariate tests was used to test H4.1 and H4.2.

Explorative Outcome

Additionally, an exploratory analysis was carried out regarding the differences in reported intrinsic experiential values, perceived effectiveness, and intention to engage between participants with different levels of experience in gaming and meditation. On the one hand, affluent gaming experiences are suspected to diminish the effectiveness of gamification [30]. On the other hand, mindfulness meditation was suggested to promote health and performance [31,32]. Both these conjectures could influence the experiential outcome.

The effects on the intrinsic value, perceived effectiveness, and intention to engage were investigated to investigate whether gaming time or meditation experience impact experiential value, instrumental value, or engagement. This was done using pairwise independent t tests on subgroups in both conditions. For the analysis of gaming experience, the subgroups were

gamers and nongamers, and for meditation experience, meditation experts and nonexperts.

Questionnaire

The questionnaire was structured for both conditions (Circle and Breeze) as follows:

- 1. Demographic questions.
- 2. Instruction video with questions regarding the intrinsic value, perceived effectiveness, and intention to engage.

The demographic questionnaire asked participants about, amongst other things, their age, gender, and their experience

with relaxation and meditation techniques (Multimedia Appendix 5).

A questionnaire with the items listed in Table 1 was employed to measure the participants' intrinsic value, perceived effectiveness, and intention to engage. Each item was rated on a 5-point Likert scale (1=strongly disagree and 5=strongly agree). Items I-IV were averaged to assess the intrinsic value, consisting of playfulness (items I-II) and aesthetics (items III-IV), and items V-X were averaged to assess the perceived effectiveness of both conditions.

The items used in the questionnaire were based on existing questionnaires, items, and keywords [12,28].

Table 1. Scale item wordings of each construct (intrinsic value, perceived effectiveness, and intention to engage).^a

Construct	Scale item wording		α
		Circle	Breeze
Intrinsic value		.72	.62
Ι	Doing the breathing training makes me feel I am in another world.		
II	I enjoy doing this breathing training.		
III	I like the way the breathing training looks.		
IV	I think the breathing training is very entertaining.		
Perceived effectiveness		.78	.72
V	The breathing training facilitates relaxation.		
VI	The breathing training is pleasant to use.		
VII	It is easy to follow the breathing training instructions.		
VIII	The breathing training effectively teaches how to breath.		
IX	The breathing training is effective in reducing stress.		
Х	The breathing training is effective in increasing attention to breath.		
Intention to engage		N/A ^b	N/A
XI	I would perform this breathing training in my everyday life to better manage stressful situations.		

^aCronbach α of each construct and both conditions Circle and Breeze are described to measure the internal consistency.

^bN/A: Not applicable, as the intention to engage only consists out of one item.

Sample Size

Prior to the study, a power analysis was conducted to determine the required sample size. A MANOVA with two groups and two response variables was chosen as the basis of the power analysis to be able to also draw conclusions about the two subdimensions of intrinsic value (playfulness and aesthetics). The parameters for the power analysis were a significance level (error probability) of .05, an effect size of 0.0625, and a power (1- error probability) of .80, suggesting a sample size of n=158. The participant sample size exceeded the determined sample size due to the inclusion of a safety margin. Thus, the study aimed to recruit 170 participants.

Participants

The study was conducted in two phases. First, a pilot study with 8 participants (all females) was carried out to eliminate ambiguities and verify the technical setup. Second, the main study was carried out with 170 participants (85 females). The

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participants were recruited from the web-based prolific.co platform [33].

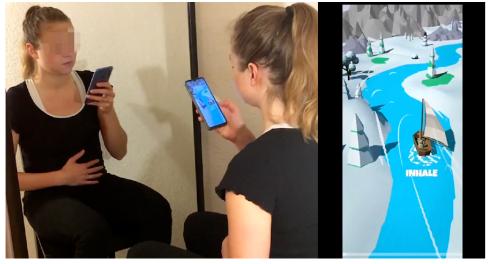
Participants were eligible for the study if they were at least 18 years old, were not pregnant, were not taking any medication to treat symptoms of depression, anxiety, or low mood, and were not suffering from any respiratory diseases, such as asthma or chronic obstructive pulmonary disease. The participants were filtered by the platform to match the selection and exclusion criteria. Moreover, participants were expected to take approximately 15 minutes for the questionnaire. After completing the experiment, the participants received compensation worth £2.09 (US

Procedure

Participants were greeted through an explanatory introduction text informing them that they would conduct a breathing exercise and subsequently answer several assessment questions. After accepting the terms and conditions, participants were asked to

answer a set of demographic questions. The participants were then randomly assigned to the Circle or the Breeze condition. Subsequently, they were shown an instruction video (Figure 3), accompanied by a tutorial. Next, they were asked to confirm that the breathing training would be taken seriously to convey a binding character. In addition, the participants were asked to follow the guided breathing instructions for 6 minutes delivered through a video of Circle or Breeze, respectively. During this time, the participants were unable to rewind or fast-forward the video. Also, the survey could not be continued before the full 6 minutes of the video had elapsed. Upon completion, the participants were asked about the perceived effects of the breathing training and how they perceived the visualization. Finally, they were led to the final debriefing view, where the purpose of this study was explained to them. For the complete questionnaire or tutorial, see Multimedia Appendix 5.

Figure 3. Exercise instruction: Person on the left showing the exercise with enlarged smartphone screen of Breeze on the right. Participants in the Circle condition were shown a similar instruction video with Circle.



Results

All analyses were performed in Rstudio (version 1.2.5042; Rstudio and PBS) and R (version 4.0.0; R Core Team). For constructs that consisted of multiple items, the average of the items was calculated to arrive at a single score for each construct. All measures met assumptions of normality, and no transformations were made.

Participant Demographics

The study was attempted by 180 participants, of which 10 did not complete the experiment, either because they abandoned the experiment or exceeded the time limit of the prolific.co platform [33]. The platform automatically replaced these failed attempts, resulting in 170 participants completing the experiment. Of these participants, 14 participants were excluded from subsequent analysis due to requiring more than 10 minutes for the breathing training. This threshold was set to account for participants who likely did not take the training seriously, as they stayed on the training page for a long time after the 6 minutes of training. This resulted in a sample size of N=156. The participants' mean age was 27 years (SD 8.47). Additional data on participant demographics are depicted in Table 2.



Table 2. Study participant demographics and mean responses.

Variable	Overall responses (N=156)	
Visualization, n (%)		
Breeze	79 (50.6)	
Circle	77 (49.4)	
Sex, n (%)		
Women	77 (49.4)	
Men	79 (50.6)	
Age, mean (SD)	27.00 (8.47)	
Gaming time, n (%)		
Never	27 (17.3)	
1-3 hours	52 (33.3)	
4-6 hours	28 (17.9)	
7-9 hours	22 (14.1)	
10-12 hours	10 (6.4)	
13+ hours	17 (10.9)	
Meditation experience, n (%)		
Strongly disagree	34 (21.8)	
Disagree	53 (34.0)	
Neither agree nor disagree	38 (24.4)	
Agree	29 (18.6)	
Strongly agree	2 (1.3)	
Breathing experience, n (%)		
Strongly disagree	34 (21.8)	
Disagree	53 (34.0)	
Neither agree nor disagree	38 (24.4)	
Agree	29 (18.6)	
Strongly agree	2 (1.3)	
Intrinsic value, mean (SD)	3.30 (0.68)	
Perceived effectiveness, mean (SD)	4.07 (0.54)	
Intention to engage, means (SD)	3.48 (1.04)	

Intrinsic Value, Perceived Effectiveness, and Intention to Engage

The questionnaire responses regarding the intrinsic value and perceived effectiveness were evaluated by factor analysis [12,34], as the intention to engage only consisted of one item. For the analyzed data sets and conditions, the Kaiser-Meyer-Olkin was greater than 0.60, and Bartlett's Test of Sphericity was significant (Table 3). Therefore, factor analysis could be conducted [12,35] (Multimedia Appendix 6).

Table 3. Barlett's Test of Sphericity observed on questionnaire data.

	KMO ^a	KMO ^a		<i>P</i> value	
	Circle	Breeze	Circle	Breeze	
Intrinsic value	0.71	0.60	<.001	<.001	
Perceived effectiveness	0.79	0.73	<.001	<.001	
Intention to engage	N/A ^b	N/A	N/A	N/A	

^aKMO: Kaiser-Meyere-Olkin.

 ${}^{b}N\!/\!A$: Not applicable, as the intention to engage only consists of one item.

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A pairwise independent *t* test was used to investigate the effects of the conditions on intrinsic value, perceived effectiveness, and intention to engage. A conservative alpha level of .025 was used to reduce type I errors [36].

effect of Breeze (Figure 4). However, there was no significant difference between perceived effectiveness and intention to engage (Table 4). The analysis yields a medium effect size (Cohen's d) for the intrinsic value and a small effect size for perceived effectiveness and intention to engage [37,38] (Table 4).

The comparison revealed a significant difference between Breeze and Circle for intrinsic value (P=.001), with a positive

Figure 4. Boxplots, representing intrinsic value, perceived effectiveness and intention to engage median of both conditions (Circle and Breeze). Error bars indicate standard error of the median.

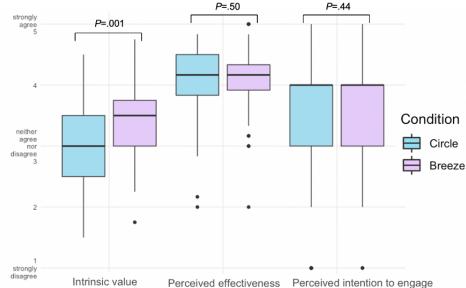


Table 4. Items of intrinsic value, perceived effectiveness, and intention to engage were averaged of both conditions (Circle and Breeze) to form a reliable scale.

	Circle, mean (SD)	Breeze, mean (SD)	t test (df)	P value	Cohen's <i>d</i> (95% CI)
Intrinsic value	3.12 (0.73)	3.47 (0.58)	-3.34 (145)	.001	0.54 (0.21 to 0.86)
Perceived effectiveness	4.04 (0.57)	4.09 (0.50)	-0.67 (150)	.50	0.11 (-0.21 to 0.42)
Intention to engage	3.42 (1.08)	3.54 (1.01)	-0.77 (153)	.44	0.12 (-0.19 to 0.44)

Differences in Subdimensions Playfulness and Aesthetics

MANOVA was performed to investigate the condition differences of the subdimensions of intrinsic values (playfulness and aesthetics). A conservative alpha level was applied to reduce the risk of type I errors, as suggested by Cohen [36] and Chittaro et al [12]. Thus, a Bonferroni corrected conservative alpha level of .0125 was used, which was assessed by dividing the anticipated alpha level of .05 for the MANOVA by 4, the number of dependent variables included in the MANOVA.

The one-way MANOVA showed a statistically significant difference between the two conditions on the combined dependent variables aesthetics and playfulness (Wilks' λ =0.915, $F_{2,153}$ =7.083; P=.001; partial η^2 =0.085).

Subsequent univariate tests (with Bonferroni correction) yielded a significant difference for the aesthetics dimension (P<.001) between conditions, with Breeze yielding a higher value. For playfulness, the difference was also higher for the Breeze condition. The difference, however, was not significant (P=.041).

 Table 5.
 Subsequent univariate tests for the MANOVA on the condition differences for the subdimensions aesthetics and playfulness of the intrinsic value.

	Circle, mean (SD)	Breeze, mean (SD)	F test (df)	P value
Aesthetics	3.20 (0.80)	3.64 (0.67)	14.20 (154)	<.001
Playfulness	3.05 (0.82)	3.30 (0.74)	4.25 (154)	.041

Influence of Gaming Time and Meditation Experience

Furthermore, explorative analysis of the influence of gaming time and meditation experience on the intrinsic value, perceived effectiveness, and intention to engage was conducted. The median of gaming time (>3 h/week) was used to assign participants into gamers (>3 h/week) and nongamers (≤3 h/week). Furthermore, participants were classified as meditation experts if they responded with "agree" or "strongly agree" to being experienced in meditation. The mean intrinsic value for gamers was slightly higher in both conditions, yet not significant (mean 3.18, SD 0.65 vs mean 3.06, SD 0.80 for nongamers; P=.50) for Circle and (mean 3.51, SD 0.60 vs mean 3.44, SD 0.56 for nongamers; P=.60) for Breeze. For perceived effectiveness, there was no difference between gamers and nongamers for Circle (mean 4.06, SD 0.61 vs mean 4.01, SD 0.54, respectively; P=.77) and Breeze (mean 4.09, SD 0.58 vs mean 4.10, SD 0.42, respectively; P=.87. For the intention to engage, there was no significant difference between gamers and nongamers for Circle (mean 3.47, SD 1.01 vs mean 3.36, SD 1.16, respectively; P=.64) and Breeze (mean 3.62, SD 1.07 vs mean 3.48, SD 0.96, respectively; P=.52). The Circle condition had similar mean intrinsic values of mean 3.13 (SD 0.71) for meditation experts and mean 3.13 (SD 0.74) for nonmeditation experts (P=.98), and the Breeze condition's mean intrinsic value significantly decreased (P=.03) between experts and nonexperts (mean 3.78, SD 0.52 vs mean 3.41, SD 0.57, respectively). For perceived effectiveness, there was no significant difference. Circle had a mean of 4.17 (SD 0.46) for meditation experts compared to a mean of 4.01 (SD 0.59) for nonmeditation experts (P=.21), and Breeze had a mean of 4.11 (SD 0.76) for meditation experts compared to a mean of 4.09 (SD 0.44) for nonmeditation experts (P=.94). Intention to engage showed a slight decrease for nonmeditation experts (mean 3.37, SD 1.10 for Circle and mean 3.49, SD 1.03 for Breeze) compared to meditation experts (mean 3.64, SD 1.01 for Circle and mean 3.79, SD 0.89 for Breeze). However, for both Circle (P=.37) and Breeze (P=.29), the differences were not significant. Additionally, there seemed to be no moderating effect of gaming time (>3 h/week) or meditation expertise ("agree" and "strongly agree") on the relationship of intrinsic value, perceived effectiveness, and intention to engage with the condition (Multimedia Appendix 7).

Discussion

Intrinsic Experiential Value and Intention to Engage Feedback

The intrinsic value for the Breeze visualization was higher than the standard breathing training visualization Circle. Therefore, the gameful visualization was well received by the respondents and successfully found to raise the intrinsic value. The analysis of the subdimensions of intrinsic value, aesthetics, and playfulness showed that both subdimensions scored higher for Breeze. The dimension playfulness, however, did not increase significantly. It could be argued that this may be because the video-delivered gameful breathing training visualization did not incorporate an interactive component. It is plausible that an interactive component of Breeze (eg, stronger acceleration of

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the boat when exhaling at the right time) might further elevate both subdimensions and the intrinsic dimension of the experiential value as a whole. However, a stronger influence on playfulness than aesthetics would be expected since the aesthetics dimension is less strongly linked to interactive aspects. Nevertheless, further research is needed to confirm this.

In addition to higher scores in intrinsic value and its subdimensions, it was hypothesized that the Breeze condition would be associated with a higher intention to engage. This would have been an additional confirmation that using a gameful visualization in breathing training would potentially be beneficial for long-term engagement. However, the hypothesis could not be confirmed as no difference in intention to engage was observed between the two conditions. Nevertheless, these results are comparable to the results of a previous study [27], in which a small number of participants engaged in both gameful and nongameful breathing training. That study also found only nonsignificant increased values for intention to engage for gameful breathing training.

Consequently, it can be concluded that while a gameful visualization component results in a higher intrinsic value, it appears not to increase the behavioral intention to engage with breathing training significantly. At this time, it remains unclear whether a gameful visualization component could help improve long-term engagement.

Perceived Effectiveness

The participants reported a clearly positive perceived effectiveness of the training. Furthermore, no significant differences were found regarding perceived effectiveness among the Breeze and Circle condition. Thus, the gameful visualization of Breeze had no impairing impact on the instrumental value of the breathing training, which is crucial as gamification should not reduce the instrumental value, even if the experiential value increases [19,25]. These results align with our hypotheses and confirm results from previous work where the influences of gameful and nongameful breathing training on the physiological outcomes were investigated [27].

Gaming and Meditation

No influence of gaming time per week (\leq 3h or >3h) was observed among conditions, as implied by the lack of significant differences in mean intrinsic value, perceived effectiveness, and intention to engage. Also, no effect was found for meditation experience on perceived effectiveness and intention to engage in both conditions. However, a significant difference (P=.03) between meditation experts and nonexperts was found for intrinsic value in the Breeze condition. Hence, the gameful visualization was better received by meditation experts, but for the Circle condition, no differences were found between the meditation subgroups. Nevertheless, the moderating effect of both gaming time and meditation did not influence the relationship between the conditions regarding the intrinsic value, perceived effectiveness, or intention to engage.

Limitations

This study was conducted with the users' feedback via video; therefore, it did not contain biofeedback similar to previous

studies employing Breeze [19,27]. Biofeedback is essential to provide individuals with real-time feedback information so they can adjust their behavior by modifying their physiological functions. As Cugelman [39] suggested, biofeedback is a core ingredient with clear linkage to those proven behavior change strategies. Therefore, it is a crucial part of gameful breathing training, and thus, the inclusion of biofeedback should be further investigated.

Likewise, the evaluation of this study was solely based on perceived indicators and not on physiological measurements. Nevertheless, it can be argued that the online format allowed the exercise to take place in a more realistic setting, as participants were conducting the training in their daily lives rather than in an experimental setting.

The intrinsic dimension of experiential value, composed of playfulness and aesthetics, was chosen as the main outcome because of the overlapping context of the appeal of the design and the emotions induced by the application [28]. However, questionnaire items were selected and slightly adapted to fit with this study. While the reliability analyses yielded scores in the acceptable reliability range [40], the score for intrinsic value in the Breeze condition was on the lower end of the acceptable range. Thus, the results regarding intrinsic value yielded acceptable reliability but should still be regarded with caution. Perceived effectiveness and intention to engage were used similar to previous studies to ensure comparability [12,27]. Moreover, the factor analysis ensured the validity of the items of intrinsic value and perceived effectiveness. However, no factor analysis was conducted for intention to engage, as it only consisted of one item.

One main goal of Breeze is to enhance long-term usage [19]. While this study was able to show an increase in experiential value for gameful breathing training, a long-term study is necessary to conclude whether this increase has a positive effect on long-term usage.

The subgroup analysis of gaming time per week and meditation expertise was secondary data analysis and consequently not powered. Thus, further investigations will be necessary to confirm that gaming time and meditation experience do not have a large impact on the intrinsic value, perceived effectiveness, or intention to engage and whether Breeze is better received by meditation experts. However, this analysis provides a first insight and preliminary results of gaming time and meditation experience influence on the studied dimensions. Finally, gamification may influence people with different backgrounds in different ways. Thus, cultural and social influences might affect how gamification is best realized regarding breathing training [41]. However, this study did not consider these potential influences since Breeze is not designed with a specific target group in mind, and the participant recruitment process did not include any cultural or social parameters.

Future Work

As this study was conducted as an online experiment consisting of one session, the conclusions regarding long-term engagement are limited. Therefore, plans exist to test Breeze in a future longitudinal field prototype with various patient populations, including healthy, vulnerable, and sick individuals that require breathing training for different purposes. Future studies might focus on students exhibiting exam stress or depression and cancer and hypertension patients that suffer from distress.

Moreover, a study that includes biofeedback will be crucial to assess whether this technique has an advantageous effect on gamification and consequently on behavior change [39].

Additionally, a collection of physiological data measurements next to the perceived indicators will be beneficial to evaluate the instrumental value of the breathing training. Other concepts, which could be integrated into further research are flow, user engagement, usability, or technology acceptance.

Conclusions

In this study, we evaluated the difference between a gameful and a nongameful breathing training guidance visualization. The variables measured were intrinsic value representing experiential value, perceived effectiveness representing instrumental value, and intention to engage representing long-term engagement. The results yielded a positive effect by showing that the experiential value of Breeze was higher than the experiential value of Circle without decreasing the instrumental value and the engagement. Subgroup analyses indicated no impact of gaming time (\leq 3h and >3h per week) and meditation (experts and nonexpert) on intrinsic value, perceived effectiveness, or intention to engage. The only difference identified was that the gameful visualization was better perceived by meditation experts than by nonexperts.

The outcomes showed that the intrinsic dimensions of the experiential value of breathing training could be increased by employing gameful instead of nongameful visualizations without impairing the perceived effectiveness of the training.

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Conflicts of Interest

YL, SK, VB, OK, EF, and TK are affiliated with the Centre for Digital Health Interventions, a joint initiative of the Department of Management, Technology, and Economics at Swiss Federal Institute of Technology Zurich and the Institute of Technology

Management at the University of St. Gallen, which is funded in part by the Swiss health insurer CSS. EF and TK are also the cofounders of Pathmate Technologies, a university spin-off company that creates and delivers digital clinical pathways. Pathmate Technologies is not involved in the study app described in this paper.

Multimedia Appendix 1

Instruction video shown to the participants assigned to the Breeze condition. [MP4 File (MP4 Video), 8856 KB - games_v9i3e22803_app1.mp4]

Multimedia Appendix 2

Instruction video shown to the participants assigned to the Circle condition. [MP4 File (MP4 Video), 8928 KB - games v9i3e22803 app2.mp4]

Multimedia Appendix 3

Training video (6 minutes) shown to the participants assigned to the Breeze condition. [MP4 File (MP4 Video), 92223 KB - games v9i3e22803 app3.mp4]

Multimedia Appendix 4

Training video (6 minutes) shown to the participants assigned to the Circle condition. [MP4 File (MP4 Video), 34510 KB - games v9i3e22803 app4.mp4]

Multimedia Appendix 5 Employed questionnaire. [DOCX File , 18 KB - games v9i3e22803 app5.docx]

Multimedia Appendix 6 Factor analyses for intrinsic experiential value and perceived effectiveness. [DOCX File , 206 KB - games v9i3e22803 app6.docx]

Multimedia Appendix 7

Influence of gaming time and meditation experience on the investigated outcomes. [DOCX File , 36 KB - games v9i3e22803 app7.docx]

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Abbreviations

MANOVA: multivariate analyses of variance

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Original Paper

A Cognitive Behavioral Therapy–, Biofeedback-, and Game-Based eHealth Intervention to Treat Anxiety in Children and Young People With Long-Term Physical Conditions (Starship Rescue): Co-design and Open Trial

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Abstract

Background: Approximately 10%-12% of New Zealand children and young people have long-term physical conditions (chronic illnesses) and are more likely to develop psychological problems, particularly anxiety and depression. Delayed treatment leads to worse health care and poorer long-term outcomes. Recently, eHealth interventions, especially those based on principles of cognitive behavioral therapy and biofeedback, have been shown to be moderately effective in reducing anxiety. However, these modalities have rarely been combined. Young people have expressed a preference for well-designed and technology-based support to deal with psychological issues.

Objective: This study aims to co-design and evaluate the acceptability and usability of a cognitive behavioral therapy and biofeedback-based, 5-module eHealth game called *Starship Rescue* and to provide preliminary evidence regarding its effectiveness in addressing anxiety and quality of life in young people with long-term physical conditions.

Methods: *Starship Rescue* was co-designed with 15 children and young people from a tertiary hospital in New Zealand. Following this, 24 others aged 10-17 years participated in an open trial of the game, accessing it over an 8-week period. The acceptability of the game to all participants was assessed using a brief, open-ended questionnaire. More detailed feedback was obtained from a subset of 10 participants via semistructured interviews. Usability was evaluated via device-recorded frequency and duration of access on completion of the game and the System Usability Scale. Anxiety levels were measured at baseline, completion, and 3 months after completion of the game using the Generalized Anxiety Disorder 7-item scale and Spence Child Anxiety Scale, and at the start of each module and on completion using an embedded Likert visual analog scale. Quality of life was measured at baseline, completion, and 3 months after completion using the Pediatric Quality of Life Inventory scale.

Results: Users gave *Starship Rescue* an overall rating of 5.9 out of 10 (range 3-10) and a mean score of 71 out of 100 (SD 11.7; minimum 47.5; maximum 90) on the System Usability Scale. The mean period for the use of the game was just over 11 weeks (78.8 days, 13.5 hours, 40 minutes). Significant reductions in anxiety were noted between the start and end of the game on the Generalized Anxiety Disorder 7-item scale (-4.6; P<.001), Spence Child Anxiety Scale (-9.6; P=.005), and the Likert visual analog scales (-2.4; P=.001). Quality of life also improved on the Pediatric Quality of Life Inventory scale (+4.3; P=.04). All changes were sustained at the 3-month follow-up.

Conclusions: This study provides preliminary evidence for *Starship Rescue* as an acceptable, usable, and effective eHealth intervention for treating anxiety in young people with long-term physical conditions. Further evaluation is planned via a randomized controlled trial.

Trial Registration: Australian New Zealand Clinical Trials Network Registry (ANZCTR) ACTRN12616001253493; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=371443

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KEYWORDS

long-term physical conditions; chronic illness; anxiety; eHealth; gaming; young people; treatment; cognitive behavioral therapy; biofeedback

Introduction

Long-term physical conditions (also known as chronic illnesses), defined as those lasting more than 3 months and impairing functioning, are common, affecting 10%-12% of children globally [1]. Such conditions include asthma, diabetes, epilepsy, and obesity, among others [2,3]. The prevalence of long-term physical conditions in childhood is increasing [4]. Owing to improvements in hygiene, immunization, and access to medical care in some high-income countries, it is greater than that of acute illness [5].

Psychological problems are more likely in children and young people with long-term physical conditions [6-11]. Of these, anxiety is the most common, with some studies identifying rates as high as 40% [12]. The likelihood of psychological problems, including anxiety, appears to be related to numerous factors that may impose a cumulative allostatic load [13]. These include developmentally related self-regulation, family dynamics, illness, and procedure-related pain or distress [13,14] and readjustment to normal life following the completion of treatment [15]. In the longer term, untreated anxiety may have a chronic and unremitting course [16] and increase the risk of other psychiatric problems, such as depression and substance use disorders [17].

Access to and effectiveness of treatments for psychological problems in children and young people with long-term physical conditions are currently limited. Although they are traditionally addressed using generic psychotherapies, such as cognitive behavioral therapy (CBT) and pharmacotherapies such as anxiolytic or antidepressant medication, there is limited evidence that such therapies are effective for this population [18]. Even in the general population, CBT only has a 60% response rate for anxiety treatment, suggesting room for improvement [19]. In addition, access to psychotherapies is often limited and dependent on the availability of community child and adolescent mental health services, pediatric consultation-liaison services, and other health services. Most interventions designed for children and young people with long-term physical conditions focus on adherence to medical treatment, education about medical conditions, and improving aspects of medical care [18].

Over the past few decades, the increasing popularity of smart technology, release of gamified and app-based interventions, and calls from international organizations, such as The Lancet Global Mental Health Group [20] for the introduction of innovative and accessible cognitive and behavioral strategies

https://games.jmir.org/2021/3/e26084

to treat anxiety, depression, and other common mental health problems, have led to the likelihood that eHealth interventions will play a significant role in future mental health delivery. Purported advantages of eHealth interventions include increased accessibility, greater anonymity, flexibility, reduced expenses, eliminated travel time, and interactivity [21,22]. Several recent systematic reviews have confirmed the effectiveness of eHealth interventions for anxiety in young people, the most recent of these citing moderate to large effect sizes compared with no treatment (g=0.53-1.41) [23-27]. The most widely used and evaluated eHealth interventions for childhood anxiety are the CBT-based interventions BRAVE (Body Signs, Relaxation, Active Helpful Thoughts, Victory Over Your Fears, Enjoy) online [28] and the Cool Kids series that includes Little Cool Kids for younger children [29], Cool Kids online for older children [30], and Chilled Out for adolescents (the latter was developed from a CD-ROM version called Cool Teens) [31]. Both have been shown to be clinically effective, but none address anxiety in the context of health-related conditions, nor are they widely available outside Australia. A number of other CBT-based interventions with evidence of effectiveness also exist [32]. A few mindfulness-based interventions, such as Personal Investigator and an unnamed problem-solving intervention, also have limited evidence of acceptability and user satisfaction [32]. To date, no eHealth interventions have been specifically designed to address anxiety in children and young people with long-term physical conditions. Given the medically related and unrelated factors that lead to anxiety in this group and the fact that anxiety management needs to be available and effective in the context of ongoing physical health care, it seems likely that they have different needs from the general population. A recent Cochrane review identified only one CBT-based, chronic pain-focused, web-based intervention, Web-MAP. Furthermore, 2 low-quality studies provided unclear evidence of their effectiveness in reducing anxiety [33].

Traditional psychological therapies often include a component of psychologically or chemically induced relaxation. There is increasing evidence that newer, more technology-based forms of therapy, such as biofeedback, may achieve similar results, either alone or in combination with traditional therapies [34]. Furthermore, some biofeedback interventions have already been combined with game-based technology to reduce stress or treat behavioral disorders [35]. Biofeedback involves the use of electrical or electromechanical equipment to measure physiologic processes occurring in a person and then feed this information back to them to develop a greater awareness and

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ability to control changes within their bodies with and without equipment [36] and improve health and performance [37]. There are several types of biofeedback, including heart rate variability (HRV), electroencephalography, and pneumography. Two HRV biofeedback-based interventions, Dojo and Relax to Win, have been demonstrated to reduce childhood anxiety [32]. A third electroencephalography, mindfulness, and CBT-based intervention—Mindlight—has also shown some promise [32]. A recent systematic review supported HRV as the most effective form of biofeedback for the treatment of anxiety and supported further research into hybrid models of therapy [38].

In a recent study, New Zealand young people with long-term physical conditions confirmed that anxiety is the most significant psychological issue that they face [39]. Together with their families and clinicians, they described limited knowledge of and access to eHealth interventions and expressed support for the development of eHealth interventions targeted toward their needs. Between 2017 and 2019, a 6-month co-design process was undertaken with 15 New Zealand young people and a local game developer (Carbon Imagineering) to develop a CBT and biofeedback-based eHealth game called Starship Rescue [40]. This involved 3 cycles or sprints during which the prototype game was developed and scrums during which feedback was collected and reviewed. At the end of each cycle, a deliverable version was made available to the tester group to garner further feedback, which was then implemented in the next development cycle. Following this, an open trial was undertaken with the aim of evaluating its (1) acceptability and (2) usability and (3) ability to provide preliminary evidence of its clinical effectiveness before conducting a randomized controlled trial (RCT).

Methods

Design

The open trial, conceptualized by 3 authors (HT, KS, and SM), used a mixed-methods design, including quantitative analysis of anxiety symptoms and quality of life outcomes, intervention use, and qualitative analysis of participant feedback.

Population

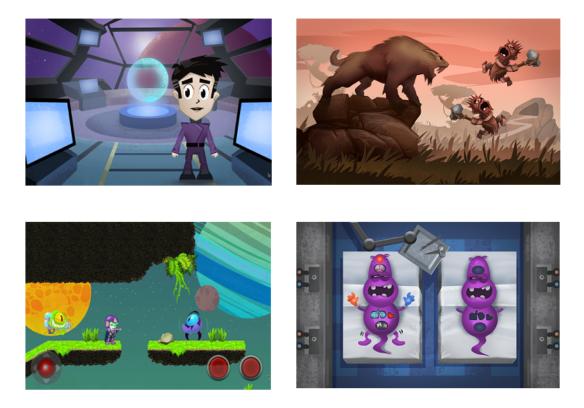
A total of 24 young people aged between 10 and 17 years were recruited from a tertiary children's hospital in Auckland, New Zealand, between October 2018 and May 2020. Eligible participants had any type of long-term physical condition lasting for longer than 3 months (eg, asthma, diabetes, cancer, and cystic fibrosis) and measurable levels of anxiety (eg, specific phobia, generalized anxiety, and nonspecific anxiety) and may or may not have had comorbid mental health conditions. Eligible participants were of any ethnicity, intellectually and physically able to use the intervention, and understood enough English to play the game and provide informed consent or assent with paired parental consent if they were aged <16 years. Participants who did not meet all these criteria and those who had recently undertaken or were undertaking CBT or other forms of psychotherapy, biofeedback therapy, or pharmacotherapy with anxiolytic medication within the past 6 months were excluded because the effect of those therapies could confound the impact of the intervention.

Intervention

Starship Rescue is a game-based eHealth intervention based on the story of a space hospital (starship) that gets caught up in a vortex of anxiety. The narrative is a new captain whose mission is to help find the lost bravery stars and restart its engine. Purposely designed to harness the correlation between shorter duration of use and outcomes [41], it includes 5 modules, each taking between 15 and 30 minutes to complete. Module 1 introduces players to anxiety and its origins and features, module 2 focuses on beating anxiety using their bodies, for example, via deep breathing and progressive muscle relaxation, module 3 teaches players how to discern between helpful and unhelpful thoughts and to prioritize the former, module 4 introduces problem solving and graded exposure to address smaller and bigger forms of worry or anxiety, and module 5 is a final quiz to consolidate the learning from previous modules. On completion of the game, players are emailed a summary of learned techniques in the form of a stay cool capsule. The intervention is provided on a tablet synced with a commercially available, wrist-based Scosche Rhythm Plus heart rate monitor which is accessed during biofeedback-based relaxation exercises. Starship Rescue is underpinned by the principles of (1) CBT, (2) biofeedback, (3) learning theory, and (4) game player taxonomy. Although most knowledge and skills are gained within modules, users must also leave the game and practice overcoming a named worry or anxiety in the real world between the fourth and fifth modules to complete the intervention. No external therapist support is required. Parental involvement has previously been shown to aid the successful completion of eHealth interventions, learning, and application of skills and systemic risk factors associated with the maintenance of childhood anxiety [42]. During the use of Starship Rescue, parents help their child choose a real-life reward to receive on completion of the intervention, validate the achievement of an out-of-game task in the fourth module by entering a four-digit code so that they can proceed to the final module, and are emailed a summary of the key learning points if their child does not have an email address. Participants were loaned a tablet with Starship Rescue installed on it and encouraged to complete all modules at home or in the hospital within 8 weeks. If they requested additional time at this stage, it was provided. Player data were saved within the game, allowing participants to pause and resume the game when participants wished to do so. Some data (eg, module completion and time taken) were manually pushed by a member of the research team from the game to an administrator email address at the end of the game. Further details of the modules and theoretical underpinnings are provided in Multimedia Appendix 1 [43-54]. Illustrative images are presented in Figure 1.



Figure 1. Illustrative images from the game—clockwise from top left: bridge of starship; learning about the origins of anxiety; exploring the anxiety monster; planet of the mind.



Outcome Measures

The primary outcomes of the open trial were evaluated as follows: (1) acceptability of the prototype intervention (ie, is the content and format acceptable to users?) was quantitatively assessed via user ratings of overall acceptability and helpfulness on scales from 0 to 10 and qualitatively assessed via feedback during semistructured interviews following completion of the game; (2) usability of the intervention (ie, is it usable?) was quantitatively assessed using the System Usability Scale (SUS) [55], time taken to complete the game and module completion and qualitatively assessed via feedback during semistructured interviews following completion of the game; and (3) clinical effectiveness (ie, does it reduce anxiety and related issues?) was assessed by measuring changes over time in the Generalized Anxiety Disorder, 7-item (GAD-7) [56], Spence Children's Anxiety Scale (SCAS) [57], a Likert scale of anxiety embedded in the game, and the Pediatric Quality of Life Inventory (PedsQL) [58], as outlined in the schedule below (Table 1). The GAD-7 is a brief (7-item), self-reported scale for measuring anxiety in people aged ≥ 13 years. It has a sensitivity of 89% for generalized anxiety disorder, and scores of 5, 10, and 15 out of a possible 21 points indicate mild, moderate, and severe anxiety levels, respectively. The SCAS is a well-validated but longer (46-item) self-reported scale measuring child anxiety with sound psychometric properties with internal consistency reported at 0.92 for the total child score. It contains 6 subscales

for panic or agoraphobia, social phobia, separation anxiety, obsessions or compulsions, fear of physical injury, and generalized anxiety. Likert scales (linear scales with items or numbers, eg, 0-10) have been shown to be useful for monitoring changes in anxiety [59] but are limited by user avoidance of extreme ratings [60]. Visual analog scales (involving images such as faces of differing sizes or nature) have also been shown to be useful for rating anxiety [61] with superior measurement qualities [62]. There is some disagreement about which type of scale is better for use with children [63,64]. Repeated brief evaluation of anxiety using simple measures such as Likert visual analog scales within a game, such as Starship Rescue, can be considered a form of ecological momentary assessment (EMA). EMA has been demonstrated to be useful for providing a richer picture of how behavioral changes occur over time [65]. To embed a repeated and accessible EMA within Starship Rescue, a combined Likert visual analog scale was developed that includes the face of an anxiety monster (as shown in Figure 1). This face can be moved with a slider to the desired point from the left (also marked 0) side of the screen to the right (also marked 10) and enlarges as this occurs. The PedsQL is a well-validated, 23-item self-report or parent-report scale measuring the quality of life. It has good internal consistency (0.88 for total scale), validity, and acceptability. It reliably distinguishes between healthy children and those with acute or long-term physical conditions.

Table 1. Schedule of outcome measuremen

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Outcome	Start of game	Start of each module	Completion of game	3 months following completion
Acceptability	N/A ^a	N/A	User feedback via questionnaires and semistructured interviews	N/A
Usability	N/A	N/A	System Usability Scale, user feedback via semistructured interviews	N/A
Effectiveness	GAD-7 ^b , SCAS ^c , Likert VAS ^d , PedsQL ^e	Likert VAS	GAD-7, SCAS, Likert VAS, Peds QL	GAD-7, SCAS, Peds QL

^aN/A: not applicable.

^bGAD-7: Generalized Anxiety Disorder-7 item.

^cSCAS: Spence Children's Anxiety Scale.

^dVAS: visual analog scale.

^ePedsQL: Pediatric Quality of Life Inventory.

Statistical Methodology

Quantitative data were analyzed by our biostatistician (CF) using Excel (version 16, Microsoft Inc) and SPSS (version 25, IBM Corp). Analyses included basic descriptive statistics (eg, number of sessions completed, number of times device accessed, duration of use, changes in anxiety score, and demographic characteristics of the sample). McNemar chi-square tests and one-tailed t tests were used to assess the statistical significance of changes in anxiety scores over time. P values of <.05 were taken to indicate statistical significance, and 95% CIs were used to establish the extent of any difference between pre- and postmeasures. A sample size of at least 20 was calculated a priori to detect changes within the study group with effect sizes of 0.65 or more as statistically significant (α =.05 with 80% power). Data from this trial will be used to inform power calculations for a more definitive RCT. An intention-to-treat analysis was used with missing data managed using the last observation carried forward method. Qualitative data were manually analyzed using a general inductive approach [66] with collated text independently analyzed by 2 researchers (HT and HK) and any discrepancies addressed by consensus.

Ethics and Consent

This study received ethics approval from the New Zealand Health and Disability Ethics Committee (HDEC, 16/CEN/136) on September 30, 2016. The lower age limit for participation was initially set at 12 years but later extended down to 10 years following a period of slow recruitment. Invitations to participate in the study were forwarded to potential participants through their own clinicians to minimize coercion using a direct approach. Verbal and written consent was obtained directly for those aged >16 years and via their parents with paired participant assent for those aged <16 years. Participants were free to discontinue engagement at any stage without consequence, and this was made clear to them. Although plans were made for any unanticipated distress occurring during participation to be managed by immediate referral to the hospital-based pediatric consultation-liaison mental health team, of which the lead author (HT) is a team member, this never occurred. Data were securely stored on a department server and kept securely for 10 years (or 10 years following younger participants' 16th birthday) according to the ethics committee requirements.

Results

Feedback and Alterations to the Intervention From the Co-design Process

A total of 15 participants aged between 8 and 16 years, of mixed gender (10 males and 5 females) and with different long-term physical conditions (cancer, asthma, bronchiectasis, cystic fibrosis, Alport syndrome, and others) provided feedback, 2 of which on multiple occasions. User feedback was incorporated to address technical issues, make instructions clearer, and develop the game's look and feel. Examples of user feedback during the first sprint and the use of this feedback are provided in Textbox 1. By the end of the third cycle, there were sufficiently minimal technical issues and common concerns to proceed with the open trial.



Textbox 1. Examples of feedback during the first sprint of co-design process.

Feedback and Proposed Alterations

- Generally positive feedback regarding look or feel, for example, "It's fun," "I liked how some monsters chase you, and others need to be found."
 - None
- Technical issue identified: "Only one little bug, getting stuck in the block."
 - To be fixed by game developer
- Unsure whether different colored crystals are the same
 - Clarification to be added to introduction to module 3
- Hard to recall positive and negative feelings when asked
 - Summary list to be added to the end of module 1
- Re. ideal audience for the game: "I think younger kids, probably 8-15 years, any (boys and girls)"
 - None, current game probably appropriate for target age range

Open Trial

Participant Characteristics

A total of 32 participants (different from those who participated in the co-design process) were referred by their clinicians to participate in the open trial of the *Starship Rescue*. Of these, 24 met all the inclusion criteria and agreed to participate (Table 2). The most common long-term physical conditions were cancer (4/32, 12%), transplant (heart, liver, and kidney; 4/32, 12%), epilepsy (2/32, 6%), juvenile idiopathic arthritis (2/32, 6%), and nut allergy (2/32, 6%). Individual participants also had stroke and nonepileptic events (1/32, 3%); asthma (1/32, 3%); cystic fibrosis (1/32, 3%); nemaline rod myopathy and restrictive lung disease (1/32, 3%); cardiovascular disease, not specified (1/32, 3%); eczema (1/32, 3%); spina bifida (1/32, 3%); chronic fatigue syndrome and postural orthostatic tachycardia syndrome (1/32, 3%); long QT syndrome (1/32, 3%); type 1 diabetes; and celiac disease (1/32, 3%). A total of 3 participants did not wish to participate after the study was fully explained. Furthermore, 3 participants had inadequate anxiety symptoms (GAD-7 score <5). One participant denied having any anxiety at all, and 1 participant did not respond to multiple invitations.

Table 2. Participant characteristics (n=24).

Characteristics	Values	
Age (years), mean (range)	14 (10-17)	
Sex, n (%)		
Male	9 (38)	
Female	15 (63)	
Long-term physical condition, n (%)		
Cancer	4 (17)	
Transplant (heart, liver, and kidney)	4 (17)	
Epilepsy	2 (8)	
Juvenile idiopathic arthritis	2 (8)	
Nut allergy	2 (8)	
Other	10 (42)	

Acceptability

Participants gave *Starship Rescue* an overall rating of 5.9 out of 10 (SD 1.87; range 3-10) and a helpfulness rating of 6.3 out of 10 (SD 2.52; range 2-10). Qualitative feedback consisted of

two main themes: helpfulness for managing anxiety and ease and enjoyment of use. The latter included 2 subthemes of positive and negative feedback, as presented with supporting examples in Table 3.



 Table 3. Qualitative feedback regarding acceptability.

Theme and subtheme	Supporting examples (participant number)					
Helpfulness for managing anxiety	 "I enjoyed the games and thought the game gave quite good techniques." [P13] "During the games where you had to keep your heart rate down, and breathing exercises, I did fi ways to slow down my breathing, and calm my heart rate, which was good." [P8] "It taught me a lot of breathing skills." [P14] "The game points out very helpful things that you don't really think about." [P15] 					
Ease and enjoyment of use						
Positive feedback						
	 "The game was fairly easy to control and fairly smooth running." [P5] "It was informative and the animations were fun." [P4] "The heart rate monitor was fun - to see where my heart was at." [P1] "It was really fun and I would do it again." [P18] 					
Negative feedback						
	 "The game was too difficult in module 3." [P4] "Bit too much talking and felt like module 2 was the same as module 1." [P20] "I don't feel like the game was for my age (15 years) and not enough shooting." [P5] 					

Usability

Participants had mixed views on the usability of *Starship Rescue*. The game received an overall mean score of 71 out of 100 (SD 11.7; minimum 47.5; maximum 90) on the SUS. Almost two-thirds (13/24, 54%) of participants rated it above 68, defined by the scale's authors as indicating *average usability*. More detailed SUS subscales are presented in Table 4. The module completion varied, as shown in Table 5. Despite the recommendation to use the game over a 4-week period, participants spent an average of 78.8 days (11-50 days; with

one participant taking 243 days) to achieve completion. As we were keen for participants to complete the game during this pilot study to provide us with feedback to inform the design of a future RCT and as there was no way to retrieve the tablets until participants had finished playing the game, the duration of use varied considerably between participants and modules, as described in Table 5. Qualitative feedback regarding the game's usability addressed technical issues, location of use, parental involvement, and recommendations for future improvement of the game. Further details are presented in Textbox 2.

Table 4. System Usability Scale subscales.

System Usability Scale item ^a	Values, mean (SD; range)
I thought the game was easy to use (+)	4.18 (0.92; 1-5)
I found the various functions in this game were well-integrated (+)	3.77 (1.05; 2-5)
I would imagine that most people would learn to use this game very quickly (+)	3.91 (0.87; 1-5)
I felt very confident using the game (+)	3.84 (1.20; 2-5)
I think that I would like to use this game frequently (+)	2.22 (1.02; 1-4)
I found the game unnecessarily complex (-)	1.91 (1.11; 1-5)
I found the game very cumbersome to use (-)	2.95 (0.67; 1-5)
I think that I would need support of a technical person to be able to use this game (-)	1.45 (0.81; 1-3)
I thought there was too much inconsistency in this game (-)	1.66 (1.20; 1-4)
I needed to learn a lot of things before I could get going with this game (-)	1.57 (0.90; 1-4)

^a(+) higher scores indicate greater usability; (-) lower scores indicate decreased usability.



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Table 5. Time taken to complete each module and the whole game.

	Completion (n=24), n (%)	Values, mean (SD; range)
Module 1	23 (96)	12.4 days (41.1; 11 minutes-142.9 days)
Module 2	23 (96)	5.6 days (7.2; 14 minutes-19.7 days)
Module 3	19 (79)	25.3 days (38.6; 26 minutes-128.3 days)
Module 4	17 (71)	13.6 days (18.7; 19 minutes-51.1 days)
Module 5	16 (67)	3.8 minutes (0.0006; 3.0 minutes-5.0 minutes)
Total	N/A ^a	79.4 days (9.52; 12.0 days-243.9 days) ^b

^aN/A: not applicable.

^bOn the basis of participants with completed data for all five modules.

Textbox 2. Qualitative feedback regarding usability.

Technical Issues

- "Some controls were a bit touchy and pressing the back button on the tablet would reset the progress on that module." [P1]
- "Module three was difficult to pass." [P11]
- "The games sometimes took a while to get the hang of." [P3]

Location of Use

- "Just at home in my room." [P19]
- "At home." [P15]

Parental Involvement

- "Sometimes, if I didn't know what to do...I asked my parents, or my bigger brother." [P15]
- "[My mum] was actually quite involved; she just asked questions about it." [P19]

Recommendations for Improvement of the Game

- "Make cut scenes skippable and add sections/chapters to each module." [P8]
- "Add a pause button that automatically pauses the game if you leave, so you don't lose progress." [P15]
- "Disable the back button or use a different tablet." [P1]
- "Have less backstory about the Starship and a more detailed description on how to play the mini-games." [P13]
- "Add a double jump bar." [for module 3; P17]

Effectiveness

Participants reported concordant changes in anxiety using three separate scales: GAD-7 [31], SCAS [32], and a Likert visual analog scale embedded in the game. The overall scores improved on all three scales with statistical significance (P<.005), as shown in Table 6. The overall effect size of the intervention was 0.6 (Cohen *d*). The change in anxiety using the Likert visual analog scale showed a positive association with the SCAS (r=0.59) and the GAD-7 (r=0.44). According to the GAD-7

scores, most participants (18/21, 86%) experienced a downgrading of symptom category (between severe, moderate, mild, and subthreshold) postintervention, whereas a few (3/21, 14%) remained the same. These changes were sustained at 3 months following completion, with the majority (15/21, 71%) continuing to report improvement, and some (6/21, 28%) remained the same (Multimedia Appendix 2). The numbers were too small to perform any reliable statistical calculations. Participants also reported improved quality of life using the PedsQL, as described in Table 6.



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Table 6. Change in anxiety on General Anxiety Disorder-7 item, Spence Children's Anxiety Scale, and Likert visual analog scales and quality of life on the Pediatric Quality of Life Inventory scale.

	- •		•							
	Generalized Anxiety Disorder, 7- item scale			Spence Children's Anxiety Scale			Likert visual analog scale		Pediatric Quality of Life Inventory scale	
	Pre	Post	3 months	Pre	Post	3 months	Pre	Post	Pre	Post
Participant, n	24	21	22	23	21	22	18	16	24	21
Value, mean (SD; range)	9.9 (5.4; 0-21)	5.3 (3.2; 1-12)	6.2 (4.7; 0-21)	35.7 (16.0; 13-69)	26.1 (13.9; 12-62)	26.0 (16.0; 8-79)	6.2 (1.5; 3.5-9.0)	3.8 (1.9; 0-7.5)	63.7 (15.9; 28.33-93.33)	68.0 (15.5; 40-88.33)
P value (vs prelevel)	N/A ^a	<.001	.001	N/A	<.001	.005	N/A	.001	N/A	.04

^aN/A: not applicable.

Discussion

Principal Findings

Our findings provide preliminary evidence that Starship Rescue is an acceptable, usable, and effective new eHealth intervention for treating anxiety and improving quality of life in children and young people with long-term physical conditions. They also confirmed the feasibility of undertaking a larger RCT to confirm these findings. Starship Rescue appears to have comparable effectiveness (Cohen d=0.6) with existing eHealth interventions designed to address anxiety in children without long-term physical conditions such as BRAVE online (Cohen d=0.76) [28]. More than 85% (21/24) of our sample demonstrated clinical improvement immediately following intervention, and most maintained this benefit at the 3-month follow-up. Starship Rescue also appears to be more effective than Web-MAP, the only CBT-based, chronic pain-focused, web-based intervention identified by a recent Cochrane review for treating anxiety in children aged 11-17 years with long-term physical conditions (Cohen d=0.53) [67].

We believe that positive design features of *Starship Rescue* include a smaller number of modules (n=5) than other eHealth interventions for anxiety such as BRAVE online (n=16) and Cool Kids online (n=8), the reduction and tunneling of CBT content to improve adolescent engagement [68], and the inbuilt ability to repeat key skills to achieve mastery [69]. The lack of therapist support makes Starship Rescue more cost-effective than existing eHealth interventions for childhood anxiety. Despite the concern of other researchers that adherence may be diminished by the absence of clinician support [68], we did not find this to be the case in the context of this small trial. Objectively collected adherence rates are higher than those in other comparable eHealth interventions [70]. As we did not collect any parents' feedback, we are uncertain whether their involvement optimized participant engagement and completion. We plan to explore this in an upcoming RCT. The study participants reported that they enjoyed biofeedback-based relaxation strategies. However, the potential additional benefit of combining biofeedback and CBT also remains unclear from these findings. Following more definitive evidence of its effectiveness, a head-to-head comparison of Starship Rescue and solely CBT and biofeedback interventions would be worthwhile to address this issue.

Despite being co-designed with its target audience, further minor modifications are warranted before the RCT to address some of the intervention's technical aspects and improve its usability and acceptability. The fact that the mean length of time taken to complete the intervention exceeded expectations may be related to a number of issues. Extensive completion times for module 1 are likely to be because of participants being assisted by us to access module 1 during the onboarding process but not actually commencing or completing it until a later date. The delay in completing module 3 is likely to be related to participants getting stuck while playing the embedded platform game. Finally, although the requirement for real-world mastery of a chosen source of anxiety during module 4 may have proved challenging for users, this remains a vital means of generalizing therapeutic knowledge into practice [71]. Other key information from this pilot trial that will influence the subsequent RCT is the slow pace of recruitment from a single site by busy clinicians. For the RCT, recruitment from multiple sites is planned to ensure more timely data collection. The outcome measures used in this open trial appear suitable for use during RCT. Adherence to the intervention (defined by us as completion of all modules) was achieved by 67% (16/24) of the participants. This is comparable with previous studies of eHealth interventions, such as Smart, Positive, Active, Realistic, X-Factor Thoughts (60%), Cool Kids online (75%), and BRAVE online (85%), and a recent systematic review that identified a mean rate of completion of 64% for technologically delivered interventions for childhood anxiety and depression [42]. This is also encouraging, given the known association between module completion and outcomes for psychological eHealth interventions [72]. Although its reach may currently be limited by reliance on a physically worn heart rate monitor, emerging technology will likely permit biofeedback to be conducted via heart rate monitoring apps in the future.

Strengths and Limitations

The strengths of this study are the co-design of *Starship Rescue* with end users, the inclusion of participants with different long-term physical conditions, and the small amount of missing data. The limitations of the study include the small sample size; the study being conducted in a single location, which may affect the generalizability of results; and the use of only self-reported outcomes. Exploration of parent or clinician ratings would also be valuable for comparison with user-rated levels of anxiety, as would an exploration of the types of anxiety participants choose to address; more detailed exploration regarding the

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combination of biofeedback and CBT; and differences in completion and acceptability between users of different genders and ethnicities during an adequately powered RCT. Given the difference between intervention use between experimental and nonexperimental settings [73], investigation of the intervention's use in a naturalistic setting would be useful. Future research would benefit from formal economic analysis to bridge the gap between researchers' interests and policy makers [74].

Conclusions

Starship Rescue remains the only eHealth intervention specifically designed for treating anxiety and is evaluated with

children and young people with long-term physical conditions. If future RCT results confirm the encouraging results from this pilot study, *Starship Rescue* has the potential to improve the short-term psychosocial well-being of this population by reducing psychological distress, improving quality of life, more optimal physical health management, reduced school absence, and improve the rates of completed education, employment, and survival.

Acknowledgments

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Conflicts of Interest

HT developed Starship Rescue as part of his PhD studies at the University of Auckland. As such, he is the owner of the intellectual property for this work and stands to gain financially from successful commercialization.

Multimedia Appendix 1 Description of content of the game and purpose of each module. [DOCX File , 19 KB - games v9i3e26084 app1.docx]

Multimedia Appendix 2

Change in symptom severity on the Generalized Anxiety Disorder Scale. [DOCX File, 14 KB - games_v9i3e26084_app2.docx]

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Abbreviations

BRAVE: Body Signs, Relaxation, Active Helpful Thoughts, Victory Over Your Fears, Enjoy CBT: cognitive behavioral therapy
EMA: ecological momentary assessment
GAD-7: Generalized Anxiety Disorder, 7-item
HRV: Heart Rate Variability
PedsQL: Pediatric Quality of Life Inventory
RCT: randomized controlled trial
SCAS: Spence Children's Anxiety Scale
SUS: System Usability Scale



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Original Paper

The co.LAB Generic Framework for Collaborative Design of Serious Games: Development Study

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Abstract

Background: Serious games are increasingly used at all levels of education. However, research shows that serious games do not always fulfill all the targeted pedagogical objectives. Designing efficient and engaging serious games is a difficult and multidisciplinary process that requires a collaborative approach. Many design frameworks have been described, most of which are dedicated to the development of specific types of serious games and take the collaborative dimension into account only to a limited extent.

Objective: Our aim was to create a generic serious game design framework that could be adapted to all kinds of serious games and implemented in a collaborative web platform.

Methods: We combined the results of a literature review with our experience in serious game design and development to determine the basic building blocks of a collaborative design framework. We then organized these building blocks into categories and determined the features that a generic design framework should include. Finally, based on the paradigm of complex systems and systemic modelling, we created the co.LAB generic design framework and specifications to allow its implementation in a collaborative web platform.

Results: Based on a total of 10 existing design methodologies or frameworks, 23 building blocks were identified and represent the foundation of the co.LAB framework. These blocks were organized into 5 categories: "context and objectives," "game design," "mechanics," "learning design," and "assessment." The arrangement by categories provides a structure that can be visualized in multiple and complementary ways. The classical view links game and learning design while other views offer project, systemic, and process visualizations. For the implementation of the co.LAB framework in a web platform, we propose to convert the building blocks into "cards." Each card would constitute a collaborative working space for the design of the corresponding block. To make the framework adaptive, cards could be added, adapted, or removed according to the kind of serious game intended. Enhancing the visualization of relationships between cards should support a systemic implementation of the framework.

Conclusions: By offering a structured view of the fundamental design elements required to create serious games, the co.LAB framework can facilitate the design and development of such games by virtue of a collaborative, adaptive, and systemic approach. The different visualizations of the building blocks should allow for a shared understanding and a consistent approach throughout the design and development process. The implementation of the co.LAB framework in a collaborative web platform should now be performed and its actual usability and effectiveness tested.

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KEYWORDS

serious game; educational game; simulation game; design; design framework; methodology; collaborative design; collaborative web platform

Introduction

Background

The term "serious games" is used in many different meanings, and there is still no strict agreement on what it exactly encompasses. In broad definitions, such as Zyda's [1] or in Michael and Chen [2], serious games may be used for achieving any kind of nonentertainment objectives, including education, health, public policy, or communication. In other definitions, such as those by Abt [3] or Loh et al [4], serious games are restricted to educational and training objectives. In this article, we use the term serious games in the sense of the definition by Loh et al [4], thus encompassing any kind of digital games or simulation created for educational or training purposes.

Serious Games for Educational Purposes

Serious games are effective tools to support learner-centered teaching practices [5-9], and interest in serious games has flourished at all levels of education. The COVID-19 crisis has accelerated the digitalization of education, and the use of digital educational resources such as serious games is expected to increase even further in the coming years [10]. However, research shows that serious games do not always fulfill all the targeted pedagogical objectives [11-13]. To reach its objectives, a serious game needs to successfully integrate gaming and learning aspects and be accepted by the teachers who will use it. Collaborative design of serious games is recognized as a success factor for both this integration and acceptance.

Collaborative Design of Serious Games

The collaborative work of a multidisciplinary team, including game developers, teachers (or trainers), and educational scientists, is required to design and develop efficient serious games [13-16]. This collaboration is recognized as a significant factor in the pedagogical relevance of the resulting development [14,17].

Integration of gaming and learning aspects, and integration of serious games into an overall pedagogical scenario, has been recognized as a key success factor [13,18,19]. Thus, the collaboration within the development team must ensure that partial contributions of different specialists who possess complementary knowledge and expertise will result in a coherent solution integrating pedagogical and playful aspects.

Collaboration in serious game multidisciplinary development teams can however be difficult [20]. Difficulties arise from the intrinsic multidisciplinarity of serious game design and from the challenging balance between game and pedagogical elements. Communication and coordination problems resulting from differences in vocabulary, background, and expectations also arise during the design and development phases [8,16,20-22]. Thus, while mandatory, collaboration in serious game design can be difficult.

Collaborative Web Platforms

Collaboration during serious game design could be facilitated by the use of a collaborative web platform. This platform should support typical collaborative dimensions such as mutual understanding, information pooling, communication management, group problem solving, reaching consensus, and task or time management [23,24].

For a multidisciplinary team, often geographically dispersed, a web platform may offer collaborative functionalities such as shared workspaces with a global design overview (mutual understanding), up-to-date documents (information pooling), discussion threads (communication management), voting systems (reaching consensus), and project management (task and time management). De Troyer [20] emphasized the need for this type of tool to support and stimulate the collaborative development of serious games. Regular tools usually employed for software development are not suitable for the development of serious games [20]. The main reason is that such tools were designed for software developers, not for multidisciplinary development teams incorporating noncomputer scientists [20]. Another reason is that existing platforms do not provide the necessary overview and integration needed for the development of both the serious game and its pedagogical integration [20].

Thus, collaborative web platforms may support collaborative design of serious games, but existing platforms are not suitable for that purpose.

Current Serious Game Design Frameworks

A collaborative platform dedicated to serious game design and development should be based on a design framework. Serious game design frameworks and methodologies are intended to provide development teams with design foundations and guidelines that support collaboration in the development of an integrated solution [8,16,25,26]. The framework implemented in a collaborative platform must allow, on the one hand, the development of the greatest number of different types of serious games and, on the other hand, be compatible and facilitate the implementation of collaborative features.

Most existing frameworks are dedicated to the design and development of specific types of educational games [16,27]. Thus, when beginning a new serious game project, the design team must choose a specific design framework and get used to it. Although not always straightforward, the task of choosing such a framework is usually rather easily feasible. However, using a framework that is too specific and not adaptable enough as the basis for a collaborative platform would force design teams to adapt to the framework, which could cause major problems. To achieve the intended serious game, the framework should be adapted to the project, rather than having to adapt the projected game to the framework.

A collaborative framework should provide the design teams with an overview of all design elements. Some existing frameworks give a broad overview of 3 or 4 categories to be

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considered (such as "Play, Pedagogy and Fidelity" in [8] or "Context, Pedagogy, Representation and Learner" in [28]) but do not provide a detailed view of specific design elements of each category. Few frameworks give a more detailed list of game and learning design elements, but do not offer a categorization and structured view that may enable understanding the role of the different experts and the link between elements. Most frameworks do not include the design of the pedagogical scenario into which the serious game will be implemented.

A collaborative framework should also provide a project management perspective. Project management during serious game design and development is challenging because of the difficulty of managing multidisciplinary teams and of the need to adopt an iterative process [16,29]. Project management support (task, time, resource allocation) during serious game design and development is highlighted as needed [30], but not included in existing frameworks. Most existing frameworks include some specific guidelines but do not support collaborative work nor provide practical guidance describing how the different steps of the development process should be carried out.

Thus, existing serious game design frameworks were not designed with the goal to be implemented in a web platform and present some shortcomings in that perspective. If some of the needed qualities are found in each existing framework, none of them include the complete set of necessary qualities. An ideal collaborative serious game design platform should be based on a framework that provides an overall structure with content that can be customized by the end users. It should be an adaptive framework rather than "one framework to rule them all" and thus be considered more as a general methodology (a set of tools and guidelines) rather than as a traditional framework. It should support a collaborative and interprofessional approach, as well as the possibility to view the development process from different angles, offering both a broad overview of design categories and a detailed view of design elements.

The co.LAB Project

The co.LAB project, which is funded by the Swiss National Science Foundation, aims at improving efficiency and relevance in serious game design and development by supporting the collaboration between all members of the multidisciplinary development team. This goal should be achieved by developing a methodological framework associated with a collaborative web platform dedicated to the co-design, co-development, and co-evaluation of serious games.

Objectives

Our main objective was to create a methodological framework suitable for implementation into a collaborative web platform. This framework should enable the design and development of all kinds of serious games. Our secondary objective was to define guidelines and basic collaborative functionalities for the implementation of such a framework in a collaborative web platform.

Methods

To identify the elements of a generic serious game design framework, we combined the results of a literature review with the authors' experience in serious game development.

The literature review was based on a search in Google Scholar using the terms "serious game design" and "educational game design." We added articles that were known by the authors and did snowballing searches from references and citations of identified articles. As the aim of the literature review was to identify the essential building blocks needed to develop the basic structure of a generic framework, we considered a systematic review unnecessary; it might have yielded more results but probably not led to the inclusion of more building blocks. We then selected the most relevant frameworks based on their suitability for our purpose. We considered a framework to be relevant when it had actually been used for the development of at least one serious game and had been described in enough detail to allow replication. While citation numbers were used to select the most influential frameworks, those less frequently cited were not excluded if deemed interesting or innovative. We also added articles and books linked to more general concepts related to game-based learning or game design.

After selecting the relevant frameworks, we identified their main design elements.

Design elements were coded using the following steps:

- 1. Design elements explicitly presented in the selected frameworks were reproduced as is (verbatim).
- 2. Design elements appearing in texts or in graphics, but not explicitly presented, were added by creating a specific and relevant terminology. The terminology was proposed by one author (DJ) and confirmed by a second author (ML).
- 3. For frameworks dedicated to the design of serious games in broader fields than training, we assigned generic design elements to the corresponding specific element of the learning domain identified in steps 1 and 2 (eg, objectives were assigned to learning objectives). This was performed by one author (DJ) and confirmed by a second author (ML).
- 4. The design elements identified during steps 1 and 2 were then reviewed to regroup identical or duplicate items. That was done by one author (DJ) and confirmed by a second author (ML).

Results of steps 1 to 4 were then debated among all authors. Any disagreement was resolved by reaching consensus.

We grouped the identified design elements into categories according to their characteristics, the available literature regarding their use in serious game development, and the experience of the authors. The organization into categories was proposed by an author (DJ) and discussed among all authors and finally validated by the last author (ML).

We then converted design elements into *building blocks*, which represent the smallest units of the co.LAB framework. When similar or identical design elements were called differently, we decided upon a terminology that was then used to refer to the building blocks. For the sake of readability and consistency,

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some elements were renamed or merged. The proposition to rename or merge elements was issued by one author (DJ), discussed among all authors, and finally validated by the last author (ML).

Finally, once the co.LAB generic serious game design framework had been established, we determined the specifications required for its implementation in a collaborative web platform. This was achieved by converting the building blocks into *cards*: Each building block corresponds to a card with its collaborative functionalities. Each card can either be used or discarded according to its relevance for the design and development of a particular serious game.

During the entire process, we also took into account the authors' experience in serious game development. Three of the authors (DJ, ML, and AH) belong to the AlbaSim research lab (Media Engineering Institute, University of Applied Sciences of Western Switzerland), which has been developing serious games for more than a decade. This lab has conducted serious game projects from design to implementation in many different educational fields such as emergency triage at hospital, cardiac clinical evaluation, oncology care, project management, computer education, energy management, or crime scene investigation [31-36]. Another author (LS) has conducted serious game projects in fields like resuscitation and COVID-19 infection prevention and control at the Geneva University Hospitals [37,38].

Results

Literature Analysis

The review and analysis of existing design frameworks confirmed that no single model or theory can currently be applied to the design of every kind of serious game. This is best explained by the fact that serious games may be of such different types and used in such different learning paradigms and contexts that a unique design framework may not be possible. This is confirmed by Plass et al [27] in their analysis of theoretical foundations of game-based learning: "It does not appear likely that a single theory will emerge that can guide the design of games for learning in general." This is also in line with our experience in serious game development.

Another observation was that not all serious game design frameworks have the same objectives. Some are more oriented toward serious game design elements [6,19,25], some more toward the design and development process [39], some cover both design elements and design process [16], and others are more concerned with theoretical foundations of game-based learning [8,27]. While most frameworks are conceived to guide the design of serious games for learning purposes, some of them are intended for the development of serious games for generic purposes (including learning, but not only) [16,40]. Most frameworks focus on game design but do not take into consideration the learning scenario in which the game should be integrated.

A synthesis of the design elements identified in the selected frameworks can be found in Table 1. In this table, frameworks are presented in descending order of number of citations. This may be a sign of the influence of the framework, but not necessarily of its intrinsic quality.

Some elements are present in most frameworks, such as play, interactivity, and feedback. Some interesting elements are however only present in a few frameworks, such as usage context (ie, the context in which the game will be used, designing the simulation model, or defining learner specifications).

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Table 1. Design elements extracted from existing serious game design frameworks and methodologies, which are presented in descending order of number of citations (from left to right).

Design elements	Plass (2015) [27]	Mitgutsch (2012) [40]	Yusoff (2009) [25]	Aleven (2010) [26]	de Freitas (2006) [28]	Rooney (2012) [8]	Marne (2012) [19]	Marfisi- Schottman (2012) [39]	Verschueren (2019) [16]	Vermeulen (2017) [41]
Learning objectives		x	X	x	·		X	x		x
Learning functions	х									
Learning foundations	х					х			х	
Learning activities			х					х		
Pedagogical scenario				х	x		х	х		
Learning mechanics	Х									
Learning incentives	Х									
Learning assessment	Х							х	х	
Knowledge content	Х	х	Х						х	х
Game goals and rules				х					х	
Structure and progression			х				х	x		х
Game mechanics	X	x	х	х					х	
Decorum, sounds, aesthetics	Х	х		х	x		х	х	х	
Narrative	х	x							х	
Game assessment	х							x		
Simulation model							х			
Fidelity					x	х				
Game incentives	Х		Х							
Usage context		x			x					x
Learners' specifications		x			x				х	
Play, interactivity, feedback	х	x	х	х	x	x	х	x	х	x
Immersion, motivation	x		х		х	х				

Besides the identification of these design elements, another key component was brought out through our analysis of the literature. Indeed, most frameworks emphasize the importance of developing an integrated system that includes and links gaming and learning aspects [6,8,19,25,26]. The successful alignment between game mechanics and learning mechanics is thus highlighted as an essential feature for the success of serious games [25,27,42,43].

Finally, many frameworks also tackle the development process, which is presented as both multidisciplinary and iterative [16,27,44]. But none of the selected frameworks provide specific project management functionalities.

Specifications for a Generic Serious Game Design Framework

Since the aforementioned analysis confirmed that no currently available framework is truly exhaustive and as the diversity of serious game designs must be acknowledged, a single design method can hardly be developed. We therefore concluded that the generic framework we sought to create should be a methodology (ie, a set of methods and best practices at the disposal of a design and development team), rather than a method. This generic framework should include elements common to most serious game designs but be *adaptive* to allow for specific designs. The framework should also foster collaboration between the various specialists involved in the design project. This could be achieved by allowing the design team to visualize the links between design elements throughout the game design process. This requires the development of a *systemic* framework.

Adaptive Features

Design specificities result from factors such as the type of serious game (which can include a simulation model, narratives, or neither of these features), usage context (ie, children or professionals, face-to-face, or online), and final objectives (eg, education, education and research, summative assessment).

Design specificities support the idea of developing an adaptive framework that would allow design teams to adapt the general model provided by the framework to their current project. This means that, depending on the design context and objectives, it should be possible to merge, add, or remove building blocks in the model.

The basic framework should therefore provide the main building blocks of most serious game designs (for example, pedagogical

objectives, pedagogical scenario, or game design), but the design team should then be able to adapt these building blocks to their specific design project.

Systemic Features

Serious game designs include many elements, all of which are interconnected. A successful design depends as much on the quality of each element as on the relevance and adequacy of the links between these elements [8,19,25,26,42]. It is the relationships between the elements that give the final product its coherence. We thus hypothesized that the paradigm of complex systems and systemic modelling [45,46] would be a suitable approach for the design of serious games as complex systems.

This supports the idea of developing a framework that shall encourage a systemic approach. The systemic features should provide a vision of the serious game design as a whole made up of interacting elements. This implies that the framework should aim to provide both an overview of the building blocks used for the design of the serious game and of the relationships between them.

The co.LAB Framework

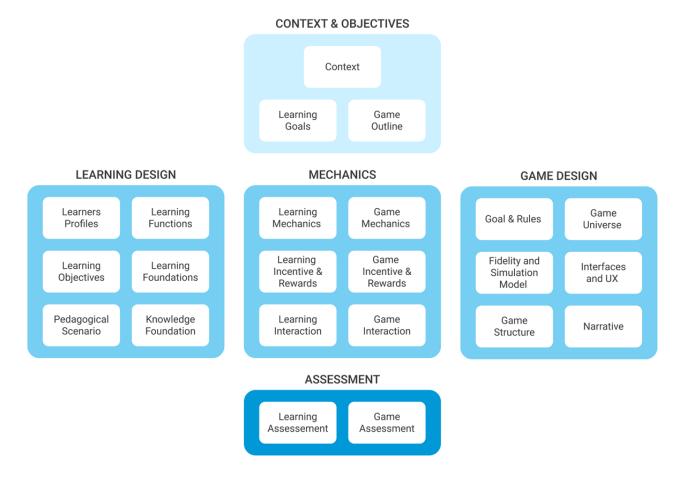
In accordance with our previous findings, we defined the *co.LAB framework* as a methodological framework for serious game design.

In order to bring together in a structured vision all the design elements identified in Table 1, we defined 5 main categories: (1) Context and objectives, (2) Game design, (3) Learning design, (4) Mechanics, and (5) Assessment.

Each design element has been assigned to a category. For the sake of readability and consistency, we rearranged the design elements into 23 building blocks. Most design elements were reproduced verbatim. To be consistent with the category to which they were assigned, some elements were either renamed ("structure and progression" became "game structure") or merged (fidelity and simulation model). Discussions between authors led to the addition of one building block ("game universe") that was not clearly mentioned in any of the selected frameworks but found in general game design literature [47]. The proposed building blocks are not intended to represent all the potential elements that could be used for the design of any serious game. Rather, these building blocks represent the basic elements of standard serious game design. They are intended to be customizable to fit specific projects.

Figure 1 presents the identified building blocks grouped into categories, which will be described in the following section.

Figure 1. The co.LAB framework with its 5 categories and 23 basic building blocks. Building blocks can be added, adapted or removed according to the serious game design considered.



Context and Objectives

The "Context and objectives" category is intended to give an overview of the problem at hand and a first idea of the solution.

Context includes a description of the environment in which the serious game will be used: classrooms or other premises, available technology, number of participants, available class hours, and all other initial constraints that should be taken into account [40,48].

Learning goals are used to give a general definition of the knowledge and skills that participants should acquire by playing the serious game. As for the game outline, defining learning goals early in the development process helps give a direction to the project even though they may evolve. A single sentence summarizing these goals can also be used for external communication.

The game outline is a short description of the serious game. It often takes the form of "The player takes the role of a _____ which is in a _____ (context/situation/environment). His/her objectives are _____. For this, he/she must ____." The game outline can evolve during the course of the development, but its definition from the start of the project gives a direction to the development team. The game outline will often be used for communication with people outside of the project (such as stakeholders).

Learning Design

Learning design aims at defining and designing the learning aspects of the serious game.

Defining the profiles of the participants, including their digital literacy [49,50], interest in learning the subject matter, and gaming and simulation experience will help adapt the content of the game and its mode of delivery [16,48].

Regarding learning functions, by definition, serious games are designed for a primary purpose other than pure entertainment [51]. When designed for learning purposes, a clear definition of the learning functions is necessary to achieve the intended goal. Development teams must define whether the serious game will be used as an exercise designed to test or apply existing knowledge or skills, to support knowledge or skill acquisition, or to prepare for future courses [27].

Learning objectives (or learning outcomes) are the results of breaking down learning goals into measurable sub-elements. They define what participants should have learned by the end of the serious game training sessions and are often stated as "at the end of the serious game, participants will be able to..." The learning objectives are the basis for building the serious game structure and content, defining appropriate teaching and learning methods, and designing learning assessment modalities. They can be used to inform students of what they are expected to learn.

For the learning foundations, appropriate learning theories and pedagogical modalities must be chosen. Depending on learning objectives, an appropriate learning theory could be behaviorist, constructivist, or socio-constructivist [8,27]. They can be declined in several pedagogical approaches such as experiential learning or problem-based learning [8]. The choice of

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appropriate learning theories and pedagogical modalities is a necessary condition for the achievement of learning objectives. For example, if the main learning objective is to develop practical palpation skills for clinical assessment and the pedagogical modalities are "observation," there will be an inconsistency that may prevent the learner from acquiring the intended skill.

For the knowledge foundations, the objective is to identify and validate the content related to the knowledge and skills participants are expected to acquire. This is the field of professional expertise. For example, evidence-based triage rules and processes should be the knowledge foundations of a serious game designed to teach emergency triage procedures. The identification of relevant knowledge foundations should be performed through a review of the relevant literature or of professional standards in collaboration with subject matter experts. It will also be necessary to define how the serious game will enable knowledge or skill acquisition [16,27].

The serious game should not be a stand-alone intervention but rather be embedded within a pedagogical scenario. The pedagogical scenario is therefore related to the general structure of the course or of the study program. The pedagogical scenario can be made up of a sequence containing game sessions, theoretical lectures, and personal working time. Depending on the pedagogical scenario, a subscenario can be required to support the use of the serious game. This subscenario generally includes 3 phases: prebriefing, orchestration of the game, and debriefing [52-55]. The activities taking place around the game (prebriefing and debriefing) are as important as the game itself.

Mechanics

Mechanics are at the core of the framework. They form the link between learning design and game design. In line with the model by Arnab et al [42], learning objectives should be linked to learning mechanics, which should be linked to game mechanics. Game mechanics should then be linked to game goals, rules, and structure.

The development team must decide upon the main learning mechanics that will be implemented in the serious game. We agree with the definition given by Plass et al [56], who defines learning mechanics as "patterns of behavior or building blocks of learner interactivity, which may be a single action or a set of interrelated actions that form the essential learning activity that is repeated throughout a game." Learning mechanics can include activities such as remembering, understanding, applying, analyzing, evaluating, or creating. Learning effectiveness increases when learning and game mechanics are aligned with learning objectives [42,56-58]. This leads participants to develop and exercise their cognitive abilities throughout the game to reach its ultimate goal.

Game mechanics are the set of actions repeated by the player throughout the game [59] and are therefore the basic elements of interactivity. A game can include a single game mechanic (such as only shooting, jumping, or answering questions) or an integrated set of game mechanics (for example, moving around freely while answering questions and collecting objects). In serious games, game mechanics have a double objective,

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resulting in 2 constraints: (1) engaging participants in taking part in the game and (2) ensuring consistency with learning mechanics. An incorrect choice of game mechanics can therefore quickly lead to failure in serious game implementation.

Learning and game incentives and rewards are used to support participant engagement and motivation. Incentives can be either intrinsic or extrinsic [58,60]. Intrinsic incentives are linked to game play and learning outcomes, whereas extrinsic incentives are not directly related to these elements. The most commonly used extrinsic incentives are points, badges, and trophies. Intrinsic incentives are more effective than extrinsic ones in achieving the learning objectives or any other intended goal. Indeed, it has been pointed out that gamification mechanisms purely based on rewards and on extrinsic motivators only bring short-term benefits and can be worthless or even harmful in the long run [58]. Intrinsic incentives may be harder to implement but are more beneficial. They can come from 3 sources: (1) mastery (learning to the point of feeling mastership regarding a specific knowledge or skill), (2) autonomy (being able to choose between several paths), and (3) relatedness (not feeling alone, feeling connected to others or to the situation) [61].

It is through interaction with the mechanics of play and learning that participants advance in the game and acquire knowledge and skills. To be successful, the interactions designed by the development team must result in both meaningful play and meaningful learning. Salen et al [59] defined meaningful play as emerging from players' actions that are discernible (players receive feedback) and integrated into the game play (players understand how their actions influence the course of the game).

Meaningful learning, as opposed to rote learning, is achieved when the learner is actively engaged in the learning process and the newly learned information is connected with previous knowledge. Mayer [62] argued that meaningful learning occurs when learners build knowledge for successful problem solving. In serious games, meaningful learning may be achieved when participants need to acquire new knowledge for solving problems encountered in the game. Meaningful learning may happen either inside the game or outside the game, for example during the debriefing phase.

The successful implementation of meaningful play and meaningful learning leads to what could be called *meaningful serious gaming*.

Game Design

The game design includes the detailed description of all the elements that form the serious game.

Regarding goals and rules, setting a goal is essential for developing the pleasure and motivation to play. The goal of the game should be understandable, concrete, simple, clear, achievable, and rewarding if achieved [47,59]. A game is an artificial conflict to be resolved by the player [59]: The development team will have to decide which activities and interactions the player will be allowed to perform (game rules) to achieve the objective (game goal).

The game universe corresponds to the world in which the game will be played. It may be a fictional world or a simulation of

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the real world. The game universe should be consistent with the learners' profiles.

Regarding the fidelity and simulation model, a simulation is a simplified representation of reality that seeks to achieve fidelity. Different kinds of fidelities have been described, all of which are used to enhance realism: sensory fidelity (audio-visual), narrative fidelity (dialogues, story), and cognitive fidelity (reflections that players make in the serious game) [8,63]. The types of fidelity chosen by the development team must be consistent with pedagogical objectives.

User interfaces (UI) and user experience (UX) are related to what the player will see and experience. They will impact the emotional feeling of the game and the pleasure of playing [26,27]. The graphical design and sounds must be aligned with the game universe and the desired fidelity. UX and game usability must be considered according to the context of usage and learners' profiles.

The game structure should include the description of both the game and the learning progression. If there are prerequisite relationships between knowledge chunks acquired during the game, they will have to be taken into account when defining the game-learning sequences [19,41]. A progression that is too difficult or too slow will decrease the player's motivation. This is in line with the concept of flow described by Csikszentmihalyi [64]. The progression must be thought of as much from a game perspective by game designers as from a learning perspective by educators [19].

Narratives are the content and structure of the story. They can include information given by a narrator, dialogues between the player and characters, and emails. Writing dialogues and narratives means creating an interactive scenario that will evolve according to the player's choices. The quality of narratives will depend on the number and quality of choices and on the number and quality of feedback.

Assessment

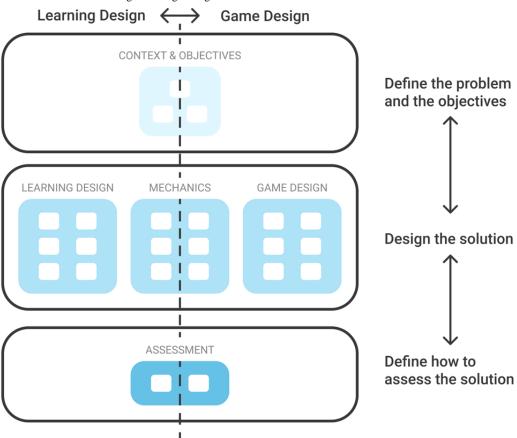
How the game and its objectives will be evaluated is part of the overall design. This may include game assessment by participants, learning assessment within the game itself, or assessments outside the game. If a research project is considered, the research questions should be clearly defined, and research protocols should be established and registered. This will help determine which data and indicators will ultimately be needed and how data processing and visualization should be carried out. Care must also be taken to ensure compliance with personal data protection regulation. Consent mechanisms and the need for ethics approval must also be considered.

Visual Organization of the Categories

By grouping design building blocks into 5 categories, the framework aims at providing a structured view of the game design. This view enables all members of the development team to focus on the building blocks on which they are working (pedagogical engineers may focus on learning design, while graphic designers on user interfaces) while simultaneously providing an overview of the project and of the relationships

between the building blocks. The categories are structured both vertically and horizontally (Figure 2).

Figure 2. Structured vision of the 5 serious game design categories.



The Game and Learning Vision

Traditionally, serious game design is viewed as a blend of learning and game design. In Figure 2, the left side of the framework corresponds to the learning design, and the right side corresponds to the game design. As in most design models [44,56], this vision emphasizes the inclusion of game and learning designs in serious game design. The Mechanics category can be seen as linking them together.

The Project Vision

The co.LAB framework can also be viewed from top to bottom. The upper section defines the problem and the overall objectives of the project. The middle section defines the solution: the game and the associated learning concept. The lower section defines how the solution will be evaluated both from the game and learning perspectives. This may in some cases be similar to the "success criteria" defined in project management theories.

Discussion

Implementation in a Collaborative Web Platform

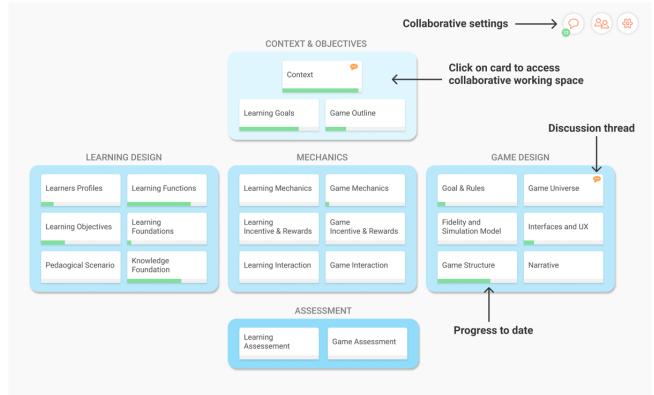
To support the collaborative work of a multidisciplinary development team often geographically dispersed and to enable all partners to have a common and up-to-date vision of the design, the co.LAB framework should be implemented in a collaborative web platform. In this section, we discuss the specifications and requirements for this implementation.

The web platform should be open source and open access, thus allowing any serious game development team to use it freely. At the beginning of a serious game project, the development team should access a visual initial design template based on the co.LAB framework. Figure 3 shows how the main screen of a design project based on the co.LAB framework could look. As team management or project monitoring functionalities would be useful to help allocate resources and quickly check on the project's advancement, they should be embedded in the web platform.



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Figure 3. Wireframe for the implementation of the co.LAB framework into a web platform: main project page.

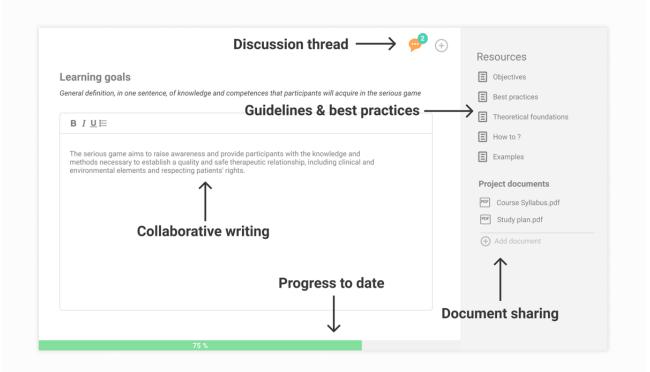


Cards as a Collaborative Workspace for Each Building Block

In the web platform, each building block (eg, context, game outline) should be implemented as a *Card*. By clicking on the card, the development team would access a dedicated

collaborative workspace. The workspace of each card should provide teamwork functionalities such as collaborative writings, discussion threads, modification proposals, and document sharing. Each card should be complemented with methodological resources such as definitions, best practices, tools, or theoretical references (Figure 4).

Figure 4. Wireframe of a Card, with collaborative working spaces and access to resources.





Implementation of the Adaptive Features

At the beginning of a serious game development project, the development team would be provided with a basic template including the most frequently used cards. This basic structure covers the conventional elements of standard serious game design and is suitable for use in this form by junior development teams. More experienced development teams could adapt this basic model by adding, modifying, or deleting cards. Cards could either be added from a store of already available optional cards or created from scratch by the development team.

Providing abilities to select the most relevant cards, to discard others, and to create missing cards should allow the initial template to be adapted toward an already existing model or to customize it for a specific serious game design.

The framework's basic template should also be adaptive. Based on the analysis of the traces of use of different development teams, the platform administrators should be able to make the model evolve.

Implementation of the Systemic Features

Figure 3 shows a default view of the model in which cards are grouped by categories. The platform should also allow the development team to develop a systemic view of the project by creating links between cards. Specific views should then be generated to allow team members to visualize such links (Figures 5 and 6).

Figure 5. Activity network diagram view, emphasizing precedence dependency relationships.

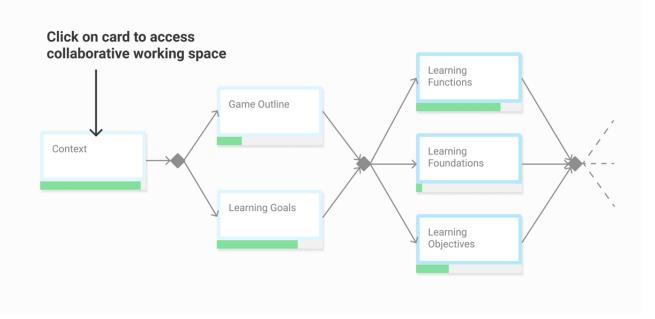
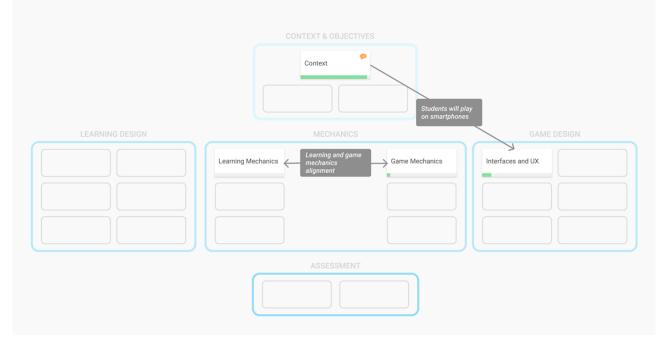




Figure 6. Causality and interdependence relationships.



There are 3 main types of relationships between cards. The first, precedence dependency relationship, is used to create the activity network diagram and for scheduling. The second, causality, is used to inform that something defined in 1 card must be taken into account in another. The third, which may be called interrelationship, indicates that 2 cards should be seen as a coherent whole. This interrelationship can also be described as a bidirectional causality.

Each relationship could also have its own collaborative workspace, with best practices and resources. Some relationships could already be defined in the initial model. For instance, as an interrelationship is mandatory to link game mechanics and learning mechanics, this relationship could already be available from the start of the project. The collaborative workspace attached to this relationship would provide best practices guidelines related to the alignment of game and learning mechanics.

The development team should also be able to create specific relationships, as, for example, a link between the context and user interfaces with a remark that the game should be playable on smartphones.

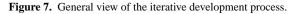
Supporting all the Project Phases

The web platform should support the development team all along the course of the project, from design to development and evaluation. In Figure 7, we propose a serious game development process that should be implemented in the web platform. This process is a quite classical adaptation of traditional agile project management. Using this kind of agile approach for serious game development is endorsed by Verschueren et al [16] and Alvarez et al [44] and by the authors' experience.

The co.LAB framework presented in this paper focuses on the Requirements and Design phases of the process. It is however possible to extend the framework to encompass the whole process (Figure 8).

By providing a coherent link between building blocks during all phases of the project, the co.LAB framework could be used throughout the life cycle of the serious game.

The different visualizations of the building blocks (grouped into categories, activities diagram, relationships, project life cycle) correspond to different ways of approaching the same problem of serious game design and development. These various visualizations should allow for a shared understanding and a consistent approach throughout the design and development process.



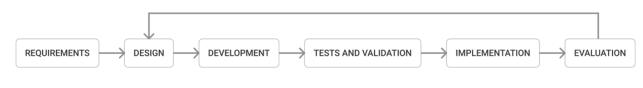
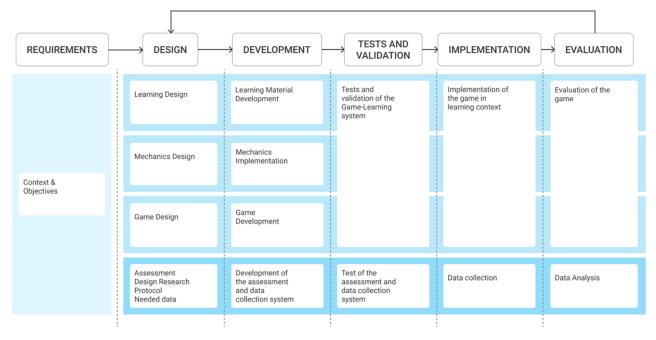




Figure 8. Extension of the co.LAB framework along the entire serious game life cycle.



Principal Findings

The co.LAB serious game design framework was created by identifying design elements commonly used to design and develop serious games. These design elements were defined and synthesized to create design building blocks, which were grouped in 5 categories: (1) context and objectives, (2) game design, (3) mechanics, (4) learning design, and (5) assessment. The framework recognizes the diversity of serious game design and is conceived to be adapted to specific contexts, by adding or removing building blocks.

The different visualizations of the building blocks (grouped into categories, activity network diagram, causality relationships, project life cycle) correspond to different ways of approaching the problem of serious game design and development. These various visualizations should allow for a shared understanding and a consistent approach throughout the design and development process.

The co.LAB framework is designed to be implemented in a collaborative web platform, with implementation recommendations that should support teamwork and knowledge sharing within a multidisciplinary team and favor an adaptive and systemic approach. The co.LAB framework may be used as a guideline along all project phases, from requirements to design, development, tests, implementation, and evaluation.

Future Work

The co.LAB framework is currently being implemented in a collaborative web platform.

Guidelines related to each card are currently being developed and will gradually be implemented in the platform. Their development is based on a literature review and on the authors' experience. Their relevance will be evaluated by end users, and they will be updated according to the feedback obtained. We plan on testing this framework and the web platform on which it is being implemented through the development of different kinds of serious games. This should allow us to troubleshoot the platform and identify the most important areas of improvement.

In a future version, we plan on implementing electronic assistance to help users find the most suitable combination of cards depending on their specific serious game project.

Limitations

The co.LAB framework is not based on a complete systematic review of serious game design frameworks, but rather on a review of the most influential and most relevant frameworks according to the authors' opinions and experience. However, should any particular design element be missing from the current version of the framework, its adaptive features should allow development teams to include them.

The co.LAB framework is also based on the authors' experience in serious game design and development. Even though the authors have developed many serious games in different subject matters and contexts, their experience is still limited and does not include all kinds of serious game development. Once again, the adaptive features of the co.LAB framework should mitigate this limitation

Finally, the co.LAB framework has been neither fully implemented on a web platform nor used to create a full-fledged serious game yet. Even though its development was theory-driven and based on relevant and authoritative references, it should be thoroughly tested before its routine use can be recommended.

Comparison With Prior Work

In comparison with previous work, the co.LAB framework proposes some novelties. First, this framework recognizes the diversity of serious game design and is intended to be adaptable



to specific contexts. Second, the framework was designed to be implementable in a collaborative web platform. Finally, this implementation in the web platform is based on a systemic approach of the design process.

Conclusion

By offering a structured view of fundamental design elements, the co.LAB framework should facilitate the design and development of serious games through a collaborative,

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Conflicts of Interest

None declared.

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multidisciplinary, adaptive, and systemic approach. The ability to visualize the building blocks and their relationships from different standpoints should allow for a shared understanding and a consistent approach throughout the design and development process. The co.LAB framework was designed to be implemented in a collaborative web platform that is currently under construction. Once fully implemented, the actual usability and effectiveness of this new framework should be thoroughly tested.

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Abbreviations

UI: user interface **UX:** user experience



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Original Paper

A Therapeutic Game for Sexually Abused Children and Adolescents (Vil Du?!): Exploratory Mixed Methods Evaluation

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Abstract

Background: Talking about experiences of sexual abuse in therapy is difficult for children and adolescents. Possible reasons for this difficulty are a lack of vocabulary to describe the situation or feelings of shame, fear, and self-blame associated with sexual abuse. The serious game Vil Du?! was developed to help children open up about their sexual abuse experiences. Vil Du?! is a nonverbal communication game that resembles a dress-up game in which children can show the therapist what happened to them.

Objective: This exploratory evaluation study examines which working elements of the game could be identified in therapy with victims of sexual abuse (aim 1). In addition, this study examines how therapists evaluate the acceptability of the game (aim 2).

Methods: The therapists completed 23 web-based surveys on the use of Vil Du?! In addition, semistructured interviews were conducted with 10 therapists. The data were analyzed in NVivo following previously reported stepwise guidelines.

Results: Regarding aim 1, therapists mentioned various working elements of Vil Du?!; for instance, Vil Du?! puts the child in control of the situation. In addition, Vil Du?! reduces barriers to disclosure because there is no need to talk or have eye contact with the therapist. Regarding aim 2, Vil Du?! was generally evaluated more positively than negatively by the therapists. For instance, therapists indicated that using Vil Du?! is time efficient and might make the treatment process less confronting and difficult for the client. According to therapists, most clients indeed experienced less tension and more positive (or neutral) emotions than negative emotions when using Vil Du?!

Conclusions: The most important working elements of Vil Du?!, according to therapists, are that it enables children to regain control over their sexual abuse experiences and reduces barriers to disclosing sexual abuse experiences. The more positive evaluation of Vil Du?! indicates the acceptability of the game for therapists as well as their clients.

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KEYWORDS

child sexual abuse; psychotherapy; serious games; evaluation; working elements; acceptability

Introduction

Statement of the Problem

Talking about experiences of child sexual abuse (CSA) is difficult for children and adolescents. Possible reasons for this difficulty are feelings of shame, fear, and self-blame, a lack of understanding or denial of the situation, or a lack of vocabulary to describe the situation [1-4]. However, therapy for child and

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adolescent victims of CSA often relies heavily on verbal narration and the processing of one's experiences. This is especially the case for cognitive behavioral therapy, which is the most often used and recommended form of psychotherapy for CSA [5,6]. To increase the suitability of cognitive behavioral therapy for children and adolescents, researchers have suggested the use of content that is tailored to the developmental needs of young clients and to emphasize elements of play [7,8]. Using

play in a therapeutic setting puts the child or adolescent in control, which is known to reduce tension and stress [9]. In addition, play provides an age-appropriate and natural manner for children to express their feelings, which they are often unable to express through language [10]. Furthermore, play makes treatment more fun and engaging [11]. Originating from these ideas, the third author (M Deen) and others developed a serious game, called Vil Du?! [12], to help children open up about their sexual abuse experiences to their therapists. This study provides an exploratory evaluation of Vil Du?! among therapists using the game in therapy for sexually abused children or adolescents. More specifically, we examined the working elements of the game (ie, elements that can explain its effects on the therapy process) therapists identified, as well as therapists' experiences with using the game (ie, benefits, limitations, and experiences of their clients).

Other Serious Games for Children and Adolescents in Treatment for CSA

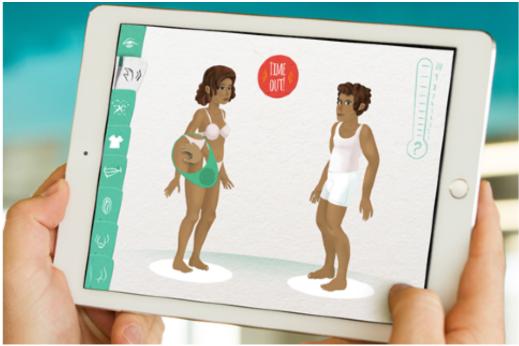
To date, there are limited serious game offerings for use in the context of CSA. One example is Orbit, a CSA prevention computer game targeted at students aged 8-10 years [13]. The goal of this adventure game is for the player to do everything they can to help the character Sammy that has suffered from sexual abuse. During several mini-games, children learn about recognizing CSA, perpetrator tactics, barriers to telling, building a healthy self-concept, and the importance of trusted adults who they can turn to. In addition, 2 unpublished master theses describe the development of serious prototype games aimed at helping children disclose CSA experiences [14,15]. Pharshy [14] developed a story-telling game in which children can create new stories of their own experiences, or edit existing stories, by using images, drawings, text, and self-created avatars. Parents or caregivers could monitor the child's stories for possible CSA experiences. Andersson [15] developed a tool for use in a

Figure 1. Overview of the game environment of Vil Du?!

therapeutic context. The prototype contained different scenes and storylines that therapists could show and play out with children, which could spark conversations about the different (sexual) abuse-related situations children might find themselves in. The 3 existing games have been developed primarily for CSA prevention purposes and not for use in a CSA therapy context, such as Vil Du?! In addition, the effects of these 3 games have not yet been evaluated.

Vil Du?! Design and Working Elements

To the best of our knowledge, the serious game Vil Du?! (Danish for "Do you want to [talk about...]?!") is the first digital game that is used in a treatment context for child and adolescent CSA victims. Vil Du?! is a nonverbal communication game in which children can show the therapist what happened to them (Figure 1). In the game, which resembles a *dress-up game*, both therapist and child operate a self-chosen character, each on their own tablet (provided by the therapist). The tablets are synchronized to each other, so actions performed on one screen are also visible on the other, enabling digital interaction between the therapist and child (without the necessity of looking each other in the eyes). Both players can perform various actions on the other character by clicking (eg, undress) or dragging explicit icons (eg, mouth, hand, penis, and buttocks; Figure 2) over the character's body. Each player can express their boundaries or pause or stop the game by pressing a Time-Out button (Figure 3). While playing, the therapist can probe the child to talk about their experiences, thoughts, and feelings. In addition to the Time-Out button, Vil Du?! does not include verbal statements or textual markers. The goal of the game is to give children a voice without the need to talk and to put children in charge of creating their own story, normative structure, and values associated with love, sex, and romance. Vil Du?! has been used by therapists with children and adolescents between the ages of 5 and 17 [16].



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Figure 2. The icons that can be used in Vil Du?!

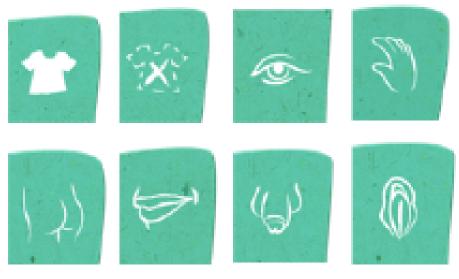


Figure 3. The time-out button in Vil Du?!



The first phase in evaluating a new tool is to define the working elements of the intervention [17]. Hereby, the goal is to find and define promising practice-based elements or components that could explain what works in the use of a serious game in therapy for CSA victims [18]. These working elements refer to important elements through which serious games (ie, Vil Du?!) might lead to beneficial outcomes in therapy for CSA [19]. Several possible working elements are identified in the game. First, Vil Du?! might reduce barriers to disclosure of CSA experiences because of its nonverbal character and because the use of the game does not require face-to-face communication between the therapist and client. With Vil Du?!, children can show, instead of talk about, what happened to them, which might help to overcome the barrier of a lack of vocabulary to describe the situation [2]. In addition, there is no need for eye contact with the therapist when using Vil Du?! because the client can look at the tablet screen. This might reduce feelings of shame, fear, and self-blame associated with CSA experiences [1,3,4]. Researchers have indeed suggested that serious games "can be used as a 'third party in the room', helping to make the therapeutic process less difficult for adolescents by taking some of the emphasis off direct face-to-face conversations" [20].

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Second, Vil Du?! provides children with an environment in which they can communicate through play. Vil Du?! resembles a dress-up game in which children can undress or redress a character and perform actions on, or with, the character by dragging icons over the character's body (eg, use the hand icon to give a high five). The play element of Vil Du?! might have an effect on several components of therapy. For instance, Vil Du?! might be helpful for the cognitive restructuring of incorrect and maladaptive thoughts related to the CSA experience. CSA victims often have incorrect or maladaptive thoughts related to the abuse experiences (eg, "I could have prevented the abuse"). For therapists to restructure such incorrect and maladaptive thoughts, they first need to explicate children's thoughts for which play (eg, with dolls, by drawing, or with Vil Du?!) can be used as a vehicle [21,22]. These explicit thoughts can be processed or restructured in successive therapy sessions. In addition, the explicit icons and characters of Vil Du?! enable children to engage in play that realistically depicts their traumatic experiences. When therapists encourage such realistic play, clients are gradually exposed to traumatic memories that might otherwise be avoided or suppressed [23]. Moreover, regarding the therapy component of trauma narration, playing

out one's experiences might help children more comfortably express the details of highly traumatic experiences, while also showing emotions and thoughts that can later be processed by the therapist [23].

Third, with Vil Du?!, children are in control of showing their experiences. This control is of particular importance in the context of CSA, in which children were not in control of the situation, and can help them regain a sense of control over their lives [24]. Moreover, children cannot achieve progress in therapy when they feel out of control [25]. With Vil Du?!, children can decide what they will show to the therapist, and they have control over stopping or pausing the game with the Time-Out button. Vil Du?! also puts children in control because the use of icons can have various connotations. For example, moving the hand icon over the back of the character can mean a pat on the back, stroking the back, or a slap on the back, depending on the context the child created or on verbal explanations provided by the child. Thus, it is not the game that guides how to interpret play; it is the player who controls the meaning of the interaction. The nondirective nature of Vil Du?! might be helpful in therapy for restructuring incorrect and maladaptive thoughts, because nondirective play can be considered as a restructuring process of one's thoughts [26].

Fourth, Vil Du?! gives children the opportunity to share and recreate their stories in a safe and nonnormative environment. With Vil Du?!, children can share the story of what happened to them by having one character performing actions on another character. Vil Du?! does not include statements or textual markers that stipulate whether a sexual relationship or action is right or wrong. As such, the game does not demonize the players or their actions, which may create a safe environment for children to open up about their sexual experiences. Normative statements about the inappropriateness of certain sexual behaviors and how children should behave in certain circumstances could problematize an already difficult CSA experience, which may increase feelings of self-blame and shame [27]. Research also shows that creating a narrative of one's CSA experiences might be a critical mechanism for producing positive outcomes after CSA [28]. In addition, children themselves often mentioned that creating a narrative of the sexual abuse by drawing or writing was specifically the most helpful part of therapy [28,29]. Stories might enable children to create a mental map of events and ideas and revisit them as and when the stories are narrated or remembered again [30]. In addition, games in which children are invited to create or tell a story have been found to help children express themselves safely, because such games aid children in absorbing complex concepts through play [31] as well as allowing children to express their feelings through an indirect medium [26].

Acceptability of Vil Du?! for its Users

Next, to evaluate the possible working elements of Vil Du?!, it is also important to evaluate the acceptability of the game for its users [17]. Acceptability refers to how intended individual users react to an intervention or tool [32]. Two users are relevant in the context of therapy—the therapist and the client. The therapist's acceptability of a tool is important in that it determines whether therapists will use the tool. Relevant in this

regard is how the therapist feels about the intervention in terms of its benefits and limitations (ie, affective attitude [33]). Client acceptability is clinically important as, if clients prematurely drop out of therapy because they are, for example, dissatisfied with how the therapy is being delivered, therapy cannot be completed and symptoms may persist unnecessarily [34]. Relevant indicators of the acceptability of Vil Du?! by clients might be the emotions, tension, and dissociation (ie, detachment from reality) experienced by clients during the use of Vil Du?! Such experiences are predictive of treatment outcome and adherence [35,36] and can thus provide preliminary information as to whether Vil Du?! is acceptable for clients.

Goal of This Study

Vil Du?! might be a valuable tool for therapy, but the use of the game in therapy is still in its infancy. For instance, a systematic user manual for Vil Du?! is currently being developed. In addition, therapists are still exploring how Vil Du?! could be used in therapy. To evaluate a tool in such an early phase, an exploratory evaluation among therapists seems most appropriate as it offers more flexibility than rigorous effect studies [17]. Such early evaluations can provide valuable indications of the possible clinical impact of new tools, as well as the acceptability of a tool by its users [37]. This information can subsequently be used for further development or refinement of a tool [17]. Therefore, our mixed-methods study aims to provide an exploratory evaluation of Vil Du?! by answering two research questions. First, which working elements can be identified in how Vil Du?! is used by therapists? We examined the following working elements specific to Vil Du?!: no need to talk; functions as a third party in the room or no face-to-face communication necessary; puts the child in control; and playful, safe, and nonnormative environment. Second, how do therapists evaluate the use of Vil Du?! in psychotherapy for CSA? We examined the benefits and limitations of Vil Du?! identified by therapists, as well as therapists' views of the emotions, tension, and dissociation (ie, detachment from reality) their clients experienced during the use of Vil Du?!

Methods

Participants

A total of 21 therapists using the Vil Du?! app at the time of the study were contacted personally, as well as via email, to fill out a web-based questionnaire every time they used Vil Du?! with a client. We could identify these therapists as they had received a working license for Vil Du?! from the app developers. The 21 therapists were also asked to forward the invitation to other colleagues who might have used Vil Du?! The therapists completed the web-based questionnaire for 23 clients with CSA experience. The mean age of the clients was 11.38 (SD 3.96; minimum=5, maximum=18) years. The majority of the clients were women (14/23, 61%). Therapists mostly used Vil Du?! in the context of client-centered therapy (13/23, 57%), followed by play therapy (8/23, 35%), and cognitive behavioral therapy (4/23, 17%). None of the therapists used Vil Du?! for psychoanalytic therapy or group therapy. The total number of therapists participating in the web-based questionnaire could not be determined because therapists could fill out the

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questionnaire anonymously. A total of 12 therapists provided contact information and indicated that they were willing to participate in the interview part of the study. The characteristics of the 10 therapists who actually participated in the interviews are presented in Table 1.

Table 1. Characteristics of therapist	s participating in the int	erview phase of the study.
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Participant ID	Age (years)	Experience in youth care (years)	Therapy with CSA ^a clients or therapy related to sexuality (hours per week)	Work organization ^b
1	42	20	5	1 ^c
2	44	15	20	1
3	42	17	32	1
4	32	12	32	2^d
5	52	30	32	1
6	47	22	16	1
7	28	5	16	1
8	42	17	32	3 ^e
9	62	10	24	1
10	38	17	24	4^{f}

^aCSA: child sexual abuse.

^bParticipants with the same number in this column work for the same organization.

^cYouth care organization providing contextual care for child sexual abuse victims.

^dSpecialized youth care organization focusing on adolescent sexuality.

^eOrganization providing specialized family care.

^fYouth care center for psychotrauma and sexual abuse.

Design and Procedure

We used a mixed-methods triangulation design with quantitative and qualitative data collected and analyzed at approximately the same time. Both types of data were merged and given equal emphasis in the interpretation [38]. Data were collected via web-based questionnaires (including quantitative and qualitative questions) and semistructured qualitative interviews. Through both methods, we derived input from therapists on the working elements of Vil Du?! and how they evaluate its acceptability. For both the web-based questionnaire and the semistructured interviews, questions and topics were based on the possible working elements of Vil Du?! identified in the literature. We also included aspects of user acceptability derived from existing measures [20].

Therapists completed the web-based survey via LimeSurvey (version 3.20, LimeSurvey Project; closed format with links sent to participants). They provided web-based informed consent for their participation at the beginning of the questionnaire. For the duration of the study (June 2019 to June 2020), we invited therapists to complete the questionnaire each time they used Vil Du?! in therapy sessions. The completion rate was 100% (23/23), as each question was mandatory. Participants were able to change their answers using a back button. The survey included 14 questions (displayed in a fixed order), of which 6 were used for this study.

Subsequently, a trained research assistant conducted and audiotaped interviews with a selection of the therapists (n=10) that completed the aforementioned web-based questionnaire.

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We selected the widest possible range in terms of the sexual abuse experiences of clients, therapy type, and background characteristics of therapists. For the interview part of this study, therapists provided written informed consent before the start of the interview. The duration of the interviews was, on average, 45 minutes.

The Ethics Committee of the Faculty of Social and Behavioural Sciences of Utrecht University approved this study (FETC19-025). Personal information collected via the survey or interviews was stored on a protected university server. Only the first and second authors had access to this server.

Web-Based Questionnaire

Background Characteristics

Therapists first had to fill out some background characteristics of the client (ie, age and gender).

Working Elements and Therapist Acceptability of Vil Du?!

Participants answered 1 open question regarding the elements of Vil Du?! they thought were effective in the therapy process (ie, "What are positive elements of using Vil Du?! in therapy? By positive elements, we mean elements of the game that can explain its effects on the therapy process"). This question (and accompanying explanation) is based on the common definition of working elements [17]. Participants also reported on the limitations of using Vil Du?! for either the therapist or the client (ie, "Is there something missing or lacking in the game that limits the use in therapy?").

Client Acceptability

Client acceptability (according to the therapist) with regard to the use of Vil Du?! was assessed with 3 questions on a 5-point Likert scale [20]:

- 1. "how pleasant/unpleasant they thought the use of Vil Du?! was for the client" (1=very unpleasant and 5=very pleasant).
- "how helpful they thought the use of Vil Du?! was for the client" (1=very unhelpful and 5=very helpful).
- 3. "how enjoyable they thought the use of Vil Du?! was for the client" (1=very unenjoyable and 5=very enjoyable).

Semistructured Interviews

The interviews were structured around a topic list, including the following topics, and were discussed in more detail than in the web-based questionnaire.

- What are the differences between using Vil Du?! and not using Vil Du?! in the treatment process or outcomes, and to which elements of Vil Du?! these differences could be attributed (ie, working elements);
- 2. therapist acceptability (eg, limitations, benefits); and
- 3. client acceptability (eg, emotions, stress levels, and entertainment value).

Analyses

Web-Based Questionnaire

SPSS version 24 (IBM Corp) was used to summarize and describe the qualitative and quantitative data from the web-based questionnaires. Frequencies were computed to determine the percentage of questionnaires in which the working element of Vil Du?! was identified for a specific client. Frequencies were also computed to determine the percentage of questionnaires in which a certain limitation of Vil Du?! was mentioned for clients of therapists. Descriptive statistics (mean and SD) were computed to summarize the acceptability of Vil Du?! for clients.

Interviews and Open Questions From the Web-Based Questionnaire

The stepwise guidelines outlined by Zhang and Wildemuth [39] were followed to increase the efficiency, repeatability, and transparency of our qualitative data analysis of the interview data in NVivo (QSR International). In step 1, we transcribed the answers to all questions literally. Observations during the interview (eg, sounds and pauses) were not coded, because they were not of interest to the research questions. In step 2, we defined the unit of analysis as themes; that is, the working elements of Vil Du?! and the experiences of therapists and clients using Vil Du?! In step 3, a coding scheme was developed, consisting of categories related to the working elements (eg, no face-to-face communication necessary, no need to talk, and child in control), benefits, and limitations of Vil Du?! (the coding scheme is available upon request from the authors). In step 4, the first (JJE) and second author (HT) tested the coding scheme on a sample of text (ie, 2 pages of text selected from a total of 4 interviews) to discover unclarities in the coding scheme. These issues have been discussed and resolved. In step 5, all text was coded by the first author while adding new categories to the coding scheme when necessary. For step 6, a

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set of randomly selected text fragments (20% of the total number of text fragments) was coded by both the first and second authors. Differences in coding were discussed until a consensus was reached. Changes were made to the coding scheme when necessary. The first author recoded the other 80% of the transcripts on the basis of this changed coding scheme. In step 7, we explored the properties and dimensions of the categories as well as the relations between the categories in the full range of data. We merged categories that reflected the same content. We also specified category names based on the content included in a certain category. Finally, we separated the single categories into multiple categories when a category contained different types of information. Answers to the open questions of the web-based questionnaire were coded using the same codes as the interview data.

Merging Quantitative and Qualitative Data From Web-Based Questionnaires and Interviews

For all instances in which data from interviews were merged with data from the web-based questionnaires, data from the interviews were used to further elaborate on the often short answers that were given in the web-based questionnaire.

For aim 1 of this study about the working elements of Vil Du?!, data from the open question about the working elements of the web-based survey were merged with the data from the interviews. More specifically, the percentage of questionnaires that mentioned a certain working element for a client was combined with the percentage of therapists who mentioned the same working element in the interview.

For aim 2 of the study regarding therapists' evaluations of Vil Du?!, the interviews were used to determine the benefits according to the therapists. In addition, for the limitations, the percentage of questionnaires that mentioned a certain limitation was combined with the percentage of therapists who mentioned the same limitation in the interview. Finally, for client acceptability, quantitative client satisfaction data from the web survey were combined with the percentage of therapists that described in the interviews the expression of certain emotions or levels of tension in their clients.

Results

Working Elements of Vil Du?!

Table 2 lists the working elements of Vil Du?! that could be identified in the questionnaires and interviews with therapists. In 30% (7/23) of the questionnaires and in 90% (9/10) of the interviews, therapists recounted experiences in which the child was in control in the game. Sometimes, control was inherent to the game. For instance, clients had control over the use of the Time-Out button. They also had control over what to show and what not to show to the therapist. Finally, they had control over the interpretation of the icons (eg, by moving the hand icon over the back of the character, they could indicate a pat on the pack, stroking the back, or a slap on the back). At other times, the therapist created the control in the game environment. For instance, some therapists invited their clients to choose characters or start up the game. Other therapists gave clients

control over the choice to use the game or just talk about CSA experiences.

Most therapists (in 8/23, 35% of the questionnaires and 8/10, 80% of the interviews) further recounted that the game reduced barriers to disclosing CSA experiences for their clients. For example, one therapist mentioned, "I noticed that the tablet helped her to disclose and also a bit to break the ice." Related to lowering barriers to disclosure, most therapists (in 8/23, 35% of the questionnaires and 9/10, 90% of the interviews) explicitly mentioned that the game could function as a *third party in the room* by creating emotional and physical distance between the

therapist, the client, and the client's CSA experiences. According to a therapist, a client described the emotional distance as follows:

It is very strange, it [the character] is not me, but yet it is me, and I never thought I could tell this much about it.

Regarding the physical distance, a therapist reported as follows:

It is not face-to-face, it is not direct, you talk in a triangle. You talk about something [the tablet] that is on the table and about that what has happened, which creates distance.

Table 2. Questionnaire and interview data about the working elements of Vil Du?!

Working elements	Questionnaires (n=23), n (%)	Interviews (n=10), n (%)
Puts child in control	7 (30)	9 (90)
Reduces barriers to disclosure	8 (35)	8 (80)
By creating a third party in the room	8 (35)	9 (90)
Because there is no need to talk	8 (35)	7 (70)
Congruence with children's digital experience	a	7 (70)
Playful environment	_	6 (60)
Safe and nonnormative environment	2 (9)	3 (30)
Interactive	—	1 (10)

^aNot available.

Another working element related to reducing barriers to disclosure was that clients do not need to talk when using the game, which was brought up by therapists in 70% (7/10) of the interviews and in 35% (8/23) of the questionnaires. As one therapist recounted, "Some children find it really difficult to find the words and then it [Vil Du?!] is a very nice tool to use." Another therapist explained, "Show me' might be easier than 'tell me'."

In 70% (7/10) of the interviews, therapists also described that the game was congruent with children's experience in the digital world. For instance, one therapist mentioned: "They think the app is interesting. It is, of course, very much targeting their digital experience."

The playful environment of the game was mentioned by therapists in 60% (6/10) of the interviews as a working element. For example, one therapist explained, "What I really like about the game is that in a playful manner you can make very difficult or shameful experiences discussable."

In 30% (3/10) of the interviews and 9% (2/23) of the questionnaires, therapists brought up the safe and nonnormative environment of the game. As an example, one therapist explained:

In that sense I really liked it and especially that it was very safe for him to tell his story [...], but also without judgement. That screen does not judge.

Finally, in 10% (1/10) of the interviews, the interactive nature of the game was mentioned as a working element. More specifically, the two characters in Vil Du?! can interact with

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each other, and both the therapist and the client have the possibility to perform actions on the characters and respond to these actions.

Therapists' Evaluation of Vil Du?!

Therapist Acceptability: Benefits and Limitations

In terms of benefits, time efficiency was mentioned most by therapists in the interviews (8/10, 80%). As an example, one therapist explained: "The benefit is in the rapidness. You are there faster, the thing you want to talk about." Interestingly, one therapist reported the rapidness of the game as a possible disadvantage, at least if you were not prepared:

If I use it I need to be very alert, very alert. Watch the non-verbal communication [...]. You need to sort of pull out all the stops and 'am I not missing something?'[...] But it is, it is not a slow thing. It is very fast. So, if somebody who is going to work with it, who has not used it before, I think 'pay attention'!

Further, in 50% (5/10) of the interviews, therapists mentioned the benefit that by using Vil Du?! you could obtain more information and details about the client's CSA experience than without the game. Benefits that were only mentioned in 10% (1/10) to 20% (2/10) of the interviews were as follows: better attention of the client during disclosure of CSA experiences, the possibility to stop the game immediately with the Time-Out button when necessary, the fact that the game is highly structured, the user-friendliness and accessibility of Vil Du?!, and that Vil Du?! is useful for many treatment components. However, of 10 therapists, 1 (10%) thought it was difficult to

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envision how the game could be used for other treatment components than creating a narrative of the clients' sexual abuse experiences.

The most mentioned limitation by therapists in 90% (9/10) of interviews and 57% (13/23) of questionnaires was that the game lacks complexity in surroundings and in the characters' movement, dimensionality, emotion expression, and appearance. For example, one therapist explained that the game lacked complexity in:

the surroundings. For instance, then we went outside, then inside, then to school [...]. So, that it can become more of a story instead of one incident. That fits with our clients, that is, rarely one incident or one place.

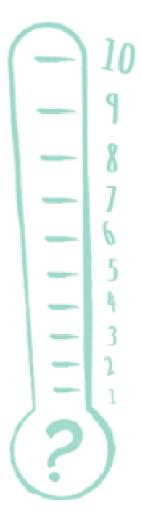
Regarding the characters, one therapist reported as follows:

It would be nice if the characters could move a bit more. At least standing, sitting, and lying down. I noticed with the girl I used it for the first time, the girl with intellectual difficulties, that it was very difficult for her, because it always happened on his bed and he was lying down. So, it was very difficult for her to show what happened.

Figure 4. The feeling thermometer in Vil Du?!

Other limitations were only brought up by a few therapists in the interviews and questionnaires. For instance, that it was difficult to visualize masturbation, penetration, or an erection, which was mentioned in 22% (5/23) of the questionnaires and 30% (3/10) of the interviews. In addition, the feeling thermometer (currently a static picture; Figure 4) cannot be manipulated by the client to indicate their levels of distress during the use of Vil Du?! (3/23, 13% of questionnaires and 3/10, 30% of interviews). Two therapists further mentioned in the interviews that the game could be boring or childish for older clients.

Finally, some limitations were recounted by single therapists only in either the questionnaire or the interview; therefore, these limitations might be subjective. For example, the game included limited content for psychoeducation or normalizing sexual behavior (mentioned in the questionnaire). Another therapist mentioned technical problems with the game during the interview. An additional limitation was that it was not possible to change the explicitness of the icons (interviews). Relatedly, the vagina icon might not be clear enough for young children (interviews). Finally, one therapist mentioned that the game is difficult to use for older therapists (interviews).



Client Acceptability: Emotion Expression, Level of Tension, and Dissociation According to Therapists

Questionnaire data showed that all aspects of client satisfaction (according to therapists) yielded mean scores above the neutral midpoint of the scale. The highest scores were given for the usefulness of Vil Du?! for the client's therapy progress. Therapists thought the use of Vil Du?! was between somewhat and highly useful for their clients (mean 4.13, SD 1.14). Therapists also thought the use of Vil Du?! was, as far as possible in the context of CSA, somewhat of a pleasant experience for their clients (mean 3.57, SD 1.47) as well as a bit enjoyable (mean 3.30, SD 1.40).

Similarly, during the interviews, most therapists (9/10, 90%) recounted their clients' positive emotions when using Vil Du?! or shortly after using Vil Du?! Examples of such positive emotions are fun, joy, happiness, and pride. In 50% (5/10) of the interviews, therapists also described clients who expressed negative emotions, such as fright, irritation, clenching, and anger. Finally, one therapist described 2 clients who were rather neutral in terms of their emotional expression.

With regard to clients' level of tension, in 70% (7/10) of the interviews, therapists described clients experienced lower or shorter bouts of tension when using Vil Du?! than by simply talking about their experiences. In 40% (4/10) of the interviews, therapists mentioned clients who experienced high levels of tension or signs of dissociation, but they did not link these experiences specifically to the use of Vil Du?! One therapist described the possibility that Vil Du?! elicits higher levels of tension because of its explicit nature, but the presence of the Time-Out button makes tension manageable.

Discussion

Principal Findings

The goal of this study is 2-fold. The first aim is to identify the working elements in how Vil Du?! was used by therapists. By combining data from questionnaires and semistructured interviews, we found that therapists identified several working elements of Vil Du?! More specifically, the therapists mentioned that Vil Du?! puts the child in control. They also described that the game reduces barriers to disclosure as there is no need to talk and no need for eye contact with the therapist. Furthermore, they thought that the game was congruent with the children's digital experience. In addition, they mentioned that the game presents a playful as well as a safe and nonnormative environment. Finally, they mentioned the interactivity of the game as a working mechanism.

The second aim is to investigate how therapists evaluated the use of Vil Du?! in psychotherapy for CSA. With regard to this aim, Vil Du?! was generally evaluated more positively than negatively by therapists, indicating the acceptability of the tool by therapists. Therapists mentioned benefits such as time efficiency and the ability to obtain more information and details about clients' CSA experiences. Limitations were more technical in nature, such as the lack of complexity of surroundings and characters in the game environment, certain sexual behaviors that could not be visualized properly, and a feeling thermometer

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XSL•FC RenderX that could not be manipulated. With regard to client acceptability, according to therapists, most clients experienced less tension and more positive (or neutral) emotions than negative emotions when using Vil Du?! to discuss CSA experiences.

Working Elements of Vil Du?!

A working element of Vil Du?! that most therapists identified was that the game reduced the barriers to disclosure. This is not surprising considering that many individuals having experienced CSA are faced with barriers to disclosure, such as lack of verbal abilities, shame, guilt, avoidance, and tension. Talking about CSA experiences is known to be difficult for these reasons (among others) [3]. Several other working elements of the game could explain why and how the game reduces which specific barriers. For example, the element that it is not necessary to talk about CSA experiences might specifically reduce the barrier with regard to lack of verbal abilities or vocabulary. Furthermore, the game does not require eye contact between therapist and client and, as such, functions as a third party in the room [20], allowing children to express their feelings through an indirect medium [26]. Eye contact might be particularly intolerable for clients who experience guilt, shame, and avoidance [40]; thus, with Vil Du?!, sharing their shameful experiences could be more tolerable. Moreover, Vil Du?! presents children with a safe and nonnormative environment that does not dictate right or wrong, which may reduce feelings of self-blame and shame [1,27]. In addition, the game presents the client with a playful environment, and play is known to reduce tension and stress [9].

The play element of the Vil Du?! app might have an effect on several components of the therapy. For example, individuals with CSA experience often have incorrect or maladaptive thoughts related to abuse experiences (eg, "I could have prevented the abuse") that need to be restructured in therapy. The type of nondirective play that is possible in Vil Du?! itself might be considered a restructuring process [26]. Playing out one's experience through Vil Du?! might also help to make thoughts related to one's CSA experiences explicit [21,22]. These explicit thoughts can be processed or restructured in successive therapy sessions. In addition, play that realistically depicts children's traumatic experiences, which might be possible with the explicit icons and the characters in Vil Du?!, can be used to achieve gradual exposure of clients to traumatic memories that might otherwise be avoided or suppressed [23]. Finally, playing out one's experiences through Vil Du?! might be the first step toward creating a narrative of one's CSA experience [28]. Creating such a narrative is most often done by drawing or writing and is experienced by children as the most helpful part of therapy [28,29].

Therapists also identified other working elements not directly linked to the barriers to disclosure. The first was that the child was in control in the game. Therapists acknowledged the importance of children regaining control over their CSA experiences. Giving children control in therapy sessions is an important factor for achieving progress in therapy [25] and helps children regain a sense of control over their lives [24]. Giving children control through Vil Du?! could be accomplished by

aspects inherent to the game, such as the client's use of the Time-Out button or control over what to show to the therapist. Therapists also actively invited clients to take control in operating the game. Giving the clients control in operating the game fits with children's experience and frequent involvement with apps and video games [41].

Congruence of Vil Du?! with children's digital experience was another working element that was mentioned by the therapists. Vil Du?! was played on the 2 tablets. Especially for young children, the touchscreen technology of tablets offers a mode of interactive experience that is congruent with children's natural ways of learning and exploring (ie, touch, repeat, trial, and error) [42]. In addition, for adolescents, the use of hand-held devices, such as tablets, mirrors the way they are used to communicating with their peers through social media [43].

Finally, one therapist mentioned the interactive nature of the game as a working element. Vil Du?! enables interactivity between the therapist and the client. Both therapist and client *play* the game on their own tablet. The tablets are synchronized to each other, so actions performed on one screen are also visible on the other. More specifically, both the therapist and client can represent a character in Vil Du?! and each character can perform actions on the other character. Researchers have suggested that interactivity in games "can bring a reciprocal effect to other participants of the communication process by turn-taking, feedback, and choice behavior" [44]. Instant reactions from another player might create quick feedback loops to provoke deeper thinking and learning, as well as making sense of previous experiences [45].

Acceptability of Vil Du?! by Therapists and Clients

In terms of the evaluation of Vil Du?! by therapists, findings show that the game might be acceptable for therapists as well as clients. For therapists, the game increased the efficiency of the therapy process and simultaneously led to the discovery of more details and information about the clients' CSA experiences. The time efficiency of the use of serious games in psychotherapy for children has also been suggested by other scholars [46,47]. Time efficiency of Vil Du?! could be because of the visual nature (ie, showing is faster than telling) or because of the safe environment Vil Du?! created by allowing children to express their feelings through an indirect medium [26]. The large amount of details and information gathered with Vil Du?! is similar to research showing that children provided more detail about emotionally laden events when they could draw or re-enact the event compared with when they were simply asked to tell [48]. An explanation could be that the icons in Vil Du?! may have provided the client with additional and effective retrieval cues for their CSA-related memories. According to therapists, the most important benefit for clients of discussing CSA experiences with Vil Du?! is a possible reduction in negative emotions and tension compared with just talking about one's experiences. Less negative experiences during the treatment process are associated with more favorable treatment outcomes and better treatment adherence [35,36].

These benefits seem to outweigh the limitations of the game mentioned with regard to the lack of complexity of characters, surroundings, and icons. These limitations were mainly technical in nature and could be incorporated into an updated version of the game. Other limitations might be specific to certain therapists or clients. For example, as mentioned by one older therapist, the game might be difficult to use mainly for older therapists, because another younger therapist recounted the user-friendliness of the game, particularly as a benefit. For older therapists or less technically skilled therapists, a user manual for Vil Du?! is particularly pertinent and could increase usability.

Limitations of the Study and Directions for Future Research

An important limitation of this study was that we focused mainly on the therapists' perspective on the use of Vil Du?!, even though we also asked therapists about their clients' experiences. However, clients themselves might evaluate the use of the game in therapy differently. At the start of the study, we aimed to include the clients' perspective more by videotaping and coding therapy sessions in which Vil Du?! was used. Even though this part of the study was ethically approved, we were unable to obtain consent from enough clients and their parents to include this method in our study. Future research could include clients' perspectives by asking clients to fill out short, age-appropriate evaluation questionnaires following the use of a serious game in psychotherapy.

A second limitation relates to the questionnaire we used to assess client acceptability, which was composed of only 3 items. Although these items have been used in previous research [20], 3 items may have been limited in their ability to fully assess client acceptability. Future evaluations of Vil Du?! could use more extensive measures of client acceptability, such as the Child Evaluation Inventory [49].

A third limitation is that we were not able to include therapists that represented a wide range in terms of the therapy type they used and the organization they worked for. The majority of participating therapists were working for the same organization and, thus, with the same treatment protocols. This may have limited the ways in which therapists used the Vil Du?! app and subsequently, the possible working elements that were identified.

It is important to note that there were some differences in the working elements and limitations identified in the questionnaire data and the interview data. Overall, the percentages of working elements and limitations mentioned by therapists were lower in the questionnaires than in the interviews. These differences could be because of the different formats of the 2 methods. In the semistructured interviews, therapists could freely and extensively discuss their experiences with using Vil Du?! In the web-based questionnaire, therapists had to write down their experiences and, consequently, their answers were generally short. However, the relative importance of specific working elements and limitations were very similar across methods. The working elements and limitations that were most often mentioned in the questionnaires were also the ones most often mentioned in the interviews.

Finally, we identified several working elements of how Vil Du?! was used by therapists. However, we could only speculate about

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the reasons for the effectiveness of these elements in the treatment of CSA victims. Future experimental or longitudinal research should examine the effectiveness of incorporating Vil Du?! in CSA treatment. These studies could also examine the specific working elements underlying the effects Vil Du?! may have on the therapy process and client outcomes. However, to take this next step in evaluating the effects of Vil Du?!, the findings of this study will be incorporated into a user manual for Vil Du?! With this manual, therapists can use the game in a more systematic way (access to the manual and Vil Du?! can be arranged through the authors).

Conclusions

This exploratory evaluation of Vil Du?! provided promising results for the incorporation of serious games in therapy sessions with children and adolescents. The case study on Vil Du?! clarifies how a game specifically designed to help children open up about CSA experiences might improve psychotherapy for child and adolescent CSA victims. Using Vil Du?! appears to be time efficient, and the game appears to make the treatment process less confronting and difficult for the client. In this study, several working elements of Vil Du?! were identified, which could explain possible improvements in the therapeutic process. First, Vil Du?! enables clients to regain control over their CSA experiences. Second, the game offers a nonverbal communication tool that empowers clients with additional vocabulary (eg, interactions on the screen). Disclosure of clients' experiences is furthermore enabled by creating a safe environment in which the client can work on their own tablet and does not need to make eye contact with the therapist. The increased amount of vocabulary, control, and safety might result in a significant time reduction in psychotherapy. This benefits both the client and health care system in general. Rigorous experimental effect studies are now necessary to test whether implementing the serious game Vil Du?! in therapy is effective in reducing barriers to disclosing CSA experiences and in regaining control over these experiences.

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Authors' Contributions

JJE, M Deen, and M Dekovic conceptualized the study. HT conducted the interviews. JJE and HT analyzed and interpreted the data. JJE drafted the manuscript. HT, M Deen, and M Dekovic critically revised the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

M Deen is the designer of Vil Du?! The other authors declare no conflicts of interest.

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Abbreviations

CSA: child sexual abuse

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The Effects of Exergaming on Sensory Reweighting and Mediolateral Stability of Women Aged Over 60: Usability Study

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Abstract

Background: Older adults tend to experience difficulties in switching quickly between various reliable sensory inputs, which ultimately may contribute to an increased risk of falls and injuries. Sideward falls are the most frequent cause of hip fractures among older adults. Recently, exergame programs have been confirmed as beneficial tools for enhancing postural control, which can reduce the risk of falls. However, studies to explore more precisely which mechanism of exergaming directly influences older women's ability to balance are still needed.

Objective: Our aim was to evaluate, in a single-group pretest/posttest/follow-up usability study, whether Kinect exergame balance training might have a beneficial impact on the sensory reweighting in women aged over 60.

Methods: A total of 14 healthy women (mean age 69.57 [SD 4.66] years, mean body mass index 26.21 [SD 2.6] kg/m²) participated in the study. The volunteers trained with the commercially available games of Kinect for Xbox 360 console 3 times (30 minutes/session) a week over a 6-week period (total of 18 visits). Participants' postural sway in both the anteroposterior (AP) and mediolateral (ML) directions was recorded with NeuroCom Balance Master 6.0. To assess and measure postural sensory reweighting, the Modified Clinical Test of Sensory Interaction in Balance was used, where volunteers were exposed to various changes in visual (eyes open or eyes closed) and surface conditions (firm or foam surface).

Results: In the ML direction, the Kinect exergame training caused a significant decrease in the sway path on the firm surface with the eyes open (P<.001) and eyes closed (P=.001), and on the foam surface with the eyes open (P=.001) and eyes closed (P<.001) conditions compared with baseline data. The follow-up measurements when compared with the baseline data showed a significant change in the sway path on the firm surface with the eyes open (P<.001) and eyes closed (P<.001) conditions, as well as on the foam surface with the eyes open (P=.003) and eyes closed (P<.001) conditions. Besides, on the firm surface, there were no significant differences in sway path values in the AP direction between the baseline and the posttraining measurements (eyes open: P=.49; eyes closed: P=.18). Likewise, on the foam surface, there were no significant differences in sway path values in the AP direction under both eyes open (P=.24) and eyes closed (P=.84) conditions.

Conclusions: The improved posturography measurements of the sway path in the ML direction might suggest that the Kinect exergame balance training may have effects on sensory reweighting, and thus on the balance of women aged over 60. Based on these results, Kinect exergaming may provide a safe and potentially useful tool for improving postural stability in the crucial ML direction, and thus it may help reduce the risk of falling.

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KEYWORDS

exergaming; sensory reweighting; older women; mediolateral sway; vestibular

Introduction

Slipping, tumbling, or any other kind of an unintentional loss of balance, which results in a fall and subsequent hospitalization due to injury, is a serious global concern for people over the age of 60 according to the World Health Organization [1].

It has been shown that age-related deficits can manifest in cognitive function [2], in neuromuscular control mechanisms [3,4], and in the following 3 sensory systems: the visual [5], the somatosensory [6], and the vestibular [7]. Various studies have shown that older individuals have a tendency to use proprioception rather than visual and vestibular cues for postural motor control. This dependence on the proprioceptive system also increases with age [3,8]. In direct contrast to this, Haibach et al [9] found that older adults tend to rely more heavily upon their visual input rather than the other sensory systems to compensate for age-related deficiencies.

According to previous studies [10,11], adults tend to experience difficulties in switching quickly between various reliable sensory inputs, which ultimately may contribute to an increased risk of falls. However, Allison et al [12] suggest that this particular process is not impaired among the target population as a direct result of aging. Regardless of whether sensory reweighting deteriorates or remains unchanged with age, therapists should aim to plan programs that can develop these previously mentioned sensory systems and thus decrease the risk of falls.

It has been confirmed that community-dwelling women over the age of 65 are at least two times as likely to suffer hip fractures due to a fall when compared with men [13]. In one study [14], osteoporosis-related fractures in Hungary were investigated and offered incidence data not only on hip, but also on several fractures between 1999 and 2003, when the total population was approximately 10 million inhabitants. According to the data reported in this 5-year period, 404,380 Hungarian women and 206,009 men over the age of 50 had at least one fracture. A possible reason behind this phenomenon might be attributed to the difference between each gender's change in the level of sex hormones during various stages in life. The changes may contribute to older women having a more significant decrease in bone mineral density [15]. Besides age-related hormonal changes, multitasking increases women's gait variability, and this has a direct relationship to the prevalence of falls [16]. Furthermore, elderly women with an abnormal balance while walking are more likely to fall [17]. According to the findings of Qazi et al [18], a static posturography test demonstrated that the mediolateral (ML) component of postural sway is most strongly associated with long-term fracture risk in postmenopausal women. In addition to that, sideward falls are the most frequent cause of hip fractures among older adults [19], meaning that it is of key importance to detect with posturography the quantifiable information on body sway that cannot be visible to the

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clinicians' naked eyes [20]. Signs of instability are sometimes not immediately apparent in the clinical setting, but sensitive measurements, such as postural sway, can predict the likelihood

of falls [18]. For this reason, it is essential to implement training programs that improve sensorimotor control in the critical ML direction.

Recently, exercise games that are played in a virtual, but realistic environment (exergames) have become popular in various fields of research. The use of different types of virtual reality (VR) systems has been considered a beneficial method to improve health gains in different populations and pathological conditions [21]. According to current systematic reviews, video game-based trainings help support physical health [22-25] and cognitive functions among older adults [26-28]. In the last decade nonimmersive VR (without the use of a head-mounted device) exergame trainings with the Kinect system have been proven to be favorable in improving postural control among older adults [29-33]. A recent study revealed significant effects on balance in older adults who had VR exercise training versus an inactive control group [34], as well as a conventional exercise training group [35]. However, the exact mechanism of action of exergaming in improving the balance ability of older adults is a complex process that remains unclear [26]. Thus, in order to provide sound recommendations for their clinical use, the authors suggested conducting further studies to explore more precisely which mechanism of exergaming directly influences an older individual's ability to balance (in other words, what are the causes of the observed changes or what are the improvements from exergame interventions).

It has been suggested that one of the underlying effects of exergames might originate from sensory reweighting. Body sway–based assessments such as the Sensory Organization Test or the Modified Clinical Test of Sensory Interaction in Balance (m-CTSIB) are sensitive tools for measuring sensory feedback reactions and processes during static stance. These measurements can confirm changes in sensory reweighting following exergaming in patients with Parkinson disease [36], in healthy and young adults [37,38], in older adults [39], in healthy women [40], and in women with fibromyalgia [41].

In the past 3 years, the effect of exergaming on sensory reweighting among older women has received little attention despite its clinical importance for physiotherapists. Because of the limited number of studies available on this topic, this usability study is focused on examining the potential effects of a Kinect exergame training on sensory reweighting and balance in the ML direction in healthy older women.

Methods

Participants

For the purpose of this study, healthy, community-dwelling older women above the age of 60 were recruited via local announcements in the senior centers within the city of Szeged,

Hungary. Exclusion criteria included self-reported comorbidities (such as cognitive impairment; disorders of the heart; circulatory, musculoskeletal, and respiratory ailments; autoimmune diseases; and neurological conditions), hearing or vision loss, prosthetics or artificial limbs, wounds or corns on lower extremities, and the use of medication that could affect balance or participation in other organized physical training exercise programs. Twenty active, community-based volunteers signed up for the training program; however, due to the exclusion criteria, only 14 of them could participate in the study. This study was performed according to the Declaration of Helsinki and was approved by the Ethics Committee of the University of Szeged, Hungary (registration No. 125/2015 SZTE). All participants gave their signed informed consent before participating in the training program.

Training Protocol

The applied equipment consists of a motion-sensing RGB camera named Kinect (v1), an Xbox 360 console, and video games developed by Microsoft. During the training, pictures of the game's scene and a player's avatar were projected onto the wall via the camera's full-body 3D motion capture.

Before the training program commenced, volunteers had not had any experience with exergames or any of the previously mentioned devices, and so it was important to have an introductory meeting prior to the first training session where instructions were given on how to play the gesture-controlled video games and an opportunity to experience them first-hand. The training took place at Albert Szent-Györgyi Clinical Center's Physiotherapy Department 3 times a week over a 6-week period (total of 18 visits). These sessions were assisted by physiotherapists. Participants were instructed to wear a comfortable outfit and safe footwear for the 30-minute training. Games were chosen based on the type of movements their performance required, with the main aspect being that games had to contain patterns of everyday functional movements which modeled usual, frequent natural motions. Commercially available Kinect games were played by the participants which demanded continual displacement of the participants' center of gravity (COG), transference of weight between lower limbs, and lateral trunk bending and frequent sidesteps. The motor stimulation during gameplay required balanced reactions and continuous postural adjustments associated with fast movement of the legs and arms. During the first half of the training sessions, games that consisted of more foreseeable movements and simple elements (eg, football, skiing) were played. Other more complex games that needed higher cognitive attention and fast reaction (20.000 Leaks, Space Pop, Reflex Ridge, River Rush) were selected to be played in the second half of the training sessions. All participants played the same type of games in pairs, in the same order on every training occasion, but were never allowed to play the same game on 2 consecutive training sessions. During the training, the players' adaptation and progression, as well as the level of difficulty of the game, were continuously recorded and modified based on each participant's overall ranking in the game. Between each game, there was approximately a 1-minute transition time so that players could take a short break.

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Measurement

In general, in order to assess an individual's ability to both integrate various senses of balance and compensation, while 1 or more of these senses may be lacking [33], NeuroCom Balance Master 6.0 (Clackamas) and the m-CTSIB [42-44] were used. The posturography measurements were performed at 3 separate intervals: before the first training, after the completion of the training program (posttraining), and 6 weeks after the last training session (follow-up).

The Balance Master 6.0's software provided the location of both the COG and center of pressure across all tests for the m-CTSIB. The m-CTSIB test was initially developed by Shumway-Cook and Horak [45] to differentiate sensory (somatosensory, visual, and vestibular) inputs involved in postural stability during a steady-state balance assessment, and it explored balance on various surface types, with and without vision, using 4 sensory conditions: (1) firm surface, eyes open; (2) firm surface, eyes closed; (3) foam surface, eyes open; and (4) foam surface, eyes closed. The results provided by the Balance Master 6.0's software package gave 3 measurements of COG $(3 \times 10 \text{ s})$ in the anteroposterior (AP) and ML directions [35]. Based on a previous study [43] with elderly females in all 4 sensory conditions, this test had good to excellent reliability of ML (intraclass correlation coefficient 0.88-0.93) and AP path length (intraclass correlation coefficient 0.85-0.90).

For the assessment of balance on the foam surface, a NeuroCom square foam balance assessment pad (size $46 \times 46 \times 13$ cm) was used. During the assessments, the base of support was fixed, and participants stood comfortably barefooted with arms to their side and their feet next to a mark on the platform. The measurements took place in a quiet room away from distractions.

Data Analysis: Sway Path

The following equations were applied to calculate the sway paths in the ML and AP directions

×
×

where *n* is the total number of samples; *i* is the sample number; s_x is the path length of ML ways; and s_y is the path length of the AP displacements of COG.

The following statistical analysis was conducted using Statistica 13 software (StatSoft). All sets of data were checked for normal distribution using the Kolmogorov–Smirnov test. Factorial analysis of variance was used to analyze sway data of the m-CTSIB test on firm and unstable (foam) surfaces to evaluate the main effects and the influences of the 2 visual conditions (eyes open and eyes closed) at all 3 time conditions (baseline, after the training, follow-up) as within-subjects factors. All values are given as mean (SD). The post hoc test was the Newman–Keuls test. A level of significance of P<.05 was applied.

Results

Overall, 14 female volunteers (mean age 69.57 [SD 4.66] years, mean body mass index 26.21 [SD 2.6] kg/m²) participated in the study without any dropouts.

Changes in Sway Path During Quiet Stance in the ML Direction

In the ML direction, the Kinect exergame training caused a significant decrease in the sway path on the firm surface with eyes open (P<.001) and eyes closed (P=.001), and on the foam surface with eyes open (P=.001) and eyes closed (P<.001) conditions compared with the baseline data. The follow-up

measurements when compared with the baseline data also showed significant change in the sway path on the firm surface with eyes open (P<.001) and eyes closed (P<.001), and on the foam surface with eyes open (P=.003) and eyes closed (P<.001; Figures 1 and 2). There were no significant differences in sway path values on the firm surface between eyes open and eyes closed conditions during the baseline (P=.81), after the training (P=.30), and follow-up (P=.48) evaluations. However, on the foam surface, results showed a significant interaction of vision × time for the sway path ($F_{2,246}$ =3.70, P=.02). Before the training, the sway path on the foam (unstable) surface with eyes closed was significantly longer (P<.001), whereas after the training the absence of visual information did not result in a significant increase (P=.16) of the sway path (Figure 2).

Figure 1. The effect of the Kinect training on sway path (mean [SD]) in the ML direction when standing on the firm surface with open and closed eyes. Statistically significant differences in sway path with eyes open (P<.001) and eyes closed (P=.001) posttraining conditions compared with the baseline data (asterisk). The follow-up measurements when compared with the baseline data showed statistically significant change in sway path on the firm surface with eyes open (P<.001) and eyes closed (P<.001) (asterisk). ML: mediolateral.

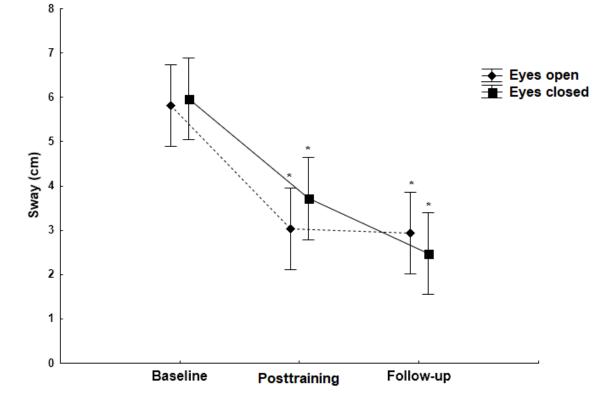
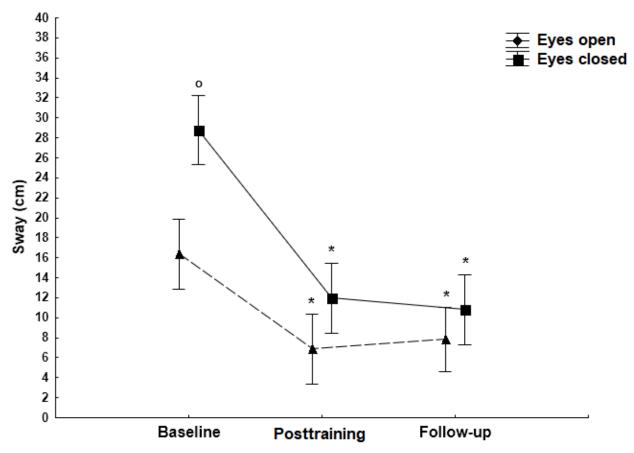




Figure 2. The effect of the Kinect training on sway path (mean [SD]) in the ML direction when standing on the foam surface with open and closed eyes. Statistically significant differences in sway path with eyes open (P=.001) and eyes closed (P<.001) posttraining conditions compared with the baseline data. The follow-up measurements when compared with the baseline data showed statistically significant changes in sway path with eyes open (P=.003) and eyes closed (P<.001) (asterisk). Statistically significant difference in sway path during baseline measurements with eyes closed (P<.001) compared with the eyes open condition (circle). ML: mediolateral.



Changes in Sway Path During Quiet Stance In the AP Direction

On the firm surface, there were no significant differences in sway path values in the AP direction between the baseline and the posttraining measurements (Figure 3; eyes open: P=.49; eyes closed: P=.18). Likewise, on the foam surface, there were no significant differences in sway path values in the AP direction

under both eyes open (P=.24) and eyes closed (P=.84) conditions. During follow-up measurements, a main effect of vision was noted; in other words, closing the eyes resulted in a significant increase of the sway path (P<.001; Figure 3). On the unstable foam surface, a main effect of vision was observed and the absence of visual information significantly increased (P<.001) the sway path length in all time conditions (Figure 4).



Figure 3. The effect of the Kinect training on sway path (mean [SD]) in the AP direction when standing on the firm surface with open and closed eyes. No statistically significant differences in sway path values on the firm surface between the baseline and posttraining measurements (eyes open [P=.49] and eyes closed [P=.18]). Statistically significant differences (P<.001) in comparison with the baseline measurement (asterisk) and in comparison with the open eye condition (circle) (P<.001). AP: anteroposterior.

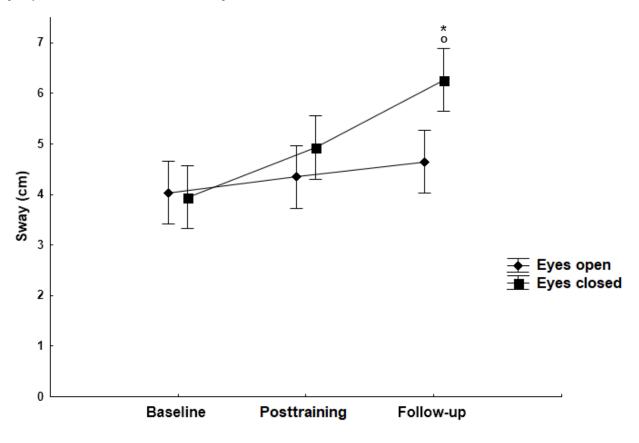
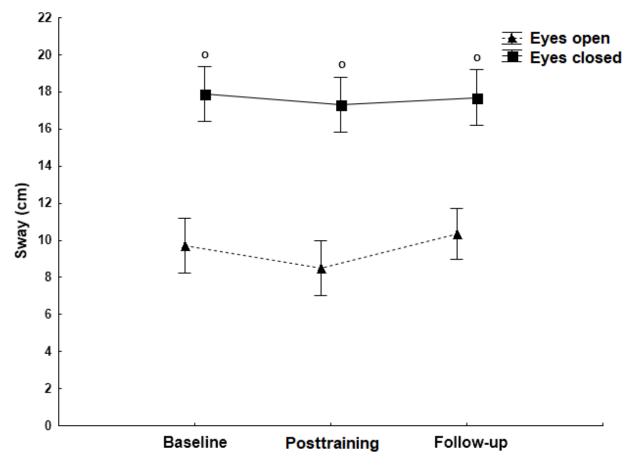




Figure 4. The effect of the Kinect training on sway path (mean [SD]) in the AP direction when standing on the foam surface with open and closed eyes. Statistically significant differences (*P*<.001) in comparison with the open eye condition (circle). AP: anteroposterior.



Discussion

Principal Findings

Several studies have previously confirmed the beneficial effects of exergames on postural control among older adults [22,23,26,29,31-35]. This usability study shows that a simple Kinect game–based balance training might be beneficial for older women by improving balance in the ML direction. This study also demonstrates that exergaming might have a favorable effect in regards to the specific process of adjusting the sensory contributions to balance control [46], namely, sensory reweighting.

Increased Lateral Stability

Based on our study results, an important finding is that the sway path in the ML direction on firm and foam surfaces, with eyes open and closed, improved statistically significantly, whereas no significant change was detected in the AP direction. However, decreased sway path indicates improved stability in the ML direction, which was concluded by Qazi et al [18] as the strongest component of postural sway predicting fractures in postmenopausal women. According to previous studies in the elderly population [47-49], ML sway can often be associated with risk of falls due to decreased proprioception and lower extremity muscle weakness in the lateral direction [50]. In light of the present findings following the training, improved sway

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results in the ML direction were observed when participants were standing on the foam surface with their eyes open. Significant decrease of ML sway might also implicate an improvement in proprioceptive function following the Kinect training. This finding is similar to the results of Sadeghi et al [51], which suggest that Kinect exergaming can improve proprioception by providing visual feedback and challenging motor skills and visual coordination.

Improvement in Sensory Reweighting

An important finding of this paper is that the Kinect exergame training program significantly reduced postural sway on the foam surface with the eyes closed. Under this condition of the m-CTSIB, the central nervous system mostly relies on vestibular information [45]. In the review by Tahmosybayat et al [52] no exergame study has been presented that would train and assess sensory integration and sensory reweighting. Moreover, the authors suggested that the elements of sensory integration are too unsafe to be trained by disturbed sensory inputs during exergames. However, Roopchand-Martin et al [39] have examined the changes in m-CTSIB results following the Nintendo Wii Fit balance training in community-dwelling adults aged over 60. They found no significant results on the foam surface with the eyes closed condition after the training. By contrast, a Kinect-based physical exercise balance intervention in women with fibromyalgia has revealed significant improvements in the m-CTSIB with eyes closed on foam

surfaces [41]. Another study [40] that examined the Wii Fit balance training for healthy women also found similar results: significant sensorimotor improvement in unilateral stance and limb strength. Nitz et al [41] concluded that these findings might not be surprising because the activities included in the Wii Fit training (such as yoga, balance, aerobic, and strength activities) involved considerable single-limb balance requirements and weight-resistance movements. body Although the aforementioned studies [40,41] investigated the effects of exergaming on balance in various sensory conditions with m-CTSIB, sensory reweighting following the trainings has not been proposed in these papers.

In contrast to these results, Yen et al [36] demonstrated that VR balance training significantly improved sensory reweighting in older adults with Parkinson disease when both visual and somatosensory inputs were unreliable. They have suggested that the VR training might be especially beneficial for fall prevention within this high-risk target group, as similar conditions may also occur in reality due to various extrinsic environmental risk factors (inappropriate footwear, poor lighting, slippery surfaces, loose rugs, or uneven steps) [36]. Other studies have found significant improvement in the eyes closed condition on unstable surface following a Wii Fit balance training among young adults [37] and healthy adults [38]. According to these studies [37,38], the reason for the improved vestibular function might be due to the quick displacement of COG in different directions, causing rapid changes in the head position. Similarly, during pretest measurements in this study, closing the eyes on the foam surface resulted in a statistically significant increase in the sway scores in the ML direction; however, posttraining measurements did not show deteriorated sway results. The reason for this might be that after the training, participants shifted to the remaining, accurate source of sensory information, and mainly relied on the vestibular system. Another possible explanation might be that during exergaming, participants had to complete several tasks containing movements such as reaching out and lateral steps while they needed to often change their head position.

Santos et al [53] have suggested that VR therapy enables patients to become immersed in an imaginary world, in which environmental perception is altered by artificial stimuli, thus resulting in a sensory conflict that can act on the vestibulo-ocular reflex (VOR). The central nervous system reacts to vestibular stimulus by reflexes such as the VOR, which stabilizes vision during head motion, and the vestibulospinal reflex, which induces a compensatory body motion to stabilize the head and body, and prevent falls [54]. Thus, types of exergames that require head movements in particular (rotation, lateral flexion, flexion) while players' eyes are focusing (gazing) at one point can function as VOR training. Based on this study's results, the applied Kinect games might improve sensory reweighting in favor of relying on vestibular inputs. In this study, while participants were playing the exergames, they had to keep their eyes on the screen while performing various head and limb movements.

Lessons Learned From Kinect Exergames

Games such as 20, 000 Leaks, River Rush, Reflex Ridge, Super Saver Football mini-game, Space Pop, and Skiing might especially challenge the VOR because they require frequent head displacement movements. Additionally, these games could also improve stability in the lateral direction because of frequent weight shifting and sideward stepping. According to Swanenburg et al [55], exergaming that requires active stepping movements and that involves moving game projection is usable and facilitates gaze stability during head movements, which resulted in improved gait in healthy older adults. As balance is determined by various factors and maintained by complex processes, designing a balance training program requires precisely defining which target components or systems ought to be trained. Health care professionals might use exergames that could display participants' changes of postural sway, reaction time, and limit of stability in various directions. Games which can train VOR by gaze stability during head movements should be provided for continuous monitoring to track players' head movements. As falls occur mostly during activities of everyday life, exergames should be designed to involve functional movements that represent motions from daily life: alternately raising the feet from the ground (eg, stair stepping, stepping out of the bathtub), or reaching movements forward and sideways (eg, taking an item off a shelf below and above shoulder height, cleaning a window, hanging out the washing).

Limitations

This usability study has encountered certain limitations as no sample size calculation was performed, and due to the lack of a control group and the relatively small sample size, the results should be interpreted cautiously. Therefore, these findings are not conclusive. Recruiting volunteers via local paper announcements for exergaming was not sufficient to get the attention we had hoped for. We believe that to attract more participants for future balance training programs, other types of advertisements should be used to generate interest. Posts on social media with video demonstrations and trials could raise interest especially among the youth, who could encourage their older relatives to participate. In this study, only older women participated, but to examine whether there is a gender difference in sensory reweighting following exergaming, future studies should also include a group of male participants. Investigating the effects of exergaming in older individuals with vestibular dysfunctions could also be beneficial, as this population is especially at risk of falling. Although there are studies that have described the positive effects of exergaming on balance ability [56,57] and on higher-order cognitive functions [58] when training independently at home, this study could not have been performed using a home-based exergame program. The reason for that is that the applied commercially available Kinect games are in English and no Hungarian translation is available. Therefore, participants needed assistance with starting and setting up the games, as well as technical help.

Conclusions

In this usability study, women's sway path decreased in the ML direction not only on the firm surface with eyes open, but also on the foam surface with eyes closed as a result of following

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the Kinect exergame training. These findings might support the idea that although the Kinect exergame training did not specifically contain direct challenging sensory tasks (eg, tilting or unstable surface or closed eyes exercises), the reduced sway results suggest that exergames could additionally result in sensory reweighting. The reason for this might be that the games contained tasks that needed constant gaze stabilizing and frequent head displacements. Therefore, this study's improved sway results in the ML direction might contribute to decreased risk of falls among older women.

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Authors' Contributions

SP and AD share senior authorship.

Conflicts of Interest

None declared.

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Abbreviations

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AP: anteroposterior COG: center of gravity m-CTSIB: Modified Clinical Test of Sensory Interaction in Balance ML: mediolateral VOR: vestibulo-ocular reflex

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VR: virtual reality

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Active Video Gaming Using an Adapted Gaming Mat in Youth and Adults With Physical Disabilities: Observational Study

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Abstract

Background: A common leisure-time activity amongst youth and adults in the United States is video gameplay. Playing video games is typically a sedentary endeavor; however, to encourage an increased level of physical activity in an engaging and enjoyable way, active video gaming has become popular. Unfortunately, the accessibility of gaming controllers is often an issue for persons with disabilities. A commercial off-the-shelf (OTS) gaming mat was adapted to facilitate use by individuals with mobility impairments to address this issue.

Objective: Our study aimed to examine energy expenditure, enjoyment, and gameplay experience in youth and adults with mobility impairment during active video gaming using an OTS and adapted versions of a gaming mat.

Methods: The study used an observational design. During visit 1, physical function was assessed, and participants were given a familiarization period with the gaming system. For visit 2, based on observation during the physical function tests and discussion with the participant, it was decided whether the participant would play in a standing or seated position. For standing gameplay, the mat was placed on the floor, and for seated play, the mat was placed on a height-adjustable and tilt-adjustable tabletop. Metabolic data were collected during a 20-minute baseline and four 10-minute bouts of Wii Fit Plus gameplay, with 2 bouts on each of the mats (adapted and OTS). During gameplay, the research staff observed and rated participants' ability to use the game controller (mat) and the quality of gameplay. At the end of each game set, participants reported their rating of perceived exertion on a scale from 0 to 10. During rest, participants completed the physical activity enjoyment scale. Participants also answered additional questions regarding the system's usability with each controller (adapted mat and OTS mat). Statistical analyses were computed using Stata 16 (version 16.1; StataCorp). Linear mixed-effects maximum likelihood regression was performed separately for individuals who could play standing and for those who played seated.

Results: A convenience sample of 78 individuals with mobility impairments between the ages of 12 and 60 years (mean 39.6, SD 15.8) participated in the study. Of the sample, 48 participants played the video games in a seated position, while 30 played the games standing. Energy expenditure and heart rate tended to be higher in the OTS mat condition for seated players, while values were similar for both conditions among standing players. However, seated participants reported greater gameplay experience, and both groups exhibited a higher quality of gameplay during the adapted mat condition.

Conclusions: Active video gaming using an adapted gaming mat provided an enjoyable exercise activity for individuals with mobility impairments. The use of the adapted controller provides a means by which this population can engage in light to moderate intensity active video gaming, thereby reducing sedentary leisure time.

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KEYWORDS

exergaming; video games; disability; exercise; physical activity; enjoyment; dance mat; serious games; gaming mat; mobility impairment; physical impairment

Introduction

A common leisure-time activity amongst youth and adults in the United States is video, with 227 million video gamers across the United States [1]. Recent statistics compiled by the Entertainment Software Association report that 74% of all households have at least one member who plays video games, with 67% of all adults and 76% of youth in the United States engaging in regular video gameplay [1]. Of those playing video games, 80% are adults, with an average age of 31 years. Across all players in the United States, 55% are male, and 45% are female, across a diverse population including those with disabilities [1]. Of note, the video game industry generates over \$90 billion in annual economic output in the United States [2].

Stereotypical video gameplay conjures up images of hours spent fixated on a screen in sedentary repose. However, the scope of video gaming has broadened and been shown to provide a role in physical rehabilitation, a tool for health promotion and behavior change, and a means for improving mental health [3-8]. A specific genre of gameplay that moves beyond the sedentary is known as active video gaming (AVG) or exergaming. Such games require large body movements of the arms or legs as opposed to the simple finger motions for standard controller operation. The goal of AVG is to encourage an increased level of physical activity in an engaging and enjoyable way.

With fewer opportunities for exercise and countless barriers to participation in leisure-time physical activity (LTPA), people with disabilities experience significantly higher levels of sedentary behavior, physical inactivity, and associated health risks [9,10]. Contributing factors include issues with transportation and facility access, costs associated with specialized equipment (eg, sports wheelchair), the absence of staff trained to accommodate special needs, and boredom with the limited options available [11-18]. Replacing sedentary behaviors with AVG play holds promise as a way to reduce those barriers and increase LPTA in people with disabilities [19-23]. Moreover, AVGs have been described as having the potential to be an engaging introduction to physical activity. Such games open the door to interest and participation in other forms of physical activity for persons with disabilities [21].

Of those who play video games in the United States, 73% own a game console [1]. However, accessibility issues with most gaming consoles are a barrier for many with mobility limitations [20,21]. For instance, many hand controllers are difficult for those with upper extremity impairments to hold and manipulate for gameplay. Likewise, individuals who use a wheelchair are unable to play Wii Fit games using the OTS Wii board. Others have worked on gaming interface adaptations to allow people with disabilities to play video games [24-27]; however, limited research and development efforts have focused on improving the accessibility of commercially available gaming controllers for use with AVGs. Our previous work as part of the Rehabilitation Engineering Research Center on Interactive Exercise Technologies and Exercise Physiology for People with Disabilities at the University of Alabama at Birmingham/Lakeshore Foundation Research Collaborative examined the accessibility of commercial off-the-shelf video game controllers, including the Wii Fit balance board system and dance pad gaming mats. Data on gameplay, participants' ability to use the controllers, user feedback, and research staff qualitative observations indicated that both controllers needed adaptation to overcome certain deficiencies for successful gameplay. These data were fed to the engineering team to develop an adapted gaming balance board and an adapted gaming mat. Subsequent research demonstrated that the adapted gaming board could increase accessibility, provide physical activity, and allow enjoyable gameplay action for people with mobility impairments [28-30]. The development of adapted video game controllers offers an innovative approach to overcoming various barriers to exercise in people with disabilities.

The aim of the study was to examine energy expenditure via metabolic equivalents (METs) and enjoyment, as measured by the physical activity enjoyment scale (PACES), in individuals with physical disabilities, specifically those with mobility impairments (ie, unable to stand, balance issues, poor motor control, or unable to use lower extremity for gameplay), during AVG play using an OTS and adapted versions of a gaming mat. Also of interest were differences in heart rate, rating of perceived exertion (RPE), quality of gameplay, and gameplay experience between the two gaming mats.

Methods

Design and Setting

This was an observational study conducted at Lakeshore Foundation, a community fitness center in the southeastern United States that provides specialized physical activity, sport, and recreation opportunities for individuals with physical disabilities and chronic health conditions. The University's Institutional Review Board for Human Use approved all study procedures (IRB-150909002).

Participants

Eligibility criteria included 10 to 60 years of age, a confirmed diagnosis of lower extremity mobility limitation (eg, spina bifida, cerebral palsy, muscular dystrophy, 1 year following a spinal cord injury, multiple sclerosis, stroke, or limb loss) with partial or full use of upper extremities and use of an assistive device (eg, cane, walker, or wheelchair) or problems with gait,

balance, or coordination. In addition, participants were excluded if they had an unstable cardiovascular condition, a visual impairment that interfered with playing video games, or weighed over 350 lbs (159 kg), including their assistive device.

Procedures

All testing for the research study took place in the Exercise and Sport Science Laboratory at Lakeshore Foundation. For this study, participants came to the lab 3 times, generally within a 3-week period. The laboratory housed a station for AVG play equipped with a 58-inch Sony high-definition television, gaming console, and controllers (gaming mats).

Before assessments began, each participant was fitted with a heart rate monitor (S610; Polar). Heart rate (beats per minute) was recorded every 3 to 4 seconds for the duration of gameplay. To assess the participants' physical function, 18 activities from the International Classification of Functioning, Disability and Health (ICF) [31,32] were preselected for use. Participants were asked to perform these activities during the first session. The research staff selected a number (0-4) to reflect the level of difficulty the participant had completing each task. As defined in the ICF manual, the scoring was as follows: 0="no difficulty," 1="mild difficulty," 2="moderate difficulty," 3="severe difficulty," and 4="complete difficulty." The specific ICF tasks selected for use in this study were based on a consensus among the research staff as to which mobility activities listed in the ICF had the potential to be required for AVG play (eg, standing, reaching, throwing, and jumping) based on prior observations. Scores on each of the 18 tasks were added together as a composite to represent participants' physical function. A lower physical function score indicated greater functional ability on the selected tasks. A description of the specific tasks has previously been published [28].

In addition, the participants rated their physical function using the PROMIS SF v1.0—physical function 20a measure. This self-reported measure assesses an individual's perception of their current function, specifically the upper and lower extremities and central region (trunk and neck). It also evaluates their ability to complete instrumental activities of daily living (eg, running errands). A single physical function capability score is obtained from the measure [33].

Adapted Gaming Mat

Prior work by our exercise science and engineering teams had identified deficiencies in commercial OTS gaming mats that could be improved upon to enhance accessibility. The deficiencies were based on the assumption that many players with mobility impairments would need to play while seated with the mat placed on a tabletop in front of them. The specific issues identified were:

- Large area button layout: The original OTS button layout was designed to accommodate players who could stand and exert body weight force through the lower extremities, utilizing a large 3 ft x 3 ft playing surface, over which the 8 controller buttons and 2 menu buttons were distributed. This large span of the buttons made it difficult for a seated player to reach all the buttons.
- 2. High button actuation force: The buttons were designed for high actuation force as would be common when used by a standing player stepping or stomping with their feet, but becomes difficult for use with the hands.
- 3. "Dead" spots in button area: The underlying design of the mat buttons was such that "dead" spots existed within the area of each button when trying to depress the button with a couple of fingers rather than a whole foot.

The OTS mat (2007; Wii) was re-engineered to create an adapted mat design to address the issues described above. Two adapted mats were built, one specifically for standing players to play with their feet and another for seated players to play with their hands (Figure 1). For both adapted mats, the underlying button technology was replaced to increase the level of accessibility. Both mats included variable button actuation force (sensitivity adjustment) and consistent button response over the entire button area. A reconfigurable button layout design using hook and loop attachments was also incorporated for the mat to be used by seated players.

Figure 1. Adapted foot gaming mat (left) and adapted hand (right) mat. Note, the exterior shell of the foot mat looks identical to an off-the-shelf mat, given that only the inside components were re-engineered.



Active Video Gameplay

Upon arrival at the lab, participants pulled a number to determine which version of the controller they would play first (adapted or OTS), then the participant would also draw a number to determine which game set (explorer or outdoor challenge) they would play first (Textbox 1). Whichever game set was selected first would be played on both versions of the mat (adapted and OTS), and then the second game set would be played on each version. Based on observations during the physical function tests and discussions with the participant, it was decided whether the participant would play in a standing or seated position. For standing play, the mat was placed on the

floor, and for seated play, the mat was placed on a height-adjustable and tilt-adjustable tabletop. Participants were then set up with the portable metabolic system (COSMED K4b2) and a heart rate monitor to assess pulmonary gas exchange and indirect calorimetry. Data collection began with a 20-minute rest period to measure the resting energy expenditure. For the rest period, participants sat quietly with no speaking or distractions besides lightly reading a magazine or viewing their cellular phone. Next, gameplay began with continuous gas exchange and heart rate data collection. Gameplay consisted of four 10-minute sets with a rest period of 5 minutes after each game set.

Textbox 1. Mini-games played on both off-the-shelf (OTS) and adapted gaming mat.

Active life explorer

- **Crocodile stomper:** Step on the crocodiles approaching from all sides to drive them away.
- Airplane panic: Save an airplane from a bandit and fly back to safety.
- Kraken battle: Fight a sea monster in an attempt to survive.
- Mummy's tomb: Run away from the mummies, lock the gates, and escape the tomb.
- Jungle vine ruins: Run, jump, and climb through the jungle ruins to get the treasure.

Active life outdoor challenge

- Sprint challenge: Run along the straight course as fast as possible.
- Jump rope: Jump over the rope following the rhythm, becoming faster as time progresses.
- Conveyor runner: Run along the moving conveyor and jump over obstacles aiming to stay on as long as possible.
- Log leaper: Jump to avoid the oncoming logs and stay on the platform as long as possible.
- Head-on hurdler: Run and jump over the hurdles placed along the course.
- Mole stomper: Whack the moles popping up from different holes on all sides.

Standing players used their feet to run, jump and stomp on the required mat buttons following the on-screen prompts; seated players used their hands.

During gameplay, research staff observed and rated the ability to use the game controller (mat) and the quality of gameplay. The ability to use the game controller assessed the participant's difficulty or ease of using the controller as required for the game and was rated on a scale of 1-5 (1=extreme difficulty, 2=severe difficulty, 3=moderate difficulty, 4=mild difficulty, and 5=no difficulty). To assess gameplay quality, the research staff considered the participants' degree of general game manipulation and user actions as prompted by the game compared to how a gamer without a physical disability would play as observed during testing with staff and preliminary usability testing. Quality of gameplay ranged on a scale from 1-5 (1=poor, 2=fair, 3=moderate, 4=good, and 5=excellent). Two research staff worked together for all testing sessions. Both recorded scores for quality of gameplay and controller usage and came to a consensus for the final scores at the end of the session. All sessions were videotaped, so in the event that testers could not come to a consensus, the recording would be available for review. Staff observation scores were combined for the 2 games.

At the end of each game set, participants reported their rating of perceived exertion on a scale from 0-10, with 0=not tired at all and 10=very, very tired. During rest periods, participants completed a feedback survey that included PACES [34]. The

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XSL•F() RenderX PACES includes 16 statements such as "I enjoyed it," "It was very exciting," "I felt bored," and "It was no fun at all." All items were rated by the participant on a 5-point scale ranging from 1=strongly disagree to 5=strongly agree. After reverse scoring 7 items, a final score was computed by calculating the average of the 16 items.

Participants also answered additional questions regarding the usability of the system with each controller (adapted mat and OTS mat): "How hard was it for you to use the gaming mat?" (unable to use=1 to very easy= 5); "Do you feel like you were able to successfully play the game?" (strongly disagree=1 to strongly agree=5); and "Did you feel like the mat recognized your body movements?" (strongly disagree=1 to strongly agree=5). Participant scores were combined for the 2 games. To gauge participants' perspective of the gameplay experience and any differences between the two games, they were asked, "Do you consider playing this game as an exercise, fun activity, both, or neither?"

Data Analysis

As the sample size was small, the data did not meet normality assumptions. Therefore, Wilcoxon signed-rank nonparametric tests were run to identify the difference between the use of the 2 gaming mats (OTS vs adapted). Given the variation in

gameplay style between seated (mat on the table) and standing (mat on the floor), all the tests were conducted separately for sitting and standing participants. As the same person played games using the OTS and adapted gaming mats, measurements cannot be considered independent. To control for within-subject variability and accommodate missing data, linear mixed-effects maximum likelihood regression tests were conducted to determine any statistically significant differences between the means of variables when participants used OTS versus adapted mats. A significance level of .05 was used in evaluating the statistical tests. Data management and analyses were performed using Stata 16 (version 16.1; StataCorp).

Results

A convenience sample of 78 individuals with mobility impairments between the ages of 12 and 60 years (mean 39.6, SD 15.8) volunteered for the study. The sample included 34 females and 44 males, with 39 non-Hispanic Whites, 37 Blacks, 1 Hispanic, and 1 Other. Of the sample, 48 participants played the video games in a seated position, while 30 played the games standing.

Descriptive statistics (Table 1) present the differences in a series of variables captured during gameplay by participants while using the OTS mat versus the adapted gaming mat. The Wilcoxon signed-rank test results are displayed with the medians and interquartile ranges for all outcome measures. There were significant differences, including gameplay METs and heart rate for sitting participants where values were higher during the OTS mat condition compared to play using the adapted mat. However, for seated players, all self-reported ratings of the gameplay experience and staff observations of gameplay were significantly higher for the adapted mat in comparison to the OTS mat. For standing players, staff observations of the ability to use the gaming mat were significantly higher for the adapted mat compared to the OTS mat. Box plots are also used to display the results in Figures 2 and 3.

Mixed-effect model results are reported in Table 2. In all models, participants' age and performance were used as control variables. Among the participants that played seated, lower energy expenditure (β =-.18; *P*<.001) and lower heart rate (β =-2.09; *P*=.01) were reported when they used the adapted mat compared to the OTS mat. For instance, seated participants using the OTS mat had a 2 point increase in heart rate in comparison to gameplay using the adapted mat.

Adapted mat use, however, was associated with higher scores in participants' measures of the gameplay experience and staff observations of controller use and quality of gameplay. For example, sitting participants using the adapted mat scored 0.68 units higher in ease of using the gaming mat, 0.62 units higher in their perceived ability to successfully play the game, 0.85 units higher in their perception that the gaming mat effectively recognized body movement. In addition, staff observations were 0.98 units higher in rating the participants' ability to use the adapted controller and 0.55 units higher in the quality of gameplay compared to their observations during gameplay with the OTS mat. Likewise, for participants that played the games standing, staff reported higher scores in their ability to use the controller (β =.35; P<.001) and quality of gameplay (β =.26; P=.001) with use of the adapted mat. Participant responses regarding each game as fun or exercise were tallied. For each game and both conditions (sitting and standing), the majority (66%-83%) of responses indicated the activity as both exercise and fun.



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Table 1. Descriptive statistics for gameplay variables, participant ratings, and staff observations (N=78).

Variables	OTS mat	Adapted mat	P valu
RPE (0-10), median (IQR)			
Sitting	4.5 (2.3-6.5)	4.0 (2.0-6.0)	.11
Standing	6.0 (4.5-7.0)	6.0 (5.0-7.5)	.52
Enjoyment (PACES ^a), median (IQR)			
Sitting	3.7 (3.4-4.1)	3.8 (3.5-4.0)	.37
Standing	4.0 (3.5-4.3)	3.9 (3.3-4.4)	.11
Energy Expenditure (METs ^b), median (IQR)			
Sitting	1.9 (1.5-3.0)	1.8 (1.4-2.7)	<.001
Standing	3.9 (3.1-4.7)	3.9 (3.1-4.7)	.21
Heart rate (bpm ^c), median (IQR)			
Sitting	93.3 (83.8-105.9)	92.3 (80.9-102.1)	.001
Standing	117.3 (106.7-134.5)	124.1 (98.0-140.4)	.32
Participant ratings			
How hard to use gaming mat (1=unable to 5=very easy), median (IQR)			
Sitting	3.0 (3.0-4.0)	4.0 (3.5-4.5)	<.001
Standing	4.0 (3.0-4.0)	4.0 (3.5-4.5)	.11
Able to successfully play (1=strongly disagree to 5=strongly agree), media	nn (IQR)		
Sitting	3.5 (2.5-4.0)	4.0 (3.5-4.5)	<.001
Standing	4.0 (3.0-4.5)	4.0 (3.5-4.5)	.24
Mat recognized body movement (1=strongly disagree to 5=strongly agree), median (IQR)		
Sitting	2.5 (2.0-3.5)	4.0 (3.0-4.0)	<.001
Standing	4.0 (3.5-4.0)	4.0 (3.3-4.5)	.41
Staff Observations			
Ability to use gaming mat (1=extreme difficulty to 5=no difficulty), media	nn (IQR)		
Sitting	4.0 (3.0-4.0)	5.0 (4.0-5.0)	<.001
Standing	4.5 (4.0-5.0)	5.0 (4.5-5.0)	<.001
Quality of gameplay (1=poor to 5=excellent), median (IQR)			
Sitting	3.5 (3.0-4.0)	4.0 (3.5-4.5)	<.001
Standing	4.0 (3.5-4.0)	4.0 (4.0-4.5)	.004

^aPACES: physical activity enjoyment scale.

^bMET: metabolic equivalent.

^cbpm: beats per minute.



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Figure 2. Descriptive statistics of active video gaming (AVG) gameplay using off-the-shelf (OTS) vs adapted gaming mat. bpm: beats per minute; MET: metabolic equivalent; PACES: physical activity enjoyment scale; RPE: rating of perceived exertion.

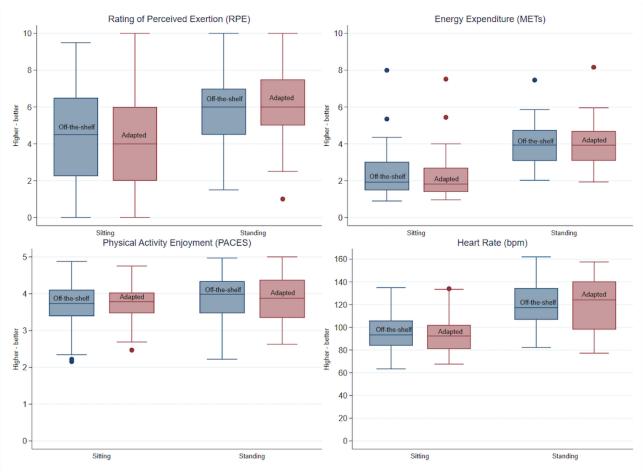
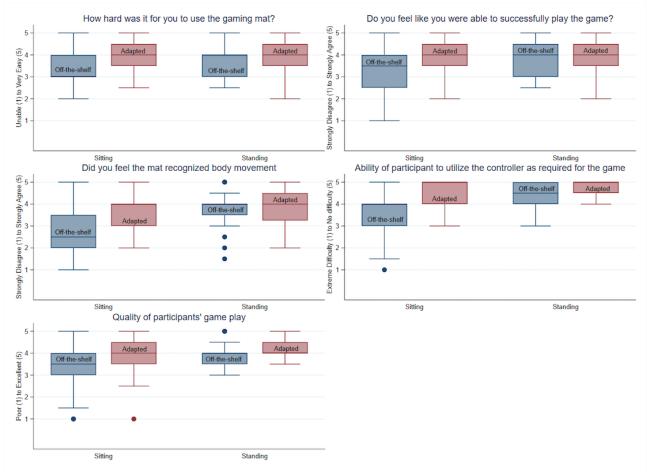




Figure 3. Gameplay experience of participants and staff observations for off-the-shelf (OTS) versus adapted gaming mat.





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Table 2. Mixed-effects model illustrating gameplay variables, participant ratings, and staff observations in using off-the-shelf (OTS) versus the adapted mat.^a

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	Adapted (vs OTS) coefficient	P value
RPE ^b		
Sitting	-0.38	.15
Standing	0.23	.34
Enjoyment		
Sitting	0.05	.42
Standing	-0.09	.09
Energy Expenditure (METs ^c)		
Sitting	-0.18	<.001
Standing	-1.10	.18
Heart rate (bpm ^d)		
Sitting	-2.09	.01
Standing	-1.08	.41
Difficulty using the gaming mat		
Sitting	0.68	<.001
Standing	0.20	.10
Able to successfully play		
Sitting	0.62	<.001
Standing	0.08	.48
Mat recognized body movement		
Sitting	0.85	<.001
Standing	0.21	.30
Ability to use gaming mat		
Sitting	0.98	<.001
Standing	0.35	<.001
Quality of gameplay		
Sitting	0.55	<.001
Standing	0.26	.001

^aControl variables: age and self-reported physical function score.

^bRPE: rating of perceived exertion.

^cMET: metabolic equivalent.

^dbpm: beats per minute.

Discussion

Principal Findings

The benefits of regular physical activity are clear, and the physical activity guidelines to achieve these benefits apply to everyone [35]. However, only approximately 20% of adults and youth in the United States are sufficiently active to improve health [36]. As noted in the Physical Activity Guidelines for Americans [35], any amount of physical activity has some health benefits. However, individuals with disabilities have fewer opportunities to engage in LTPA, thereby having even higher physical inactivity rates [9] and at greater risk for chronic

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disease. In the general population, AVG has been shown to be a fun and engaging way to increase physical activity [37,38].

Increases in energy expenditure during AVG have been reported for individuals with mobility impairments. For example, among children and adults with cerebral palsy moderate levels of physical activity were achieved during Wii Sports gameplay while standing [39,40] and seated [22]. Similar results were found for adults poststroke who played Wii Sports in a standing position [41]. In another study, moderate-intensity activity was achieved in both seated and standing positions among poststroke adults playing Xbox Kinect and Wii games [42]. Increases in energy expenditure were also found in seated players with spinal

cord injury during Wii Sports and PlayStation 3 [43,44]. Other efforts have focused on supplementing existing exercise equipment with gaming for various youth and adult populations (ie, spina bifida, spinal cord injury, and cerebral palsy), achieving increases in exercise intensity [24] and enjoyment [45-47].

Incorporating accessibility features into the design and development of AVG controllers has the potential to reduce barriers to physical activity and improve the overall gameplay experience. However, little work has been done to incorporate design features into commercially available AVG controllers as a way to engage and promote active play in persons who require a wheelchair for mobility or need to play in a seated position. A feasibility study using an adapted upper-extremity Dance, Dance Revolution gaming mat on a table found increases in energy expenditure among 3 nonambulatory functionally diverse young adults [22]. Recognizing the potential for AVG play to increase energy expenditure among people with mobility impairments led our team to develop 2 adapted gaming controllers, an adapted version of the Wii Fit balance board [28,29] and the Wii gaming mat as described in this study. Previously reported results of the adapted Wii board study found that participants were able to achieve light-intensity (<3 METs) to moderate-intensity (3-6 METs) exercise with high levels of enjoyment [30]. The current study aimed to examine similar outcomes in persons with mobility impairments using OTS and adapted versions of the Wii gaming mat during AVG play.

Use of the adapted gaming mat in this study allowed for successful AVG play by a cohort of youth and adults with physical disabilities, specifically lower extremity mobility limitations. Furthermore, individuals were able to play either seated or standing, depending on their functional needs. The gameplay was enjoyable, and participants achieved light-intensity to moderate-intensity exercise. Although significant differences in energy expenditure and enjoyment between the 2 gaming mats were not found, the subjective experience of the seated players was improved by the adapted mat. As shown in the results, seated players reported greater ease of use, success, and recognition of body movements during gameplay on the adapted mat. Additional comments from the participants suggested a preference for the adapted mat due to it being more sensitive to their movement inputs (ie, hand or foot touch) and less frustrating. For the seated players, the adjustable button placement and smaller play area contributed to greater gameplay success by reducing the required reach and being more responsive. These features contributed to better control and players feeling more competitive in the games and achieving better scores. As noted, due to the increased sensitivity of the adapted mat, less force was required for game input. This feature may have inadvertently resulted in the slightly lower MET values for seated players during the adapted condition. However, with continued use and extended gameplay sessions,

the requirement of less force would help minimize upper extremity injuries while having the potential to increase energy expenditure with greater familiarization, practice, and selection of games. Regardless, engagement in AVG play using the adapted mat will at minimum reduce sedentary time and produce light-intensity to moderate-intensity exercise for all players.

Limitations

As an observational study, the generalizability of the results is limited, and claims regarding causality or efficacy cannot be made. Individuals were recruited from a community organization that provides physical activity, recreation, and sports programming for individuals with physical disabilities. Current physical activity levels varied among participants, as did their experience with video gaming. Measurements of exercise intensity (RPE, METs, and heart rate) may have been influenced by various factors not accounted for, such as the nature of the preselected games, the limited amount of time for participants to get familiarized with the gaming system, medications, and discomfort wearing the COSMED system for the measurement of oxygen consumption. Some degree of gameplay learning may have occurred during data collection, given the short familiarization period. In addition, since participants played only a select group of games, potential differences in enjoyment and energy expenditure between OTS and adapted controllers may not have been fully captured.

Furthermore, with regard to the assessment of exercise intensity based on METs, it must be noted that values do not consider the effect of impairment level on exercise intensity. Future studies should expand participant recruitment, conduct age group comparisons, examine a wider range of video games, provide an extended familiarization period, and compare outcomes during AVG play to other leisure-time physical activities. Further analyses with a larger sample that explore the multivariate correlation and variance-covariance matrices in the outcome measures (RPE, heart rate, MET, and PACES) would provide a better understanding of the relationship between exercise intensity and enjoyment and of clinically meaningful differences during AVG in this subpopulation.

Conclusions

The adapted gaming mat allowed adults and youth with mobility impairments to engage in AVG, seated or standing. Energy expenditure and RPE indicated the activities to be light to moderate intensity. Although energy expenditure and heart rate tended to be higher in the OTS mat condition for seated players, the adapted mat provided the advantage of greater sensitivity, better responsiveness, and adjustable gameplay area. The adapted mat with adjustable buttons allowed for varying upper extremity mobility and arm reach lengths, thereby facilitating greater success and quality of gameplay. Overall, the adapted gaming mat provides an enjoyable option for increasing LTPA.

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Conflicts of Interest

None declared.

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Abbreviations

ACL: Administration for Community Living AVG: active video gaming HHS: Department of Health and Human Services ICF: International Classification of Functioning, Disability and Health LTPA: leisure-time physical activity MET: metabolic equivalent NIDILRR: National Institute on Disability, Independent Living, and Rehabilitation Research OTS: off-the-shelf PACES: physical activity enjoyment scale RPE: rating of perceived exertion

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Original Paper

Development of a Search Task Using Immersive Virtual Reality: Proof-of-Concept Study

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Abstract

Background: Serious games are gaining increasing importance in neurorehabilitation since they increase motivation and adherence to therapy, thereby potentially improving its outcome. The benefits of serious games, such as the possibility to implement adaptive feedback and the calculation of comparable performance measures, can be even further improved by using immersive virtual reality (iVR), allowing a more intuitive interaction with training devices and higher ecological validity.

Objective: This study aimed to develop a visual search task embedded in a serious game setting for iVR, including self-adapting difficulty scaling, thus being able to adjust to the needs and ability levels of different groups of individuals.

Methods: In a two-step process, a serious game in iVR (bird search task) was developed and tested in healthy young (n=21) and elderly (n=23) participants and in a group of patients with impaired visual exploration behavior (ie, patients with hemispatial neglect after right-hemispheric stroke; n=11). Usability, side effects, game experience, immersion, and presence of the iVR serious game were assessed by validated questionnaires. Moreover, in the group of stroke patients, the performance in the iVR serious game was also considered with respect to hemispatial neglect severity, as assessed by established objective hemispatial neglect measures.

Results: In all 3 groups, reported usability of the iVR serious game was above 4.5 (on a Likert scale with scores ranging from 1 to 5) and reported side effects were infrequent and of low intensity (below 1.5 on a Likert scale with scores ranging from 1 to 4). All 3 groups equally judged the iVR serious game as highly motivating and entertaining. Performance in the game (in terms of mean search time) showed a lateralized increase in search time in patients with hemispatial neglect that varied strongly as a function of objective hemispatial neglect severity.

Conclusions: The developed iVR serious game, "bird search task," was a motivating, entertaining, and immersive task, which can, due to its adaptive difficulty scaling, adjust and be played by different populations with different levels of skills, including individuals with cognitive impairments. As a complementary finding, it seems that performance in the game is able to capture typical patterns of impaired visual exploration behavior in hemispatial neglect, as there is a high correlation between performance and neglect severity as assessed with a cancellation task.

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KEYWORDS

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virtual reality; serious game; search task; stroke; neglect; usability; development; immersion; concept; gaming

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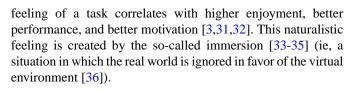
Introduction

A crucial component of neurorehabilitation and its success is therapy adherence and repetition. One promising possibility to improve patients' therapy adherence, and thereby its outcome, is to enhance training motivation by means of serious games [1] and immersive virtual reality (iVR) [2,3]. The combination of serious games and iVR allows for the investigation of visual exploration behavior, which is highly relevant in activities of daily living and therefore frequently used in the diagnosis and rehabilitation of patients suffering from a neurodegenerative disease [4-7].

The primary purpose of serious games is not to be fun, but to teach, train, or assess skills in an entertaining way [8]. Due to technological achievements in recent years, their importance in education [9] rehabilitation [10], and medical training [11] is growing, as they have several advantages. First, serious games are standardized, which means that each user will experience the same task. Second, different game settings offer the possibility to automatically adapt the task difficulty to the user's individual skills and performance level. Finally, serious games offer the possibility to track the user's game performance (eg, achieved scores) and game behavior as a measure for activities of daily living (eg, reaction times) [12].

The different settings and measured performance values have been used to implement adaptive difficulty scaling, which has shown to be an important element of serious games leading to 2 key elements [13-16]. First, a balance point (ie, when game difficulty is still challenging, yet does not exceed the player's abilities) can be achieved. Second, changes in game mechanics should allow adapting the difficulty throughout the game, to continuously and optimally match the increasing skill level of the player [17]. Importantly, both elements are essential to keep the player motivated [18].

The benefits of serious games can be further improved by the use of iVR [19-21]. iVR presents computer-generated artificial, but interactable (ie, hand-held controllers), 360° environments or pre-rendered 360° videos inside a head-mounted display (HMD). With technological improvements over the last decade, iVR is now also increasingly used in clinical applications such as in motor rehabilitation for gait and balance [22,23], surgery training [24-26], or anxiety treatment [27]. Particularly in tasks that involve any kind of motor activities, iVR has some advantages, such as the possibility to objectively measure progressive improvement in trained skills, perform task-oriented repetitive training, and apply multisensory feedback and task variation [28,29]. Rizzo et al [12] summarized evidence showing that skills gained in the iVR environment can be transferred to activities of daily living (eg, crossing the street [30]) reflecting the ecological validity of tasks in iVR. The high ecological validity can be explained due to fewer distractions from external stimuli and the intuitive interaction with the virtual environment, whereas the interaction and thus behavior in the virtual environment can be tracked by recording head and hand movements. Conclusively, tasks in iVR tend to feel more naturalistic, and several studies have shown that the naturalistic



Visual exploration behavior is a crucial element of activities of daily living (eg, crossing the street, grocery shopping) [37] and corresponds to purposefully looking around in the present environment (ie, actively acquiring visual information through coordinated movements of the eyes and head [38]). Therefore, an impaired visual exploration behavior could lead to a reduction of performance in activities of daily living and thus in quality of life [39,40]. Impairment of the visual search behavior is also one landmark of patients suffering from hemispatial neglect [37,41]. Hemispatial neglect is a visuospatial attention disorder that frequently occurs after a right hemispheric stroke. Its characteristic is the inability to attend or respond to stimuli presented within the left contralesional space [42].

Therefore, the aim of this proof-of-concept study was to develop a serious game using iVR in which participants perform a visual search task that encourages the exploration of their environment. We hypothesized that the given task has high usability and limited or no side effects and that the performance can be adapted dynamically to the skills of the participants.

Methods

The main goal of this study was to develop a gamified search task that encourages players to explore their visual environment. We named it the bird search task, and development and evaluation were divided into 2 steps.

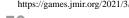
First, the 2D game "Crazy Chicken" (ak tronic Software & Services gmbh, Saerbeck, Germany) was used as inspiration, and the game mechanics were transferred to a 3D iVR environment and then modified and tested with healthy young and elderly participants. Based on the findings of the first step, in the second step, the task was further adapted and tested with patients with hemispatial neglect after a right hemispheric stroke.

Game Development and Apparatus

Bird Search Task for Healthy Participants

The 2D game "Crazy Chicken" was identified as a suitable gamified task because it encourages players to explore their visual environment. In the original "Crazy Chicken" game, the chickens (visual targets) appear at random locations on the computer screen and fly at a constant velocity in random directions. The player, by constantly scrolling left and right on a scrollable, 2D screen, has to search and tag the targets before they disappear after a constant time delay.

To transfer the task into 3D, a simple virtual environment was designed using the gaming development platform Unity3D [43]. The environment was built as a wide circular area surrounded by trees and mountains, as shown in Figure 1 and Figure 2. A mobile gaming laptop was used to render the virtual environment (HP-Omen, graphic-card NVIDIA GTX1050 and CPU Intel i7).



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Figure 1. Immersive virtual reality game, with (A) the participant's field of view (yellow) within the head-mounted display, which moved if the player (blue) turned his or her head, and the area where the target could appear (dashed line; spawn area), which was locked to the midsagittal plane; and (B) a schematic representation of a participant wearing the head-mounted display and performing the task.

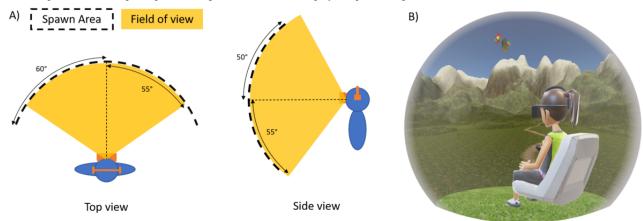
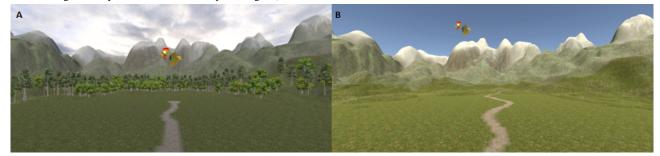


Figure 2. Exemplary scene of the gameplay, (A) as implemented in step 1 (healthy individuals) and (B) after the modifications performed in step 2 (patients with right hemispheric stroke and hemispatial neglect).



The iVR hardware consisted of an HMD and a hand-held controller (HTC Vive, High Tech Computer Corporation, Taoyuan, Taiwan; resolution of 2160 x 1200 pixels; full HD; horizontal and vertical field of view of 110 degrees [yellow area in Figure 1A]; frame rate of 90 Hz). The x-y position of the handheld controller was continuously recorded. Using iVR hardware, 360° of the virtual environment could be explored by moving the eyes and turning the head. The targets (eg, birds) could be tagged by aligning the handheld controller with the target and simultaneously pressing a trigger on the controller. Target appearance was set to randomly take place within a restricted area in front of the player (\pm 60° horizontally and \pm 50° vertically, as defined with respect to the trunk's midsagittal plane; see dashed lines in Figure 1A). In order to promote exploration of the whole extent of the virtual environment, the horizontal area in which the targets could appear was 10° larger than the player's field of view (ie, additional 5° on either side; Figure 1A).

To alert the player of a new appearing target, a short (1 second) auditory signal (chicken cackle) was presented binaurally via headphones (XQISIT oE400, Strax Americas Inc, Miami, FL). Then, the target appeared at a position randomly determined within the spawn area and flew horizontally towards the right or left (direction randomly selected) with a constant velocity of 2 °/second. If the target was detected and successfully tagged, it fell vertically and disappeared. In case the target was not tagged within the maximum presentation time of 15 seconds, it disappeared. In either way, after a fixed interstimulus interval

of 2 seconds, a new target appeared, again with an alerting cackle.

The game was played in rounds. Each of the 10 played rounds consisted of 30 targets. For each target, the time until it was found was measured, and the percentage of found targets was calculated for each round.

We modified the task further by integrating several difficulty levels, to be able to adapt the task to participants with different needs and skills.

We implemented 15 difficulty levels, in which changes in difficulty were achieved by manipulating both target behavior and task mechanics. For each of the 15 levels, the values of the settings changed stepwise, according to the "Change Per Level" threshold presented in Table 1. Concerning target behavior, both the maximum lifetime and speed of the targets were manipulated across levels. For instance, in the easiest level (Level 1), the targets moved with a speed of 2 °/second and were presented for 15 seconds before they disappeared; in the most difficult level (Level 15), the targets moved with a speed of 35 °/second and were presented for 4 seconds before they disappeared. Hence, the more difficult the level, the faster the participants had to explore the visual environment in order to find the targets before they disappeared. Concerning task mechanics, the task adapted its difficulty (ie, changed the difficulty level) automatically, based on performance in the previous round. Each level had a level-up threshold (ie, if the threshold value was reached, the next round started in a higher difficulty level) and a level-down threshold (ie, if the threshold

value was not reached, the next round started in a lower difficulty level), defined according to the percentage of found targets. If the percentage of found targets in a particular round was not higher than the level-up threshold and not lower than the level-down threshold, the difficulty in the next round did not change.

For example, in a round at level 6, the targets move with a speed of 13.8 °/seconds, and the maximum lifetime of the targets is

Table 1. Change per level algorithm.

11.07 seconds. Assuming that the participant would find 25 of the 30 targets in this particular round (ie, 83.3% found targets), then the next round would start at level 7 since the percentage of found targets is above the level-up threshold of level 6 (ie, 77.1%). If the player finds only 15 of the 30 targets (ie, 50% found targets), then the next round would start at level 5, since the percentage of found targets would be below the level-down threshold of level 6 (ie, 67.1%).

Task and target parameters	Level 1	Change per level ^a	Level 15	
Lifetime (seconds)	15	-0.786	4	
Speed (°/second)	2	+2.36	35	
Level-up threshold (%)	>70	+1.42	>90	
Level-down threshold (%)	<60	+1.42	<80	

^aThe stepwise change per level between Level 1 and Level 15.

Bird Search Task for Patients With Hemispatial Neglect

In a second step, based on the findings collected in healthy participants and on recommendations of the clinicians, the version for patients was developed. As neglect's clinical picture is very heterogeneous across patients, the task needs to be easily adaptable to the patients' individual needs. The aim was that patients would not get overwhelmed and frustrated due to too great a difficulty but also not get bored by a task that was too easy. For this purpose, we implemented an easy-to-use setting file, in which the total number of targets, number of targets per round, and starting difficulty level could be set individually for each patient. Additionally, several adaptations in design and task mechanics were performed. First, as patients with neglect process visual information slower [44,45], the landscape of the gameplay would be too complex; therefore, in order to reduce the number of distractive elements, the trees in the background and the clouds in the sky were removed from the game scenery (see Figure 2). Second, based on the recommendations of clinicians, the minimal speed of the targets was lowered from 2°/second to 0.1°/second; this manipulation generally lowered the difficulty level as well as reduced the need for fast head movements that could promote side effects.

Participants

The study was approved by the Ethics Committee of the Cantons of Bern and the Ethics Committee of north-west and central Switzerland and was conducted in accordance with the latest version of the Declaration of Helsinki. All participants gave written informed consent before participation.

In step one, the feasibility of the task was assessed with 21 younger healthy participants recruited at the University of Bern (10 women; mean age, 28.1, SD 5.5 years) and with 23 older healthy participants recruited during a chess tournament for seniors (1 woman; mean age, 71.3, SD 6.3 years). All participants had no history of neurological nor psychiatric disorders. Previous VR experience was reported by 16 of the younger participants and 1 of the older participants.

In step two, 11 inpatients with hemispatial neglect (5 women; mean age, 69.6, SD 13.0 years) after right hemispheric, subacute stroke were recruited at the Neurorehabilitation Clinics of the Inselspital, Bern University Hospital (sites Bern and Riggisberg) and of the Kantonsspital Luzern, Switzerland. Demographic characteristics for each patient are presented in Table 2. The study was always conducted with a mobile setup in the place where the patient was currently hospitalized. All patients showed significant left-sided neglect in activities of daily living, as assessed with the Catherine Bergego Scale (CBS, Range 0-30, 0 = normal) [46], and had normal or corrected-to-normal vision. One of the patients reported previous VR experience.



Table 2. Individual demographical and neuropsychological data from step 2 for patients with hemispatial neglect.

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Patient code	Age range (years)	Gender	Lesion type	Time since stroke (days)	CBS ^a	CoC ^b (SNT ^c single)	Number of played chickens	Play duration (min)
P_26	70-75	Male	Ischemic	85	6	0.184	195	16.5
P_27	55-60	Male	Hemorrhagic	145	2	0.208	100	10.4
P_28	80-85	Male	Bleeding	49	8	0.746	50	9.4
P_29	80-85	Female	Ischemic	52	9	0.998	44	8.1
P_30	75-80	Male	Ischemic	42	8	0.293	80	9.2
P_31	50-55	Female	Ischemic	106	3	0.414	80	13.2
P_32	65-70	Female	Ischemic	59	2	-0.067	80	10.2
P_33	70-75	Female	Ischemic	58	3	0.824	80	9.3
P_34	85-90	Male	Ischemic	29	18	0.998	80	8.4
P_35	50-55	Male	Hemorrhagic	39	10	0.046	150	13.0
P_36	60-65	Female	Ischemic	38	17	0.191	100	10.1

^aCBS: Catherine Bergego Scale (0-30).

^bCoC: Center of Cancellation (-1 to 1).

^cSNT: Sensitive Neglect Test.

In addition to CBS, where a value ≥ 1 means the patient has a neglect, the objective neglect severity was assessed on the day of the task by means of the paper-and-pencil Sensitive Neglect Task (SNT), single version [47]. The SNT is a cancellation task in which patients are asked to mark 40 targets among 240 distractors. Based on the distribution of the marked targets, the Center of Cancellation (CoC) [48] was computed, representing an objective measure of neglect severity. The CoC reflects the mean deviation of the marked targets from the center and is normalized to values ranging from -1 to 1. Zero indicates no spatial bias, where a CoC ≥ 0.081 represents a significant rightward shift (ie, left-sided neglect).

Outcome Measures

Questionnaires

To evaluate the feasibility and usability of the newly implemented task, several questionnaires were used to assess the participants' individual gaming experience.

To assess acceptance, usability, and participant's perception of the visual search task and of the VR system, 3 questions from the System Usability Scale (SUS) [49] were used, as previously reported by Gerber et al [50] and Knobel et al [51]. The questions were answered using a 5-point Likert-scale, ranging from "fully disagree" to "fully agree." The mean score across all questions was calculated for each participant. The Simulator Sickness Questionnaire (SSQ) [52] was used to assess side effects such as cybersickness, oculomotor problems, and disorientation [53,54]. In order to reduce the workload of the study participants, a subset of 7 questions from the SSQ was used, as previously reported by Gerber et al [50] and Knobel et al [51]. The questions were answered using a 4-point Likert-scale (ie, "None," "Slight," "Moderate," "Severe"). Again, the mean score across all questions was calculated for each participant.

Additionally, in order to assess the enjoyment of the task, the Perception of Game Training Questionnaire (PGTQ) [55] was administered. The PGTQ consists of 4 questions that are answered using a 7-point Likert-scale, ranging from "fully disagree" to "fully agree." Each question represented a different aspect of the perception of the task (ie, motivation, frustration, how challenging it is, entertainment). Therefore, no mean score was calculated across questions; instead, each score was considered independently.

Furthermore, to assess immersion and presence, questions from the Igroup Presence Questionnaire (IPQ) [56] were used. The question subset was already used in another iVR study by Gerber et al [50] and was answered on a 5-point Likert-scale.

The questions from each questionnaire are shown in Table 3.



Table 3. Exact formulations that were asked in the questionnaires.

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Questionnaire, number	Question	Domain
SUS ^{a,b}		
1	I thought the system was easy to use	Usability
2	I think that I would like to use this system frequently	Usability
3	I felt very confident using the system	Usability
SSQ ^{c,d}		
4	General discomfort	Sickness
5	Stomach awareness	Sickness
6	Sweating	Sickness
7	Nausea	Sickness
8	Headache	Oculomotor problems
9	Eye strain	Oculomotor problems
10	Dizziness	Disorientation
IPQ ^{e,f}		
11	In the virtual world, I had a sense of "being there." ^g	Immersion
12	Somehow, I felt that the virtual world surrounded me.h	Presence
PGTQ ^{i,j}		
13	I was motivated for a good performance.	Motivation
14	The game was frustrating.	Frustration
15	The game was challenging.	Challenge
16	The game was entertaining.	Entertainment

^aSUS: System Usability Scale.

^bFully disagree to fully agree; score range, 1-5; midpoint, 3; scored as the mean of Q1-Q3.

^cSSQ: Simulator Sickness Questionnaire.

^dNone to severe; score range, 1-4; midpoint, 2.5; scored as the mean of Q4-Q10.

^eIPQ: Igroup Presence Questionnaire.

^fScore range, 1-5; midpoint, 3; each question is scored individually.

^gNot at all to very much.

^hFully disagree to fully agree.

¹PGTQ: Perception of Game Training Questionnaire.

^jFully disagree to fully agree; score range, 1-7; midpoint, 4.5; each question is scored individually.

Performance Indicators During the Task

The presented task allowed us to measure several performance indicators, namely the changes in difficulty levels over time and the mean search time to detect the targets.

Based on the mean search time of the targets, the mean search time per participant was calculated, representing the mean time until a participant tagged a target (not-found targets were excluded). Moreover, the controller position of the VR setup was recorded over the entire task, which allowed us to track the participants' hand positions over time, hence delivering information concerning their spatial search behavior.

Evaluation of the Difficulty Scaling

There are different possibilities to assess whether an adaptive difficulty scaling is successful. An easy indirect, but less

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objective, possibility is to simply evaluate the results of the questionnaires concerning entertainment and frustration. A more elaborate and objective approach is to consider the number of level changes over the task rounds with respect to the starting level. A population in which the starting level is much easier than the average balance point should show a greater increase in difficulty (ie, more upward level switches) in the initial phases of the task (ie, when they increase to their balance point) and then a smaller increase over time (ie, when the balance point is reached, but the participants still gradually get better at the task due to practice). The better the starting level matches the abilities of the group, the smaller the difficulty changes should be in the initial phases of the task. Nevertheless, due to practice (eg, better aiming, better search strategies), participants are expected to get better in the task, and there should thus be at least a small difficulty level increase over time.

A plateau reflects the balance point at which the level did not change anymore between rounds. This indicates that participants reached their optimal task difficulty level (ie, their performance was not at the ceiling in a particular difficulty level so that the algorithm would increase it in the next round and not at the floor that the algorithm would decrease the difficulty level in the next round).

Statistical Analyses

The mean SUS and SSQ scores, reflecting the usability and number of side effects, respectively, were computed for each group (ie, young, elderly, and stroke). The 3 and 7 items of the SUS and SSQ, respectively, were averaged.

The means of the groups for the PGTQ and the IPQ questions were calculated per question and were displayed as histograms.

The change in level for every participant was computed by subtracting the starting level from the levels they were in the consecutive rounds. This change of level was used as a performance measure and visualized as the level change over time relative to the starting level. The position over time of the hand was illustrated by plotting the controller x-y position over time.

The difference in search time between the young group and elderly group was calculated using a 2-sided t test. For the neglect group, a Pearson correlation was calculated between neglect severity (CoC in stroke group) and the mean search time of targets in the VR game. For the statistical analysis, the alpha was set to 0.05.

All analyses and visualizations were performed with R [57] and MATLAB [58].

Results

Questionnaires

In step one, the feasibility and usability of the task were assessed in 2 groups: young and elderly healthy participants. The analysis of the SUS scores (mean of the 3 questions; see Table 3) revealed high usability in both groups (Table 4). Both young and elderly participants reported that they would even like to play the task frequently (mean scores: young, 3.95, SD 0.74; elderly, 4.04, SD 1.26).

In general, almost no side effects were reported, as assessed with the SSQ score (mean of the 7 domains; see Table 3). In the young group, the mean score reflected minimal side effects (Table 4). More precisely, only 3 young participants reported severe side effects in 1 of the 7 domains (2 cases of stomach awareness and 1 case of dizziness). In the elderly group, the mean score was similarly low (Table 4). Only 1 elderly participant reported a severe side effect (sweating).

The PGTQ consisted of 4 questions (for details, see Table 3) concerning motivation, frustration, challenge, and entertainment. The participants of both groups were very motivated (mean scores: young, 6.38, SD 1.12; elderly, 6.73, SD 0.46), entertained (mean scores: young, 6.28, SD 0.56; elderly, 5.83, SD 1.70), and not frustrated (mean scores: young, 2.57, SD 0.90; elderly, 1.83, SD 1.44). The extent to which the task was challenging was rated above midline in both groups (mean scores: young, 4.29, SD 0.90; elderly, 5.61, SD 1.23).

The question for immersion (mean scores: young, 3.81, SD 0.75; elderly, 3.96, SD 1.02) and presence (mean scores: young, 4.24, SD 0.70; elderly, 4.48, SD 0.59) were rated high in both healthy groups (Figure 3).

In step two, the feasibility of the task was assessed in patients with neglect. Patients with neglect rated the task as highly usable (Table 4), and almost no side effects were reported on the SSQ (Table 4). More precisely, none of the patients reported any severe side effect. Only 3 patients reported side effects. One patient reported moderate sweating, while 2 others reported mild sweating and mild headache.

According to the PGTQ scores (Figure 3), the patients were highly motivated (mean 6.18, SD 1.17), entertained (mean 6.27, SD 0.79), and not frustrated (mean 1.91, SD 0.70). Furthermore, the degree of challenging score was around the midline (mean 3.82, SD 1.33; ie, most patients rated the task as neither too difficult nor too easy). The patients felt high immersion (mean 3.64, SD 1.43) and presence (mean 4.09, SD 0.83)

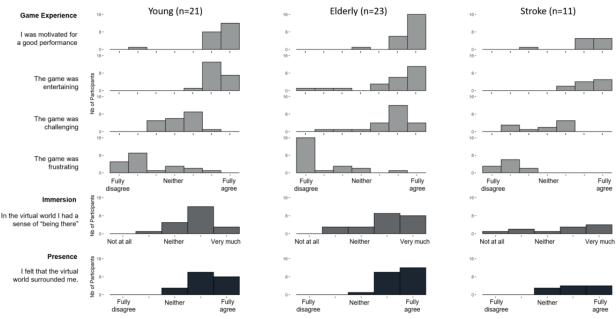
Table 4. Results of the System Usability Scale (SUS), where 1 means "unusable" and 5 means "very usable," and the Simulator Sickness Questionnaire (SSQ), where 1 means "None" and 4 means "Severe" side effects.

Study group	SUS, mean (SD)			
Young	4.41 (0.49)	1.42 (0.45)		
Elderly	4.46 (0.73)	1.27 (0.24)		
Stroke	4.73 (0.44)	1.05 (0.10)		



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Figure 3. Igroup Presence Questionnaire results from the healthy participants (young, elderly) and the patients (stroke).



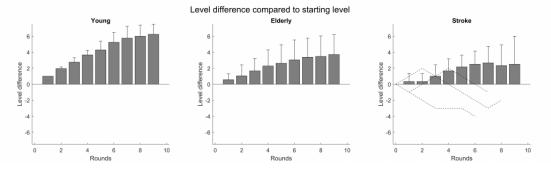
Adaptive Difficulty Scaling

In all 3 groups, the qualitative illustration of the increase in the level differences shows a plateau over time (Figure 4).

In young participants, a steep increase in the level difference (ie, the levels get more difficult) was found at the beginning of the task, reaching a plateau (optimum difficulty) at a level that was close to the possible maximum of 7 increases. There were only 7 increases possible because they started at level 8, meaning they could level up to 15 by increasing their level 7 times.

In elderly participants and stroke patients, the increase in the level difference revealed a more moderate and heterogeneous change over time. Both groups needed more rounds to reach their optimum; compared visually, this optimum was lower than in the young group.

Figure 4. Level difference (and standard error) in the number of levels over the round compared to the starting level. In the neglect-group for the bars, only the 6 patients that played for 10 rounds were included. The raw values are included for the other 3 patients. The level difference is the mean of the difference between the level in round x minus the starting level.



In-Game Measures

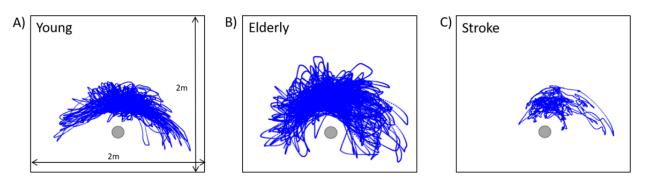
Controller Position Over Time

During the task, the controller position was continuously recorded and could be extracted for offline analysis. Figure 5 presents the exemplary data of the controller position (highlighted in blue) for one participant per group.



In the exemplary participants of the young group (Figure 5A) and the elderly group (Figure 5B), the controller movements were symmetrically distributed. In the exemplary participants of the stroke group (Figure 5 C), a narrowing of the movement as well as a clear rightward shift can be observed: The patients' hand movements mainly took place within the right hemispace due to left neglect.

Figure 5. The 3 panels show 3 exemplary controller movements (within a 2x2 m space), which represents the participant's hand movement around the participant's position (grey circle) over the total course of the task.

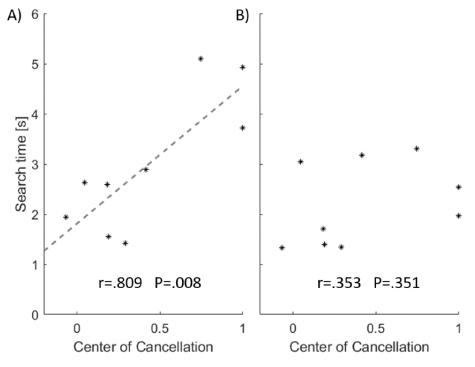


Search Time

The mean search time in young (mean 1.533, SD 0.342) and elderly (mean 1.694, SD 0.275) participants did not significantly differ ($t_{38.4}$ =1.71, P=.095). There was a significant, strong correlation between the mean search time and neglect severity (ie, the CoC in the SNT; r=0.70, P=.037; [59]). An additional analysis investigating the correlation between search time per

hemispace (ie, targets appearing within the left vs right hemispace) and neglect severity revealed a hemispace-dependent effect (Figure 6). A significant correlation was found for targets appearing within the left hemispace (r=.809, P=.008; strong correlation [59]). However, for targets appearing within the right hemispace, no significant correlation was found (r=.353, P=.351).

Figure 6. Correlation between the Center of Cancellation (CoC; as an objective measure of neglect severity) in the Sensitive Neglect Test (SNT) and the mean search time for the (A) left hemispace and (B) right hemispace in patients with neglect.



Discussion

For this study, we developed and evaluated a dynamic visual search task in iVR. As hypothesized, the task could easily be adapted to different skills, impairments, and experience levels. Further, the developed system has high usability and acceptance and resulted in only slight or no side effects in healthy participants and in right-hemispheric stroke patients with hemispatial neglect.

Questionnaires and Feedback

The ratings for usability and acceptance of the bird search task were high in both healthy participants and stroke patients with hemispatial neglect. This result is in line with previous findings from studies investigating the acceptance of HMD-VR in elderly [60,61], studies using VR for neglect diagnostics [51], and studies in which a similar VR setup was used to apply audio-visual stimulation in critically ill patients [62].

Regarding side effects, overall, only slight to none were reported. Furthermore, the nature and intensity of side effects

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were in line with the literature [51,54,62]. In the group of patients with neglect, no severe side effects were reported (only 1 participant reported moderate sweating). This is potentially due to the game adaptations (eg, slower targets require slower head movements), simplification, and individual adjustments performed for the patients in step two. This low rate of side effects is also in line with the high values for immersion and presence, as those correlate negatively [63].

The game experience was assessed by means of a questionnaire with 4 parts (frustration, degree of challenge, entertainment, motivation). Indeed, motivation, entertainment, and low frustration levels are crucial aspects for any possible future application [64]. In the bird search task, all participants were highly motivated, entertained, and even though not all participants found all targets, they did not feel frustrated. In particular, the group of patients with neglect had high levels of motivation and entertainment and low frustration levels due to 2 possible reasons. First, this might be the result of the adaptive difficulty scaling; second, this could be the result of the ability to individualize the starting conditions to the patients' needs and abilities. According to the literature, high motivation is also in line with the high values for immersion the participants reported [31,32,65,66].

Interestingly, the question as to whether the task was challenging was answered very differently among the 3 groups. While elderly healthy participants reported the task to be very challenging, the young healthy participants did find it rather easy. This difference between the elderly and young groups is not surprising, as most of the participants in the elderly group did not have any VR experience, whereas the young group was rather experienced in VR. The distribution of answers in patients with neglect was rather spread, indicating that, for some patients, the task was not particularly challenging, while for others, it was. A possible explanation for this result might be found in the individual settings adapted for the group of patients with neglect. As the individual performance level was estimated, some might have been under- or overestimated. Nevertheless, even if the performance level of some patients with neglect would have been under-or overestimated, according to their ratings, they were still highly entertained and motivated.

Difficulty Levels and Adaptive Difficulty Scaling

The descriptive analysis of the change in difficulty levels over time evidenced that the participants in the young group showed a steep increase in the initial phases of the task, suggesting a higher balance point than the one they started with. In the elderly group, the initial increase was less steep, but it was still clearly observable and gradual over time. In the neglect group, the initial increase seems to be delayed, but over time, there is a level increase relative to the starting level. This might be due to the attentional impairments and other cognitive deficits, resulting in a need for more rounds to get better at the game. Nevertheless, based on this measure, we could show that the individualized task was able to adapt to the individual level of impairment of the patients over time and thus keep them motivated and not overwhelmed [18].

Therefore, as the feedback regarding motivation and frustration assessed by means of the questionnaires shows clearly, the

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adaptive difficulty scaling was able to address the issue of very different skill levels and different progression speeds across participants.

In-Game Measures

VR tasks offer several opportunities to individually evaluate participants' task performance using in-game measures. One of these possibilities is the analysis of the hand position over time, reflecting the spatial search behavior of the participants. As patients with neglect typically fail to explore the contralesional space, the assessment of the individual hand movements may be a valuable parameter to characterize neglect manifestations and severity. Indeed, in exemplary data sets, we were able to show typical neglect patterns (ie, healthy participants move their hand in the peripersonal space symmetrically during the search, whereas for patients with neglect, these movements are limited within the left, contralesional side).

Another parameter to estimate the ecological validity of the task in patients with neglect is the average search time relative to the objective neglect severity. Our results revealed the typical neglect pattern [37,67]; the worse the neglect — as measured by the CoC — the more time the stroke patients needed to find targets appearing within their contralesional, left side.

Limitations

The main limitation of the present study is the small sample size of the neglect group and the fact that the patients were not assessed with a comprehensive test battery (ie, including other measures of neglect severity like behavior in free visual exploration [6], other cancellation tasks [68], or line bisection tasks [69]). Furthermore, even though the group was age-matched, there were mainly male participants in the group of healthy elderly participants, and as they were all chess players, the generalizability of the results in this group are limited. For this, further research with a more representative sample would be needed.

Due to the 2-step process, no direct comparison of the in-game performance between participants with normal and impaired visual exploration behavior was possible.

Outlook and Conclusion

The presented bird search task was shown to be entertaining, motivating, and even immersive. Due to the implemented difficulty levels, it adapted well to different populations with different skills and previous VR experience and even in patients with cognitive disturbance after stroke. In particular, the bird search task seems to be able to pick up on typical patterns of neglect and to correlate with the results of established instruments.

Future studies should investigate and evaluate these aspects for potential application in diagnosis or therapy. For the further evaluation of the potential diagnostic or rehabilitative value, the frequency and duration of playing the task should be investigated in a longitudinal randomized clinical trial. Furthermore, the tool should be compared with the standard care of patients with neglect.

Acknowledgments

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Authors' Contributions

SEJK, SMG, DC, BCK, RMM, T Nef, and T Nyffeler designed the study. SEJK, SMG, and T Nef developed the tool and the setup. SEJK, BCK, and PU recruited the participants. SEJK, BCK, T Nef, and RMM analyzed the data. SEJK, DC, BCK, and PU wrote the manuscript. All authors approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CBS: Catherine Bergego Scale CoC: Center of Cancellation HMD: head-mounted display IPQ: Igroup Presence Questionnaire iVR: immersive virtual reality PGTQ: Perception of Game Training Questionnaire SNT: Sensitive Neglect Test SSQ: Simulator Sickness Questionnaire SUS: System Usability Scale

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The Influence of Gamification and Information Technology Identity on Postadoption Behaviors of Health and Fitness App Users: Empirical Study in the United States

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Abstract

Background: The use of health and fitness apps has been on the rise to monitor personal fitness and health parameters. However, recent research discovered that many users discontinue using these apps after only a few months. Gamification has been suggested as a technique to increase users' interactions with apps. Nevertheless, it is still not clear how gamification mechanisms encourage continued use and inspire user self-management.

Objective: The main objective of this study was to articulate how gamification mechanisms in studies of designing and using health and fitness apps can contribute to the realization of information technology (IT) identity and positive behavioral outcomes. The broader goal was to shed light on how gamification mechanisms will translate into positive use behaviors in the context of mobile health apps.

Methods: Data were collected from 364 users of health and fitness apps through an online survey to empirically examine the proposed model.

Results: Based on identity theories, this study suggests the fully mediating role of IT identity to describe how gamification elements can lead to continued intention to use health and fitness apps, and increase users' tendency for information sharing through the apps. The findings indicate that perceived gamification can increase users' IT identity. In turn, a higher IT identity would encourage users to continue using the apps and share more personal health information with others through the apps.

Conclusions: The results of this study can have practical implications for app designers to use gamification elements to increase users' dependency, relatedness, and emotional energy associated with health apps. Moreover, the findings can have theoretical contributions for researchers to help better articulate the process in which gamification can be translated into positive use behaviors.

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KEYWORDS

gamification; health and fitness apps; IT identity; continued intention to use; information-sharing tendency; mHealth; app design; user interaction

Introduction

Mobile Health

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In recent years, many companies have invested in developing mobile health (mHealth) apps. The concept of mHealth is

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defined as a medical and public health practice supported by mobile devices and applications [1], including using a mobile app to monitor a patient's blood pressure remotely or using an app to monitor, control, and track personal health data for fitness or diet purposes. mHealth provides an alternative to improve communication, care delivery, real-time medication monitoring,

and adherence support [2]. mHealth technologies have the potential to significantly impact health care and health outcomes [3]. The increasing adoption of smart devices and the development of health and fitness apps have enlarged the growth of the mHealth market. Despite the large number of health care apps developed, the majority have encountered issues of underutilization and decline in user eagerness [4].

Gamification in mHealth

Different health-related apps have attempted to leverage various techniques to attract and retain more users and enhance user interactions. One of the frequently used methods is creating a gameful design for health app services [5]. Gamification in services is defined as "a process of enhancing a service with affordances for gameful experiences in order to support user's overall value creation" [6]. Structural gamification uses game elements to encourage users to attain a goal. Structural gamification does not modify the content of a process but instead changes the structure of that process [7]. Gamified elements used in mHealth are important to enable user self-management. Gamification mechanisms in developing health and fitness apps include badges, leaderboards, points and levels, challenges and quests, as well as social engagement [8]. For instance, badges are used to identify individual achievements in accomplishing goals, whether relative or nonrelative to other peers [9]. There are many health apps with gamification mechanisms currently available, such as mySugr with a challenges mechanism, RunKeeper with leaderboards and social engagement elements, and Fitocracy with badges.

As the mHealth market size is booming, gamification is now recognized as an influential factor affecting self-engagement in care management. However, approximately 80% of apps that use gamified elements will fail due to the poor design of gamification mechanisms [10]. Gamification is an engaging mechanism of video games used in nonvideo game contexts [11]. However, game design elements would not lead to more engagement or continued intention to use health apps if they cannot trigger users' dependency, relatedness, and emotional energy associated with the apps. Previous studies indicate that using gamification elements may not be sufficiently exciting for users to continue using the apps without further motivation and reinforcement [12]. This is why many users discontinue using health-related apps (even gamified apps) after only a few months [13]. Thus, gamification mechanisms may encourage people to interact with the apps; however, they cannot necessarily guarantee continuous engagement of users with their health apps to control their health status or check personal health information.

Using self-management tools to monitor health information is consistent with the premises of patient-centered health models, which consider more control and responsibilities for patients as an important stakeholder in the health care ecosystem [14]. Nevertheless, little is known about how gamification mechanisms can motivate people to actively use health and fitness apps, and share their personal health information through such apps [15]. Thus, further research is required to investigate users' beliefs and perceptions of their health apps to uncover the missing link between gamification and positive use

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behaviors. To fill this gap, the concept of information technology (IT) identity was adopted as a theoretical basis for this study to describe how gamified health apps can result in increased use behaviors and improved information sharing through apps.

IT Identity

Previous studies have examined the topic of IT and identity and their relationship using different approaches [16]. For instance, one method treats IT as part of self-perception and identity to explain who people are in relation to IT. This approach proposes the possibility of viewing IT as an integral part of the self. One study highlighted that technology could be an essential part of people's identities if they are emotionally attached to it [17]. IT identity is conceptualized using theories on social structures and self-concept to describe how people categorize themselves in relation to an IT object [18]. Thus, IT identity is defined as the extent to which the use of IT is saliently related to who people think they are (self-identification) [19]. IT can affect people's self-perceptions by activating their original selves in using IT's capabilities and resources. In turn, using IT frequently, individuals may feel empowered, creative, independent, and accessible. Through gamification elements such as points, leaderboards, and challenges, gamified health apps can be integrated into a user's sense of self as they may spend a significant portion of their time interacting with the apps as a repeated behavior. This point is consistent with previous studies proposing that repeated behaviors may directly lead to identity recognition if such interactions initiate emotion, dependence, and affiliation [20]. In the context of gamification, individuals may use gamified health and fitness apps to become autonomous in controlling their fitness and wellness, monitoring physical changes, and managing emergency cases. These functionalities may enrich users' original self-perceptions and make them feel autonomous, empowered, and capable. Thus, gamification elements may elevate users' IT identity, and inspire them to continue using the apps and share more health information with other users through gamified features.

Objectives and Research Questions

The main objective of this study was to examine how gamification mechanisms in studies of designing and using health and fitness apps can contribute to the realization of IT identity and positive behavioral outcomes. IT identity may provide a possible foundation for answering questions about how individuals become more likely to continue using the apps and share their personal health information with others using a gamified health app. The main hypothesis of the study is that gamified health apps will lead to positive use behaviors only when a strong IT identity related to the apps is activated. Consistent with the study objective, a research model was developed by drawing on the recent appearance of the IT identity concept in the information systems literature, which was adapted for using health and fitness apps. In short, this study addresses the following questions: (1) Can gamification mechanisms influence users' continued intention to use apps and their information-sharing tendency? (2) Does IT identity fully mediate the relationship between perceived gamification and positive use behaviors?

Literature Review

Gamification Mechanisms in Health and Fitness Apps

According to Werbach [21], gamification is the process of making activities more game-like. Thus, a combination of components that constitute games can result in the holistic experience of gratefulness. Robson et al [12] define a framework consisting of three gamification principles—mechanics, dynamics, and emotions—to explain how gamified experiences can be created. Previous studies highlight that gamification can be used in different contexts to affect individuals' behaviors or attitudes [22].

Gamification is composed of two subcategories: structural and content gamification. Using structural gamification, designers leverage some game elements (such as digital badges and leaderboards) to encourage users to achieve a goal [23]. Content gamification modifies content to make it more game-like. An example of this type of gamification would be adding story, challenge, curiosity, mystery, and characters to change content to engage the learner [24]. There are different gamification mechanics; however, the commonly used game elements in mHealth apps can be categorized into five main groups: badges, leaderboards, points and levels, challenges and requests, as well as social engagement loops and onboarding [10].

Badges are used to identify and reward individual achievements. Users can achieve badges by completing the task described. Gamified apps use a dashboard to provide a summary of all badges obtained by users. Digital badges enable users to visualize their performance and review their personal progress [25]. For instance, users of a fitness tracker app should enter some details (eg, weight lifted or distance run) to pass a threshold value and achieve a badge. Leaderboards mainly rank individual user progress and achievements as compared to their peers. Users understand what constitutes their position on the leaderboard compared with their peers [26]. For instance, users of a fitness tracker app may see how they are ranked compared to their peers in the context of their local and global networks.

Points and leveling systems are implemented to inform the user of their level of familiarity, and reward continued expertise and knowledge using the system. Progress bars are also a standard feature of points and levels, where users can monitor how many points they have already attained along a continuum and how many more points they need to obtain to move up to the next level [27]. For instance, users of a nutritional supplement manager app will advance to higher levels by achieving points. This process is reinforced by tangible rewards in cash and the intrinsic reward of effectively using the app to manage their regimen. Continued challenges and quests may motivate users to interact with the app frequently, especially where these challenges confirm their understanding of the app's goals [10]. For example, users with diabetes may complete daily challenges, and an avatar provides feedback to them concerning whether they have taken satisfactory steps in managing their diabetes for the day. Finally, social engagement loops enable information sharing between app users. The integration of social media platforms such as Facebook and Instagram into health and fitness apps can increase user enjoyment and engagement through

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personal information sharing [10]. Users may want to share health-related data and personal achievements from their apps to nurture social capital with other users and gain support from these peers. The social loops also facilitate onboarding in which new users can join the network via invites from existing users. For instance, users of a fitness tracker app will have an option to register through their Facebook or Twitter accounts. The "friends" tab then enables users to find their friends and add them to their personalized fitness network. Thus, users can exchange fitness challenges with their peers, and track and post their progress on social media.

IT Identity in the Context of Health and Fitness Apps

Previous studies suggest that using IT can expand the actual self along with the meanings and insights related to the self [28]. By incorporating health and fitness apps into routine health-related activities, achieving personal goals and challenges (such as diet, nutrition, and heart rate) will be significantly dependent on using the apps [29]. Technology's functionalities and capacity can amplify individuals' personal and social resources in attaining their goals [30]. Health and fitness apps allow users to expand the self by offering valuable resources and capabilities that help them accomplish self-management goals. As mentioned in previous research, identities can be altered through interventions such as interactions with IT [31]. IT identity can be actualized when individuals frequently engage with technology as an end user. Some technologies are more likely to foster IT identity than others because users may consider them an inherent part of themselves, affecting their behavioral choices. For instance, health and fitness apps are consumer IT that can become part of users' identities due to their routine use for self-monitoring and self-management purposes [32]. As individuals frequently interact with different features of health and fitness apps to check their health status, the apps provide self-confirming feedback to users, which in turn nurtures their IT identity.

IT identity represents the extent to which the use of a target IT contributes to the sense of self and self-identification [18]. IT identity associated with a target IT is reflected in users' emotional reactions (emotional energy, relatedness, and dependence) to thinking about themselves in relation to the IT with which they interact. Thus, IT identity consists of three subdimensions: relatedness, dependence, and emotional energy attached to IT [18]. Relatedness refers to a sense of connection felt when interacting with a target IT. Users' perception of the self and what they can do with a target IT is a function of a strong connection with the IT [33]. For example, when individuals with stronger IT identity think of themselves in relation to health and fitness apps, they see themselves as linked with the apps. Emotional energy refers to the emotional attachment, passion, and self-assurance that users associate with a target IT when thinking about their interaction with it. Enduring user-IT engagement can elevate the user's emotion and confidence with the IT, and allow the user to be more spontaneous with the technology [34]. For instance, when individuals with formed IT identity think of themselves with their health and fitness apps, they feel enduring enthusiasm about the apps. The dependence dimension describes how individuals rely on a target IT to characterize their

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self-perceptions. For instance, people may need to rely on digital communication platforms to manage their relationships with others and meet social expectations [35]. When individuals with activated IT identity think of themselves with health and fitness apps, they feel that they can count on the apps to monitor their health and fitness data.

Hypotheses Development

Gamification and IT Identity

The main proposal of this study is that gamified features of health and fitness apps influence individuals' self-identification with a target technology. Theory on IT identity suggests that technologies with broad application across social situations (eg, mobile devices and software applications) are most highly expected to enact IT identity [18]. Gamification mechanisms are mainly applied to health and fitness apps to better engage users to monitor their health status and check their personal information. On this basis, the gamified elements can influence individuals' IT identity via two means: (1) giving more control over the apps through gamified and customizable features and (2) intrinsic benefits that foster emotional responses in relation to the apps.

There is evidence to support that self-identification of individuals with material objects that they can manipulate are more likely to be activated than with those they are less likely to exercise control over [19]. Interactions with the gamified features of apps result in feelings of mastery, competence, and a belief in one's ability to control health-related tasks (such as health status monitoring). For instance, individuals who can choose to achieve specific digital badges, participate in customized challenges, and share their data on selected social platforms are more likely to identify with the app than those who cannot. A fitness app provides users with a personalized meal plan and workout plan consistent with a chosen body goal. Thus, when an individual connects gamified elements while exercising control over an app, the subsequent feelings of competency and passion will create a sense of adapting to the app's gamified feature set. Consequently, this evaluation positively shapes the user's self-identification with the technology.

Previous research indicates that individuals need some degree of internal gratification to initiate and continue a job [36]. People are more likely to activate identities that generate more intrinsic enjoyment and satisfaction than those with few material benefits [37]. According to identity theories, the level of benefits (such as emotional attachment) offered by a target IT could foster positive self-identification with the IT [38]. Gamified apps can build emotional responses through increasing enthusiasm, dependence, and affiliation in relation to the apps. Net benefits (such as energy, joy, and connection) that users associate with use of an IT can motivate users to identify the self with the IT [39]. Previous studies highlight that the intrinsic benefits positively impact emotional responses to an IT through the sense of reliance and dependence on the IT [40]. For example, rewards and incentives (such as points and badges) offered by health and fitness apps will lead to more engagement and connection with the apps. Gamified features motivate users to complete the task described to achieve their personal goals and gain defined

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rewards (eg, reaching better positions relative to others in the ranking system). Gamification mechanisms incentivize users to earn inherent benefits (such as informational and emotional support) by sharing personal data on social engagement loops. Moreover, people are more likely to consider IT an integral part of their self-concept when interactions with IT can improve their desired self-image [41]. For example, a gamified app will provide useful feedback to users to take adequate steps and attain their preferred self-concept. Therefore, the first hypothesis is as follows:

H1: Perceived gamification mechanisms used in health and fitness apps positively influence users' IT identity.

IT Identity and Positive Use Behaviors

Recent studies recognize a need for alternative theoretical perspectives to examine technological and individual factors in the postadoption stage of using IT [13]. For instance, the concept of IT identity, which reflects positive self-identification using familiar technology, can encourage positive IT usage [19]. IT identity offers a richer understanding of users' postadoption interactions with IT. For instance, users with a strong IT identity are more likely to explore different IT features and use them to complete additional tasks [18]. In the context of personal health devices, a recent study showed that IT identity is positively associated with feature use behavior and enhanced use behavior [15]. On the same basis, individuals' emotional responses to themselves concerning health and fitness apps may motivate them to continue using the apps. Users with a stronger IT identity are more dependent, related, and emotionally connected to the apps they are using. Thus, this strong sense of connection and enthusiasm they attach to the apps inspire them to keep up with the apps.

IT identity affects how people use the various features of personal health devices in different situations [15]. When individuals consider a health and fitness app an integral part of the self, they may become more likely to continue using a significant number of its features in the future. Higher levels of emotional energy, confidence, and dependency attached to the apps may motivate users to continue interacting with the apps and explore new functionalities. Users with an activated IT identity tied to health and fitness apps would desire to carry on with its features to achieve multiple health-related purposes. For example, they may continue with the apps to track activity, diet data, calories burned, and control fitness as well as wellness data [42]. Therefore, the second hypothesis was framed as follows:

H2: IT identity attached to health and fitness apps positively influences continued intention to use the apps.

A feeling of dependency and enthusiasm in relation to mHealth apps can result in continuous, effective, and long-term use [16]. One line of evidence supporting the effective use of mHealth apps is their application to disclose health information in the hope of receiving more accurate feedback [43]. Users with a strong IT identity are more likely to develop autonomy to use interactive apps; thus, they become more open to deliberately

share further personal health information to complete additional health-related tasks. A sense of connection and dependence on an app may assure users to reveal more health data to better accomplish fitness and wellness goals. Moreover, they may share personal information to seek new ways of using the apps in other situations to fulfill the optimal self-identity expression [44].

Positive emotional energy between users and a health app may empower them to discover previously unused features [18]. Using feature extensions may indicate sharing more personal information, and allowing the apps to access their data to participate in more challenges and obtain extra points. For instance, exploring an underutilized set of features may require users to frequently report their health status every week. The sense of connection and enthusiasm may give more confidence to users to disclose more data for performing tasks such as monitoring and checking health measures. Thus, individuals with a stronger IT identity may desire to verify themselves by sharing personal data to use broader features of a health and fitness app.

IT identity can stimulate users to explore more resources and capabilities offered by the health and fitness apps. For example, IT identity holders who were unaware of remote care and medical surveillance afforded by a health and fitness app will attempt to reveal more personal data to explore these capabilities and add these services to their to-do list. Thus, attraction toward the app may encourage individuals to share more personal data to find new situations to apply the apps in the daily roles they maintain. Individuals with a strong IT identity may actively involve collecting more facts about an IT's features to use them for additional tasks [45]. Holders of IT identity may search for more information, educate themselves about the apps' features and requirements, and share more personal data to use new and existing features to perform various health-related tasks, leading to the following hypothesis:

H3: IT identity attached to health and fitness apps positively influences information-sharing tendency.

Mediating Role of IT Identity

The related literature indicates that gamified features of mHealth apps are necessary but not sufficient to motivate users to keep up with the apps or encourage them to share their personal health information [46]. Applying various gamification mechanisms to health and fitness apps is insufficient because they alone cannot shape postadoption behaviors (such as information sharing and continued intention to use the apps). Previous studies demonstrate that users will not continue using gamified apps or are not likely to disclose their health information simply because they have gamified designs [47]. On the same basis, gamification mechanisms may result in positive use behavior only if the gamified design first fosters IT identity. The activated IT identity in relation to the gamified apps will then lead to positive postadoption behaviors. Thus, gameful and playful designs should first form the feeling of emotional energy, dependence, and relatedness in relation to the apps, and then in return intensify intention to stay with the apps and share more personal health information via the apps. This proposal is formally hypothesized as:

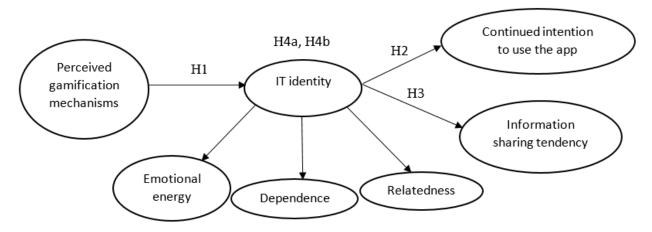
H4a: IT identity attached to health and fitness apps fully mediates the relationships between perceived gamification mechanisms and continued intention to use them.

H4b: IT identity attached to health and fitness apps fully mediates the relationships between perceived gamification mechanisms and information-sharing tendency.

Research Model

According to the theoretical rationale for the proposed causal relationships, the research model presented in Figure 1 was developed to guide this study. This research model suggests a framework to examine the effects of perceived gamification on positive use behaviors. In particular, the model proposes that perceived gamification mechanisms used in health and fitness apps directly foster IT identity, which positively shapes continued intention to use the apps and information disclosure willingness. The model further posits that IT identity in relation to the apps fully mediates the relationship between perceived gamification and positive use behaviors.

Figure 1. Research model. IT: information technology.



It should be mentioned that, consistent with prior studies, IT identity is considered as a second-order construct with three reflective factors [48]. The rationale behind this measurement is that IT identity is reflective of the three dimensions (ie, relatedness, emotional energy, and dependence) and the expected interactions among them. Therefore, all of these dimensions can reflect the same theme and may covary. According to Kayhan [49], reflective modeling is a better option than formative modeling when first-order factors are expected to interact, correlate, or share a common theme. Thus, a set of interrelationships among these three factors is an essential component of measuring IT identity.

Methods

Research Approach

To achieve this study's objective, an online survey was administered to examine the proposed relationships between gamification mechanisms, IT identity, and positive use behaviors. First, a scenario was designed about why people are attached to their health and fitness apps by describing the "IT identity" and "gamification" concepts. One screening question limited the participants to those who used a gamified health app to monitor, control, and track health data for physical activities, weight loss, fitness, or diet purposes. Respondents were then asked to fill out the survey considering one health or fitness app (with gamification aspects) that they used. For instance, when a respondent named MyFitnessPal as the app that they used,

they would answer all questions with consideration of that particular app. The logic behind this filter was to measure perceived gamification mechanisms and IT identity in relation to a target IT (ie, a specific mHealth app). This enabled examining the roles of gamification and IT identity in shaping positive use behavior (ie, continued use and information-sharing tendency) associated with that particular app.

Moreover, respondents were asked to describe how long and how often they used the app and to what extent they were familiar with the particular app they mentioned. In the second section of the survey, respondents were asked to think about the scenario that they read in the survey, and express their perceptions about the gamification mechanism designed for the app, IT identity in relation to the app, continued intention to use the app, and willingness to share information with the app. The next section of the survey was dedicated to demographic variables and general IT experience questions.

Survey Development

The approach used to measure the variables of the research model was based on existing literature. The survey items were adapted from previously validated surveys with slight changes made to fit the context of this study. The description of the proposed variables and the sources used to develop the questionnaire are provided in Table 1. The measure items (ie, all the questions included in the survey) are listed in Multimedia Appendix 1.

Construct	Construct definition	Source
Perceived gamification mechanism	The extent to which an app uses gamification elements (such as badges, leaderboards, points, challenges, and social engagement) in its design	Miller et al [10]
IT ^a identity	"The extent to which an individual views use of an IT as integral to his or her sense of self"	Carter and Grover [18]
Continued intention to use the app	The extent to which an individual is willing to continue using an app	Karahanna et al [50]
Information-sharing tendency	The extent to which an individual is likely to disclose his/her personal health infor- mation through an app	Bansal and Gefen [51]

^aIT: information technology.

Pilot Test

Once the initial questionnaire was developed, six professionals in the health app domain were consulted to improve the content validity of the study, and finalize the gamification mechanisms and the questions used in this study. Consistent with the experts' suggestions, the terms used to define gamification were modified, and the scenario and questions were improved to ensure that they were sufficiently transparent and easy to understand for the public. Face validity was then performed with 23 students (6 PhD candidates, 7 with Master's degrees in information systems, and 10 undergraduate students) to ensure that the readability and wording of the questions were acceptable and consistent with the objectives of the study. Thus, some ambiguous terms were reworded, and technical language and jargon were removed so as to describe the scenario in the most understandable way. Finally, prior to the main data collection, a pilot test was performed with 152 undergraduate students at

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a large university in the southeastern United States to ensure that the instrument had acceptable reliability and validity. The Cronbach α was computed for each construct (ie, perceived gamification mechanism α =.91, IT identity α =.90, continued intention to use the app α =.94, and information-sharing tendency α =.90). All Cronbach α values were above the cut-off point of .70, indicating that the instrument was internally consistent [52].

Data Collection

Data collection was performed in October 2020 through Amazon's Mechanical Turk (MTurk). Previous studies have provided strong evidence to show that MTurk is a suitable survey tool to collect individual-level data [53]. According to Behrend et al [54], subjects recruited using MTurk are more representative of the US population in terms of age, gender, race, and work experience. Moreover, data collected through MTurk have been reported to be more reliable than those obtained through traditional data collection means, and meet

the standards of social behavior studies [55]. Researchers as requesters can use this crowdsourcing website to reach out to potential subjects (ie, MTurk workers) in numerous countries to conduct a survey.

Several studies have compared MTurk to conventional data collection methods in the health and medical literature. The vast majority of these studies support the use of MTurk for a variety of academic purposes (eg, in health care research) [56]. Existing literature in clinical research highlights that due to a large number of users, the MTurk population is more representative of the US population at large than other online surveys [57]. In this study, the respondents' location was limited to the United States. The incentive for participation was a monetary reward (US \$1). The average completion time for the three groups was 4.3 minutes, which implied acceptable responses in terms of the time spent by respondents to complete the survey. Initially, 395 respondents attempted the survey.

As reported in previous studies, one main concern in online data collection is that subjects choose answers randomly or participate with less attention [58]. Therefore, two filters were used in this study to enhance the quality of the collected data. First, participation was restricted to MTurk workers with a high reputation (at least 80% approval ratings). Second, another solution for detecting careless, rushed, or haphazard answers in behavioral research is using "captcha" questions [59]. Thus, attention check questions were used to identify and exclude responses of participants who simply picked an answer choice without reading the questions or did not correctly answer reverse-coded filler items [60]. Insufficient answers and dropped responses that failed the response quality questions were removed. After removing unsatisfactory answers (31 data points), the final set of valid and useable responses included 364 samples.

Instrument Validation

Confirmatory factor analysis was performed using IBM SPSS AMOS (Version 22) to find evidence for convergent validity and discriminant validity. The results of model fit indices for the measurement model demonstrated a good fit (goodness of fit index $\chi^2_{2.92}$ =0.83, adjusted goodness of fit index=0.80, comparative fit index=0.90, normed-fit index=0.91, incremental fit index=0.90, standardized root mean square residual=0.02,

and root mean square error of approximation=0.03), all meeting their respective common acceptance levels.

Multicollinearity was checked by computing the variance inflation factor (VIF). The VIF values ranged between 1.218 and 1.551, which were below the cut-off value of 5 [52]. This confirmed that multicollinearity was not an issue in this study. Furthermore, because using a self-report survey can cause the common method variance issue, the potential for common method bias was carefully examined [61]. The Harman one-factor test was performed to check if the common method bias would be a considerable problem [62]. All factors together could explain 74.231% of the total variance, whereas none of the factors accounted for most of the covariance among measures (<20%). Thus, the test results indicated that common method bias is not a significant threat in the study sample.

According to Gefen et al [63], convergent validity can be determined by examining measures such as standardized factor loading, composite reliability, and the average variance extracted (AVE). The convergent validity test results are displayed in Table 2. The composite reliability values for all of the constructs in the model were above the threshold acceptance value of 0.7, highlighting the adequate reliability of constructs [64]. The reported standardized factor loadings for all of the constructs were found to be greater than 0.7, and according to Hair et al [65], a factor loading of 0.7 or greater is acceptable. The AVE was calculated using the standardized factor loading values for each of the constructs. All reported values of AVE were greater than 0.5, which is the minimum acceptable value [66]. These measures provided evidence that the convergent validity of the measurement model was acceptable. As the instrument validation results were satisfactory, no items were excluded from further analysis.

Discriminant validity analysis of the constructs was also performed. In Table 3, the main diagonal elements, representing a construct with itself, indicate the square roots of the AVEs, and the off-diagonal values represent the correlation coefficients between the constructs. All diagonal values were higher than 0.70 and exceeded correlations between any pair of constructs [67]. Therefore, the model fulfills the discriminant validity requirements, and it was assumed that the model also has adequate discriminant validity.



 Table 2. Results of convergent validity.

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Construct	Standardized factor loading (>0.70)	Composite reliability (>0.70)	AVE ^a (>0.50)
IT identity			
Relatedness		0.914	0.679
REL1	0.82		
REL2	0.80		
REL3	0.83		
REL4	0.86		
REL5	0.81		
Emotional energy		0.921	0.699
EMO1	0.83		
EMO2	0.85		
EMO3	0.84		
EMO4	0.82		
EMO5	0.84		
Dependence		0.915	0.682
DEP1	0.82		
DEP2	0.81		
DEP3	0.82		
DEP4	0.85		
DEP5	0.83		
Perceived gamification mechanism		0.907	0.619
PEG1	0.80		
PEG2	0.77		
PEG3	0.79		
PEG4	0.79		
PEG5	0.81		
PEG6	0.76		
Continued intention to use the app		0.875	0.638
CIU1	0.73		
CIU2	0.81		
CIU3	0.83		
CIU4	0.82		
Information-sharing tendency		0.875	0.636
IST1	0.72		
IST2	0.72		
IST3	0.78		
IST4	0.80		

^aAVE: average variance extracted.



Table 3.	Results	of the	discriminant	validity test. ^a
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Construct	Mean (SD)	ITI-REL ^b	ITI-EMO ^c	ITI-DEP ^d	PEG ^e	CIU ^f	IST ^g
ITI-REL	3.664 (0.890)	0.824	0.514	0.523	0.311	0.371	0.338
ITI-EMO	3.865 (0.823)	0.514	0.836	0.598	0.369	0.114	0.319
ITI-DEP	3.937 (0.798)	0.523	0.598	0.825	0.301	0.125	0.248
PEG	3.639 (0.904)	0.311	0.369	0.301	0.786	0.431	0.374
CIU	3.938 (0.889)	0.371	0.114	0.125	0.431	0.798	0.372
IST	3.820 (0.853)	0.338	0.319	0.248	0.374	0.372	0.797

^aDiagonals in italics (construct compared with itself) represent the square root of the average variance extracted; off-diagonals are the correlation values. ^bITI-REL: information technology identity-relatedness.

^cITI-EMO: information technology identity-emotional energy.

^dITI-DEP: information technology identity-dependence.

^ePEG: perceived gamification mechanism.

^fCIU: continued intention to use the app.

^gIST: information-sharing tendency.

Results

Respondent Characteristics

Table 4 shows the participants' characteristics. The descriptive statistics were calculated with IBM SPSS version 27. The most frequent apps mentioned by respondents were Fitocracy, Fooducate, MyFitnessPal, My Diet Coach, RunKeeper, Strava, and JEFIT Workout. Slightly less than half of the respondents reported that they have been using the app for 6 months to 1 year, and slightly more than half of the respondents indicated that they used the app on a daily basis. The majority of participants (78%) stated that they were either "extremely experienced" or "very experienced" with the app they mentioned in the survey. The demographic data demonstrated that the respondents were fairly equally distributed in terms of gender.

Age range and income were normally scattered, with age range between 30 and 39 years and an annual household income between US \$50,000 and \$74,999 showing higher ranges among the provided categories. The majority of respondents were white, followed by African American and Hispanic. The majority of respondents had a full-time job. The most common education level was a bachelor's degree, followed by some college degree.

Regarding experience with general technology, the respondents were mostly familiar with mobile devices, with the majority (92%) rating themselves as either "extremely" or "very" familiar with mobile devices (such as phones and tablets). Concerning familiarity with health care technologies, approximately 73% of the respondents reported that they were either "extremely" or "very" familiar with mHealth apps. Finally, the majority of respondents participated in an online health community (eg, information sharing or posting comments).



 Table 4. Sample characteristics (N=364).

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Variable	Participants, n (%)
Gender	
Male	204 (56.0)
Female	160 (44.0)
Age (years)	
<20	15 (4.1)
20-29	84 (23.1)
30-39	146 (40.1)
40-49	66 (18.1)
50-59	33 (9.1)
≥60	22 (6.0)
Annual household income (US \$)	
<25,000	55 (15.1)
25,000-49,000	76 (20.9)
50,000-74,999	124 (34.1)
75,000-99,999	58 (15.9)
100,000-150,000	36 (10.0)
>150,000	15 (4.1)
Education	
Less than high school	4 (1.1)
High school graduate	33 (9.1)
Some college	95 (26.1)
2-year degree	40 (11.0)
Bachelor's degree	135 (37.1)
Master's degree	47 (12.9)
Doctorate	11 (3.0)
Employment status	
Employed full time	251 (69.0)
Employed part time	51 (14.0)
Unemployed	40 (11.0)
Retired	15 (4.1)
Student	7 (1.9)
Race/ethnicity	
White	189 (51.9)
African American	84 (23.1)
Asian	22 (6.0)
Hispanic	58 (15.9)
Mixed	7 (1.9)
Other	4 (1.1)
Apps used	
Fitocracy	142 (39.0)
Fooducate	66 (18.1)
MyFitnessPal	51 (14.0)

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Variable	Participants, n (%)
My Diet Coach	44 (12.1)
RunKeeper	33 (9.1)
Strava	18 (4.9)
JEFIT Workout	11 (3.0)
How long have you used the health app?	
Less than 6 months	36 (9.9)
6 months to 1 year	167 (45.9)
1-2 years	135 (37.1)
More than 2 years	25 (6.9)
How often do you use the health app?	
Daily	186 (51.1)
Weekly	138 (37.9)
Monthly	40 (11.0)
To what extent are you experienced with the particular health app y	you use?
Extremely experienced	153 (42.0)
Very experienced	131 (36.0)
Moderately experienced	66 (18.1)
Slightly experienced	15 (4.1)
To what extent are you familiar with mobile devices (eg, phones, tak	blets)?
Extremely familiar	244 (67.0)
Very familiar	91 (25.0)
Moderately familiar	25 (6.9)
Slightly familiar	4 (1.1)
To what extent are you generally familiar with mobile health apps?	
Extremely familiar	153 (42.0)
Very familiar	113 (31.0)
Moderately familiar	66 (18.1)
Slightly familiar	33 (9.1)
Have you ever participated in an online health community (such as ments)?	information sharing or posting com-
Yes	244 (67.0)
No	120 (33.0)

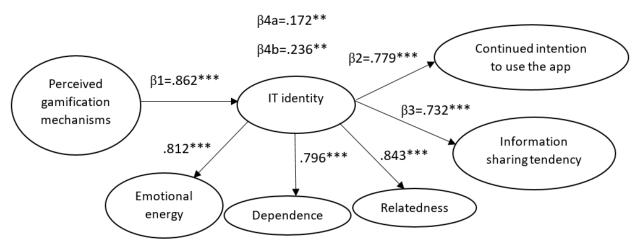
Structural Model

IBM SPSS AMOS (Version 22) was used to test the hypotheses within a structural equation modeling framework. According to Ho [68], the goodness of fit statistics can access the entire structural model and measure the overall fit. The normed χ^2 value was 2.03, which was between the recommended values of 1 and 3 [69]. The values for the comparative fit index (0.914), normed fit index (0.926), relative fit index (0.912), and Tucker-Lewis index (0.903) were above 0.9, and the standardized root mean square residual (0.034) and root mean

square error of approximation (0.058) were below 0.08 [70]. The value of the adjusted goodness of fit index was 0.921, which exceeded the threshold of 0.90. All mentioned measures of fit were in the acceptable range, and only the goodness of fit index (0.837) was marginal. Based on Kline [71], at least four statistical indices should meet the minimum recommended values. More than four indices satisfied the cut-off values in this study, which supported a good fit between the hypothesized model and observed data. Figure 2 exhibits the standardized path coefficients of the structural model.

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Figure 2. Model paths. IT: information technology. ***P*<.01, ****P*<.001.



Consistent with a previous study [18], IT identity was measured using three interrelated dimensions (relatedness, emotional energy, and dependence). In a reflective construct, dimensions have positive and significant intercorrelations as they share the same pattern [72]. The loadings (β values) were .812 for emotional energy, .796 for dependence, and .843 for relatedness. The results imply that the three dimensions of IT identity as first-order factors load significantly on the second-order construct. Thus, the combination of three dimensions reflects IT identity in relation to health or fitness apps.

Path coefficients were examined to assess the structural model. The results of the hypotheses testing are summarized in Table 5. The findings support H1 by showing that perceived gamification mechanisms significantly enact IT identity. H2 was also supported in which a higher IT identity in relation to health or fitness apps significantly shapes continued intention to use them. The findings also provided sufficient evidence to support H3, which indicates that users with a stronger IT identity in relation to health or fitness apps are more likely to share their personal health information via the apps. The indirect effect of perceived gamification mechanisms on continued intention to

use through enacted IT identity was significant. However, the direct relationship between perceived gamification mechanisms and continued intention to use was not significant (β =.031, P=.12). Thus, it can be concluded that the impact of gamification mechanisms on continued intention is fully mediated by IT identity, supporting H4a. The analysis also demonstrated that perceived gamification mechanisms indirectly help build information-sharing tendency through activated IT identity. Nevertheless, there was no significant direct relationship between perceived gamification mechanisms and information-sharing tendency (β =.071, P=.10). Therefore, there is sufficient evidence to conclude that IT identity fully mediates the relationship between perceived gamification mechanisms and information-sharing tendency, supporting H4b.

Finally, the model explained 74% of the variance in IT identity, 60% of the variance in continued intention to use the app, and 53% of the variance in the information-sharing tendency. These R^2 values suggested that the model provides relatively strong explanatory power to predict the variance in the positive use behaviors associated with health and fitness apps.

Table 5. Structural equation modeling results.

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Hypothesis	Path	Standardized β coefficient (SE)	P value	Critical ratio	Results
H1	PEG ^a to ITI ^b	.862 (.078)	<.001	11.160	Supported
H2	ITI to CIU ^c	.779 (.068)	<.001	10.812	Supported
Н3	ITI to IST ^d	.732 (.073)	<.001	10.847	Supported
H4a	PEG to ITI to CIU (Mediating role of ITI)	.172 (.081)	.009	2.625	Supported
H4b	PEG to ITI to IST (Mediating role of ITI)	.236 (.094)	.003	2.471	Supported

^aPEG: perceived gamification mechanism.

^bITI: information technology identity.

^cCIU: continued intention to use the app.

^dIST: information-sharing tendency.



Discussion

Principal Findings

Many companies and vendors have developed various mHealth apps with the use of gamification principles. Building a gamified health and fitness app requires substantial investment. However, a highly competitive market and misalignment of gamification mechanisms with main users' motivations could result in switching or discontinuance uses [47]. According to Conroy et al [73], many fitness apps use similar designs with ineffective gamification techniques. Moreover, few studies have been performed to identify how the best gamification mechanisms should be used in mHealth apps [11]. This study helps both theory and practice to build a better understanding of the relationships among gamification, IT identity, and positive use behaviors (such as continued usage and information-sharing tendency). This study has implications for theory building on IT identity in the context of health and fitness apps. Without a clear picture of beliefs associated with the three dimensions of IT identity (ie, emotional energy, dependence, and relatedness), postadoption behaviors may be compromised. Therefore, the IT identity concept can be integrated into the postadoption research area, as it can help researchers recognize why individuals use health and fitness apps in their own ways. The results can confirm previous studies explaining why people try to maintain consistency between identities and behaviors [74].

This study further contributes to knowledge by shedding light on how gamification mechanisms will translate into positive use behaviors for regular users of mHealth apps. The findings highlight that gamification itself does not necessarily encourage users to share their personal data and keep up with health and fitness apps. Based on the fully mediating role of IT identity, gamified designs will be a successful technique to encourage meaningful interactions with the apps only if gamified elements can enact users' emotional responses to thinking about themselves in relation to health and fitness apps. This could be a plausible reason for the insufficient effectiveness in the design of many gamified health and fitness apps to attract and keep their users. Previous studies have mentioned that infective gamification may lead to the users' discontinuance intention in the context of health and fitness apps [47]. This study provides a richer explanation and defines ineffective gamification as gamified elements that cannot contribute to individuals' self-identification. The main theoretical contribution of this study is to determine the missing link between gamification and positive use behaviors. Based on identity theories, it is proposed that IT identity is an overlooked factor that can bridge the effects of gamification to positive use behaviors. According to this logic, if gamified features of health and fitness apps cannot generate a sense of emotional energy, dependence, and relatedness to the apps, current users are more likely to discontinue interacting with them after a few months. Using the same reasoning, gamification that is not coupled with IT identity may not motivate existing users to have more interactions with the apps by sharing their personal health information.

Previous studies indicate that gamification directly influences personal information disclosure [75]. Individuals may use a

gamified fitness app to share their experiences and information with friends, and gain social value. This study extends this point by incorporating the IT identity view to examine information-sharing willingness triggered by self-identification with the apps. Individuals may use gamified elements to generate a sense of challenge and compete with other users. This feeling gives rise to a sense of need and enjoyment with the apps. To stay in the social engagement loops and participate in social interactions with others, they saliently rely and depend on their apps. Thus, the use of the apps will be integral to their sense of self to exhibit how they are in completing challenges and quests. This strong IT identity represents positive self-identification, and motivates them to share more personal information and stay highly engaged with the apps.

Focusing on pure gamification mechanisms to increase market share can be a quick fix for the designers of mHealth apps. Using various gamified elements (such as badges, leaderboards, and points) can inspire individuals to use the apps, but they cannot automatically motivate them to stay with the apps. This is consistent with previous studies suggesting that gamified designs (such as using badges) should not be used alone because users may not be excited enough to continue to use the apps without further motivation and reinforcement [9]. This study proposes that continuous and enhanced use of health and fitness apps will need another source of motivation rooted in emotion, positive energy, enthusiasm, and a strong sense of reliance and connection with the apps. Gamified elements should be meaningful if users are awarded for achieving specific goals appropriate for the apps.

This finding could be a practical contribution to mHealth designers by demonstrating that gamified features that are not consistent with the apps' main purposes will not act as a meaningful incentive. This is in line with previous studies highlighting that putting too much emphasis on gamification mechanisms may negatively affect users' experience with the apps [76]. A suitable blend of gamification designs that help users complete defined tasks should foster IT identity by connecting app usage with users' habits. If users find the combination of gamified elements useful in accomplishing goals, they feel a strong sense of competence and enthusiasm. Thus, to enact these positive feelings and satisfy the experienced emotion, they are more likely to stay with the app and use it for additional health-related tasks. The activated IT identity may then inspire current users to think of themselves in relation to the apps on a daily basis and provides a basis for understanding the self in relation to IT.

Robust gamification mechanisms will help shape IT identity only when an individual has confidence in using their app to complete various tasks in different situations that can actualize intrinsic benefits and emotional rewards. The findings imply that effective rewards and incentives (eg, points and badges) accessible through gamified health and fitness apps should first create durable enjoyment, reliance, and connection with the apps. Otherwise, these gamified features may not motivate users to identify the self with the apps. If users do not consider the apps as an integral part of the self (due to lack of emotional responses), they may use the apps for a while but are very likely to switch to other alternatives supporting their self-concept. The

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results suggest that app designers may not increase feature use behaviors and enhanced use behaviors through gamification alone, but use behaviors can be improved through positive self-identification. Therefore, gamified incentives that foster self-identification by creating self-confirming sense, positive energy, and emotion associated with mHealth apps are more likely to encourage current users to keep up with them. Effective gamification mechanisms accompanied by a strong IT identity can reinforce health and fitness apps' usability, encourage continued use, and inspire patient self-management.

Finally, these findings have important practical implications for those tasked with the responsibility of developing health and fitness apps. There are several active alternatives and a wide range of health and fitness apps on the mHealth market [77]. Thus, developers and vendors of such apps should pay close attention to the importance of the IT identity verification process if they desire to engage users and promote positive postadoption behaviors. The absence of emotional energy, reliance, and connection between users and health apps may create negative feelings such as boredom and lack of interest. Considering IT identity, vendors should make an effort to understand its three dimensions (ie, dependence, relatedness, and emotional energy) and how to support each of them through effective gamification mechanisms. Vendors must have a thorough understanding of what combination of gamified elements (eg, badges, leaderboards, points and levels, challenges, and social engagement) can contribute to the verification of IT identity in relation to health and fitness apps. Moreover, vendors need to consider the indirect role of gamification to encourage continued intention and information-sharing tendency. By examining IT identity and its relationships with active use behaviors, vendors and developers can be provided with practical recommendations about improving users' value derived from mHealth apps and retaining as well as engaging users.

Limitations and Future Study

First, in this study, data were collected from a sample of respondents from the United States. The culture of using health and fitness apps is diverse among different countries. Therefore, caution should be exercised when generalizing the results. It is recommended that future studies consider subjects from other geographical locations such as other developed countries and developing countries with different technology infrastructure.

Second, it is important to mention that a general limitation with cross-sectional or short-term gamification studies is the study duration. Thus, longitudinal studies can provide a clearer understanding of the long-term effects of gamification on behavior outcome, user engagement, and continued use behavior.

Third, this study used a self-rated sample through an online survey to recruit participants digitally. Although several measures were taken to provide clear definitions, there is still a small chance that some respondents were not completely aware of the gamification mechanisms and may have formed their own perceptions of the IT artifact. For this reason, perceptions (perceived gamification mechanisms) were included in the research model to tackle this issue. Further studies should use an alternative method (eg, experiment) to ensure that subjects

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are knowledgeable about gamification to measure this construct more accurately.

Fourth, current users of gamified health and fitness apps were recruited for this study; focusing on a population of engaged users can also limit the generalizability of the findings. The role of IT identity may apply to this population but may be different in nonapp users. Thus, these findings are applicable among regular users of mHealth apps. This study calls for more research to improve generalizability by using a more comprehensive user status (such as current users, potential users, previous users, and nonusers).

Fifth, data were collected from respondents of some gamified health and fitness apps. All of the mentioned apps shared a combination of the most commonly used gamification mechanisms in mHealth apps (such as badges, challenges, points, levels, and feedback), which can satisfy this study's objectives. As suggested previously [11], gamification is considered a collection of multiple conditions, and none of these conditions alone is sufficient to constitute a gamified service. However, it should be acknowledged that their designs and goals may be different, and there may be a different effect with varying gamification strategies. Therefore, future research is required to further analyze how different aspects of gamification may affect users' perceptions. Moreover, future research can examine the proposed model by focusing on only one gamified app.

Sixth, using an online survey may generate a sample selection bias. Data were collected only from people who could access a computer, mobile devices, and the internet to participate in the online survey. Future studies can use other data collection means and sampling strategies to recruit a sample that is generalizable to a wide range of health care consumers. Seventh, this study did not focus on a specific brand of health and fitness app. It would be interesting to examine whether alternative mHealth brands could influence verification of IT identity and, in turn, shape positive use behaviors.

Finally, consistent with this study's purpose, the main goal was to develop and test a research model centered on the IT identity concept. Thus, many other widely used constructs from technology adoption models were not included in the research model. Future studies can incorporate other constructs that may enhance the amount of variance in IT identities, such as social influence, performance expectancy, and effort expectancy. Further research can also use objective measures to analyze the continued intention and positive use behaviors, such as usage frequency or number and the recency of sharing personal information via health and fitness apps.

Conclusions

Given the increasing importance of gamification and its impacts on the continuance of usage among regular users of health and fitness apps, this study proposes a model centered on the IT identity lens to fill current research gaps. Based on IT identity theories, it is proposed that effective gamification mechanisms embedded in health and fitness apps can activate users' IT identity and improve postadoption behaviors. The results suggest that an appropriate mix of gamified elements helps users

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emotionally connect to health and fitness apps and have more control over their feature set. These feelings foster their self-identification in relation to the apps, and in turn, they will be more likely to engage in information sharing and enhance use behaviors. Based on the results of this empirical study, it is proposed that IT identity fully mediates the effects of gamification on positive use behaviors. On the same basis, only gamified elements that effectively activate individuals' IT identity will result in continuous interactions with the apps and enhanced information sharing. Gamified features that better communicate the purpose of a health app and help users identify themselves with the app are more likely to foster active information sharing and continued intention to use. The findings propose theoretical implications to the gamification literature by demonstrating the mediating role of IT identity in shaping positive use behaviors. This study contributes more in-depth knowledge to the gamification principles in the context of mHealth apps and provides useful insights into the design of an effective gamified application platform. With a deeper understanding of IT identity and its relationship with gamification, mHealth app developers may be better positioned to design gamified features supportive of IT identity to improve postadoption use behaviors.

Conflicts of Interest

None declared.

Multimedia Appendix 1 Online survey. [DOCX File , 16 KB - games v9i3e28282 app1.docx]

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Abbreviations

AVE: average variance extracted IT: information technology mHealth: mobile health MTurk: Amazon's Mechanical Turk VIF: variance inflation factor

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Original Paper

An Interactive Computer Game for Improving Selective Voluntary Motor Control in Children With Upper Motor Neuron Lesions: Development and Preliminary Feasibility Study

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Abstract

Background: Computer game–based interventions are emerging in pediatric neurorehabilitation, as they can provide two key elements for motor learning—motivating environments that enable long-term compliance, which is particularly relevant for children, and augmented feedback for improving movement performance.

Objective: The overall aim of this study is to develop an interactive computer play for children with upper motor neuron lesions to train selective voluntary motor control and give particular attention to motivation and feedback. We also aim to determine features that make games engaging, investigate which sensory feedback modality is noticed the fastest during play, develop an interactive game, and evaluate its feasibility.

Methods: We identified engaging game features by interviewing 19 children and adolescents undergoing rehabilitation. By using a test version of the game, we determined the response times of 10 patients who had to react to visual, auditory, or combined feedback signals. On the basis of the results of these two subprojects, we developed and designed a game environment. Feasibility was studied in terms of the practicability and acceptability of the intervention among 5 children with upper motor neuron lesions.

Results: The game features deemed the most important by pediatric patients were strategic gameplay (13/29, 45% of answers) and choice (6/29, 21%). While playing the game, an acoustic alarm signal (reaction time: median 2.8 seconds) was detected significantly faster (P=.01) than conditions with other feedback modalities (avatar velocity reduction: median 7.8 seconds; color desaturation: median 5.7 seconds). Most children enjoyed playing the game, despite some technical issues.

Conclusions: The careful identification of game features that increase motivation and feedback modalities that inform children quickly led to the development of an interactive computer play for training selective voluntary motor control in children and adolescents with upper motor neuron lesions.

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KEYWORDS

virtual reality; game therapy; rehabilitation; augmented feedback; motivation; mobile phone

Introduction

Background

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Patients with upper motor neuron lesions (ie, due to traumatic brain injury, stroke, or spastic cerebral palsy [CP]) exhibit a

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variety of motor impairments. These symptoms are typically categorized as positive or negative motor signs [1,2]. Positive motor signs are related to excessive muscle activity or movement, such as increased muscle tone and spasticity. Negative motor signs describe insufficient (control of) muscle activity or movement, such as weakness or loss of selective

motor control. Reduced selective voluntary motor control (SVMC) is defined as "the impaired ability to isolate the activation of muscles in a selected pattern in response to demands of a voluntary posture or movement" [2]. Loss of SVMC can clinically manifest as impaired movement control and a multitude of involuntary movements (ie, unintended movements that co-occur with the performance of a voluntary task [3]), such as mass flexion or extension patterns, synergies of muscle activation (ie, obligatory grouped multi-joint movements), or mirror movements (ie, simultaneous, identical movements on the contralateral side) [4,5].

Although impairments in SVMC can be categorized according to the International Classification of Functioning, Disability, and Health into the domain of body function, they can interfere with movements of daily life activities and limit the patients' independence. For example, children with unilateral spastic CP who exhibit mirror movements require more time for bimanual activities of daily life than peers without mirror movements, independent of their unimanual capacities [5]. In children with CP and lower limb impairments, gross motor function abilities are more strongly related to SVMC than other common impairments, such as muscle weakness or spasticity [6,7]. This relationship between SVMC and gross motor function was not only observed in cross-sectional evaluations but also in longitudinal studies, where an impairment in SVMC was found to be the strongest predictor of a less favorable course of gross motor function [8,9]. When focusing on ambulation, impairments in SVMC were associated with a reduction in gait speed due to decreased knee extension at initial contact, resulting in a reduced step length [10].

Training Methods of SVMC

Multi-disciplinary rehabilitation programs aim to reduce children's limitations in daily life activities to improve their participation. Despite the known importance of SVMC, only a few interventions have specifically aimed at improving selective control [11]. Robot-assisted ankle movement training implemented in a computer game was used to train the graded ankle dorsiflexion and plantarflexion [12]. After 18 training sessions over 6 weeks, children with spastic CP significantly improved their ankle SVMC. In another pilot trial, 4 children with spastic CP played a commercial video game, which was controlled by surface electromyography (sEMG) signals. It aimed to reinforce activity in a desired muscle and to reduce cocontraction of an agonist-antagonist muscle pair, thus training selective muscle activation [13]. In total, 3 of the 4 children could reduce muscle cocontraction during the game. A therapy program by Adler et al [14] specifically addressed mirror movements interfering with bimanual activities in children with unilateral spastic CP. However, exercises to suppress mirror movements emphasizing the independent use of both hands led to improved bimanual function without reducing the occurrence of mirror movements.

Although these interventions targeted certain aspects of SVMC (eg, improving joint movement control or reducing mirror movements), no approach covered all features of reduced selective motor control. We became interested in designing an intervention that would include training both aspects, improving

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accurate motor control while simultaneously reducing any sort of involuntary movement. On the basis of our experience with the application of rehabilitation technologies to improve upper and lower extremity functions in children and adolescents with neuromotor disorders [15,16], we started considering the design of a technology-assisted system combined with a game played in a virtual environment. Many technology-assisted interventions based on interactive computer play (ICP), exergames, and virtual reality (VR) have emerged to complement conventional therapies during rehabilitation [15,17,18]. The distinction between these terms describing similar technologies is not always easy, and VR is often used improperly [18,19]. ICP is defined as "any kind of computer game or VR technique where the individual can interact and play with virtual objects in a computer-generated environment" [20]. What distinguishes VR from more general ICP technologies is the immersive component of VR systems [21]. The purpose of exergames is to provide physical activity or exercise through interactive play [22]. An advantage of ICP is that it can provide key aspects relevant for motor learning during rehabilitation; for example, a playful environment increases motivation and thereby enables large numbers of repetitions, whereas the performance of movements can be improved based on augmented feedback [23].

Objectives

Thus, the project's overall aim was to develop an intervention for children with upper motor neuron lesions to improve SVMC by exploiting the advantages of ICP technology. Our basic idea was to develop an ICP that should train accurate joint movement control while providing immediate feedback when involuntary movements would occur.

Previous studies have already identified the properties of video games that are relevant when designing games because they affect motivation and player engagement, as follows: reward, optimal challenge, feedback, choice or interactivity, clear instructions, and socialization [24]. In addition to the theoretical background of game design principles and motivation, we wanted to consider the game design preferences of the target users. Augmented feedback should make the player aware of the occurrence of involuntary movements while playing an attention-demanding ICP. Therefore, special attention should be given to the question of how such warning feedback is ideally provided. Finally, we aimed to follow up the ICP design process with a small feasibility trial. Therefore, we formulated the following specific research questions for the development of an ICP to train SVMC: (1) which features of commercial games do children and adolescents undergoing neuro-orthopedic rehabilitation like, (2) which modality of feedback indicating a negative occurrence is perceived most easily by these patients while playing an ICP, and (3) is it feasible to use the new ICP as an intervention for children and adolescents with impaired SVMC due to an upper motor neuron lesion?

Methods

Study Overview

To develop an ICP that should motivate children and adolescents with impairments in SVMC to practice for a longer time, we conducted three subprojects: (1) identifying motivating game

features by conducting interviews; (2) identifying which *warning* feedback signal is detected the quickest while playing the game; and (3) based on the results from these subprojects, the ICP is developed and its preliminary feasibility is evaluated.

This game development study did not fall under the Human Research Act, which was confirmed by the Ethics Committee of the Canton Zurich through two clarifications of responsibility (Req-2019-01005 and Req-2019-00623).

Motivating Game Features

For the survey, we recruited children and adolescents regularly playing games on smartphones or tablets undergoing neuro-orthopedic inpatient rehabilitation at the Swiss Children's Rehab. The participants and their parents were verbally informed about the interview. Verbal consent was obtained from both before the structured interviews were conducted. In the interview, we gathered ideas and explored the participants' opinions with the following open-ended questions (in German):

- What are your favorite games?
- What do you like about them? Several answers were possible for each game.
- What feature is the most important for you and would need to be included if you could design your own game?

We asked participants to think of games for smartphones or tablets rather than for game consoles. The latter have extensive control options (eg, many keys or joysticks) that allow complex user interactions. Smartphone or tablet games usually include simpler control modes, which are in line with our idea of training SVMC using basic isolated joint movements to control the ICP. If participating children or adolescents had difficulties in naming game features spontaneously, we provided suggestions including graphics, actions, shooting, the story, music, being challenged, puzzles, different strategies, character development, large game world, and multiplayer.

Feedback Modalities

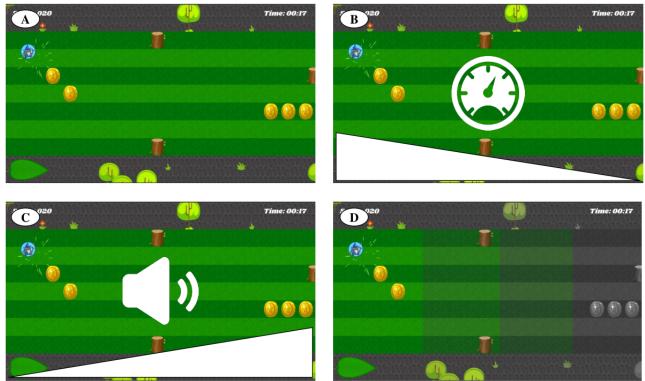
Participants

For the second subproject, we again recruited children and adolescents undergoing neuro-orthopedic inpatient rehabilitation. They had to be able to use the arrow keys and press the spacebar on a regular computer keyboard. The exclusion criteria were severe visual or auditory impairments. All participants and their parents were informed orally and written about the protocol. Parents and adolescents aged ≥ 14 years provided written informed consent. All participants provided verbal informed consent.

Test Game

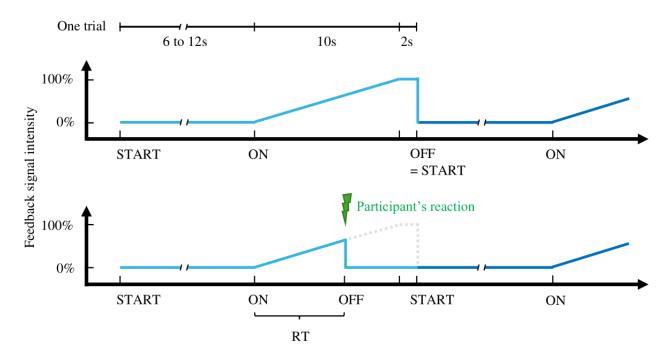
We created a reaction time (RT) task to investigate in which modality a *warning* feedback signal is noticed most easily while playing the game. Thus, in this experiment, the augmented feedback signal did not inform the player about undesired comovements, but the signal was simulated and participants had to detect it while playing. The game environment was a preliminary version of the ICP programmed in Unity (Figure 1). The goal of the game was to move an avatar up and down on the screen to collect coins and avoid obstacles. The avatar was controlled with arrow keys on a commercial computer keyboard to provide similar conditions for all participants.

Figure 1. Preliminary game environment and schematic illustration of feedback modes for testing different feedback signal modalities. (A) Game environment in which the avatar had to be navigated up and down. (B) Baseline mode where the avatar's speed was reduced. (C) In the acoustic mode, the feedback signal was an alarm sound of increasing sound volume. (D) Illustration of the conversion from color to gray scale in the background color mode.



We investigated three modes of gradable feedback signals. Feedback 1, *Baseline*: no additional signal apart from reducing the avatar's speed, which had the aim of facilitating the game to enable focusing on the purpose of the game again; Feedback 2, *Acoustic*: playing an alarm sound; and Feedback 3, *Background color*: converting the background from color to grayscale (Figure 1). We tested four conditions: (1) Feedback 1 alone, (2) Feedback 1 and 2, (3) Feedback 1 and 3, and (4) Feedback 1, 2, and 3. The feedback signal was introduced randomly between 6 and 12 seconds after a trial had started and gradually increased from 0% to 100% feedback signal intensity (ie, speed reduction from normal game speed to completely static, increase in sound volume of the alarm, and color desaturation to complete gray scale) in 10 seconds. It remained for 2 seconds at 100% signal intensity before the test automatically continued with the next trial. The participants' task was to press the space bar to turn off the signal as soon as they had detected the feedback signal while continuing to play the game. In this case, the time remaining until the next trial started was normal game play, such that feedback detection success had no influence on the duration of the game. A schematic illustration of the feedback simulation trial design is provided in Figure 2.

Figure 2. The upper part shows the organization of one trial, illustrating the start of the trial, the feedback initiation (ON) and increment, and the start of the next trial. The lower part of the figure illustrates the changes that occurred as soon as the participant responded to the feedback signal and how the reaction time was defined. RT: reaction time.



Procedures

The participants were instructed to collect coins by moving the avatar with the arrow keys and pressing the space bar when they noticed one of the feedback signals. During the familiarization phase (approximately 2 minutes), they could try the game and experience each feedback condition once. Each condition was tested five times, resulting in 20 trials. Trials were completed in a blocked randomized order [25] to control for fatigue. The trials were tested consecutively such that the test appeared to be a continuous game, which lasted approximately 7 minutes.

Data Analysis and Statistics

The main outcome was the RT, extracted from the game that logged the onset of the feedback signal and when the participant pressed the space bar. RTs below 0.1 seconds were excluded because they likely reflected pressing by chance (healthy adults did not achieve faster RTs). The average RT per person was calculated for each condition. Not reacting to a feedback signal was counted as a missed response and led to an entry of 12 seconds as the RT (as penalty).

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We used the R statistical package (version 3.4.4; R Foundation for Statistical Computing). Normality of the data was evaluated using Shapiro-Wilk tests and by visual inspection of the Q-Q plots. As not all data were normally distributed, conditions were compared using a nonparametric Friedman test with pairwise Wilcoxon signed-rank tests. The significance level α was set at .05, with a Bonferroni correction for multiple comparisons.

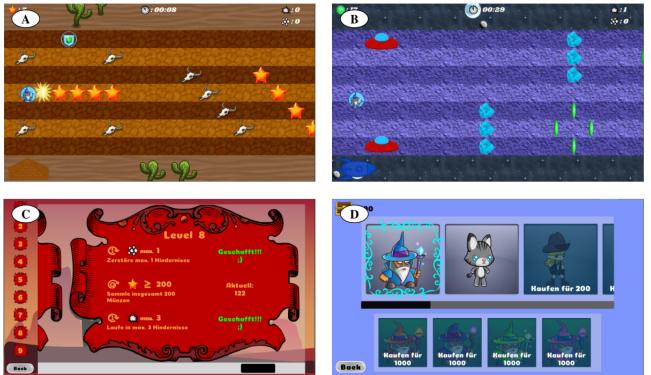
Game Design and Feasibility Trial

SVMC Runner Game

The game environment was programmed in Unity (version 2019.3.0f6, Unity Technologies) and included sounds and background music. The game design was based on the results of the two previous subprojects, hence the survey on favored game features and the investigation of feedback modalities. A video of the game can be seen in Multimedia Appendix 1. The goal of the game was to move an avatar up and down on the screen to collect coins and avoid certain obstacles (Figure 3). The avatar's horizontal position was fixed while the game environment moved at a steady pace of shifting by one screen

width in approximately 6.5 seconds (ie, an object appearing on the right side of the screen required 6.5 seconds until it disappeared on the opposite side). As soon as involuntary movements occurred, an auditory augmented feedback signal made the player aware of the occurrence of involuntary movements (based on results from the second subproject). The signal volume was graded according to the extent of the involuntary movements. Furthermore, the avatar's speed gradually slowed, relative to the involuntary movements. This response to involuntarily occurring movements was implemented to make game play temporarily easier. It should enable the player to focus again on the game and reduce the occurrence of comovements, because these often appear in conditions of increased effort [3].

Figure 3. Game environment. The purpose of the game was to collect stars or coins and avoid the obstacles by moving the avatar up and down on the screen. (A) This screenshot from a game level shows a shield power-up in the top-left corner. After collecting it, the avatar was protected from obstacles for the next 10 seconds. (B) This level had a different theme, although the game elements stayed the same. (C) An example of challenges in one level. Each challenge required a different focus. (D) Players could use the collected coins to personalize the avatar.



The game included six thematically different game environments (worlds). The six worlds covered 54 levels of increasing difficulty (eg, from shorter to longer duration; from a few, small, static obstacles to more, larger and moving obstacles; and from no enemy to multiple enemies). Each player had their own profile. Initially, only the first level was playable, whereas the others remained locked. After successfully finishing a level, the next higher level became unlocked. At the onset of each level, certain challenges (eg, collecting a certain amount of coins) that the player needed to achieve were presented. Players were provided three challenges per level that required them to adopt (varying) strategies (Figure 3). Advancing to a new world needed fulfillment of at least 80% of these challenges. The players experienced choice as they could freely decide which challenge or challenges they wanted to tackle. Variability was further enhanced by adding power-ups (ie, objects that add temporary extra abilities to the game character, such as increasing speed, a shield protecting against enemies; Figure 3) to the environment. Once enough coins had been collected, they could be used to personalize the avatar (Figure 3).

In addition, we considered the visual presentation of the game to be important. The appealing and motivating effect of visual features had to be balanced against the risk of confusion or

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distraction from the basic task, which can be particularly important for children with a recently acquired brain injury. With glasses simulating a strong visual impairment (provided by the *Swiss National Association of and for the Blind*), we verified that contrasts between essential gaming elements were high, as more than 50% of the children with CP experience visual impairments [26].

Game Controllers

We pursued the following two control strategies for the ICP to improve SVMC: (1) a strategy based on muscle activity and (2) a strategy based on joint movements (Figure 4). The first approach trained the selective activation of a target muscle (group) while reducing activity in another muscle (group) that should remain inactive (similar to Rios et al [13] and Yoo et al [27] but not restricted to agonist-antagonist muscle pairs). The sEMG signals of these two selected muscle groups were recorded using a varioport-e device (Becker Meditec) at a sampling frequency of 1000 Hz. The sEMG signals were transferred via Bluetooth to the ICP computer, where they were filtered (exponential smoothing with a smoothing factor of 0.0015, followed by taking a moving average with a window size of 10 frames) and fed into the game. The avatar was steered up by increasing the activation of the target muscle (group),

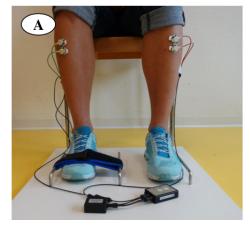
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while lowering the sEMG activity caused a downward movement of the avatar. The *warning* feedback signal was triggered by activity in the muscle (group) that should remain inactive.

For the second approach, we used the ArmeoSenso system (version 1.0; Hocoma AG). This motion capture system was developed for arm rehabilitation and included three wearable inertial measurement units to detect movements of one arm and trunk movements. Although it was originally intended for unilateral upper extremity rehabilitation, it could also be used to track lower extremity movements (unilateral). Joint angles delivered by the inbuilt software were transferred via the user datagram protocol to the ICP computer and served as input signal for the game to train selective movement of the chosen target joint and record involuntary movements in another joint. The upward and downward movements of the avatar were caused by moving the target joint in an upward and downward direction, respectively. Movements of the joint that should not move activated the *warning* feedback signal.

Figure 4. Game controllers. (A) Electromyography-based control of the game via activation of the right tibialis anterior muscle (green cables). Mirror activity on the left side (red cables) would trigger the feedback signal. (B) ArmeoSenso with its three sensors (chest, upper arm, and lower arm). In this example, the game was controlled by elbow flexion and extension without simultaneously moving the shoulder (ie, shoulder abduction would lead to a warning feedback signal).





Pilot Tests

Before testing the game in children and adolescents with impairments in SVMC, we performed pilot sessions in healthy adults and children to identify and resolve bugs in the game design and explore different hardware configurations.

Participants

For the feasibility trial, we recruited children and adolescents with impaired SVMC due to upper motor neuron lesions. Improving SVMC was identified by their physical or occupational therapist as a reasonable rehabilitation goal of their inpatient stay at the Swiss Children's Rehab. All participants and their parents were informed verbally and in writing about the protocol and provided written informed consent.

Study Design

The study encompassed six sessions of 40 minutes scheduled over 2 weeks. In the first two sessions, we tested each control system (one system per session in randomized order). In the following four sessions, we used the more appropriate system. Together with the participants' physical or occupational therapist, who treated each participant, we determined the muscle group or movement that had to be trained (target joint) and the involuntary muscle activation or movement that needed to be suppressed.

Outcomes

Study participants were characterized by age, sex, diagnosis, and SVMC impairment measured using the Selective Control Assessment of the Lower Extremity or Selective Control of the

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Upper Extremity Scale [28-30]. We evaluated the domains' practicability and acceptability, as described in the model of clinical utility by Smart [31]. We recorded any technical issues related to setting up the ICP, playing the game, and whether the game's purpose was clear to the participant. To compare the hardware approaches and hints on which strategy to pursue further, participants decided on their preferred system and the therapist indicated which system was more appropriate in terms of reaching the therapy goal. In view of using the ICP in an intervention study in the future, we assessed the time the participant was actively playing. Therefore, the game logged the time when levels were played, excluding all breaks.

After each session, participants were verbally asked whether they enjoyed the game (three-point Likert-scale with answers "no," "a little," and "a lot of fun"), whether they would like to play again, and if they experienced any discomfort or harm.

Procedures

Each session started by attaching the sensors or electrodes and calibrating the game, which was accomplished by moving the joint once through the active range of motion or maximally contracting the muscle. In the sEMG mode, the limb was then strapped to a custom-made board with loops for Velcro straps to prevent any movement of the target joint. We decided to control the game by isometric muscle activation after pilot tests, which revealed that when movement was allowed, the joint was mostly held in a position at the end of the range of motion. This led to pain only after a short period of playing. We used standardized, tutorial-like, step-by-step instructions to guide participants in the game environment. Participants decided on

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their own level of play and which challenge to tackle. In the first two sessions, played with the different control systems, participants started at level 1 with separate game profiles. This enabled participants to start at the easiest level with both control systems. Sessions 3-6 continued progressively with the system the therapist deemed more appropriate (also considering the participant's opinion).

Results

Motivating Game Features

We interviewed 19 inpatients from our rehabilitation center (9 males; mean age 14.3, SD 2.5 years; range 8.0-17.0 years). The

most common diagnosis was traumatic brain injury (n=6). Participants mentioned 29 games, of which Minecraft was mentioned three times, followed by 4 Elements, Clash of Clans, and Fortnite, each mentioned twice. They considered requiring a strategy to play the game as the most important feature of the game (13/29, 45% of all answers), followed by having multiple *options* (6/29, 21%). The term *options* encompasses that the game allows the player to decide between multiple possibilities to achieve the goal. Further characteristics that participants liked were the possibility of playing in a multiplayer mode, power-ups, and character evolution (Table 1). A full list of answers can be found in Multimedia Appendix 2.

Table 1. Features of the participants' favorite games. Several game features could be mentioned per game (n=29).

Game feature	Answers, n (%)
Multiplayer	13 (45)
Strategic gameplay	13 (45)
Power-ups	11 (38)
Multiple options	8 (28)
Character evolution	7 (24)
Creativity	3 (10)
Fighting	3 (10)
Animations	2 (7)
Shooting	2 (7)
Speed	2 (7)
Timing challenge	2 (7)
Machines	1 (3)
Simple idea	1 (3)
Sport	1 (3)

Feedback Modalities

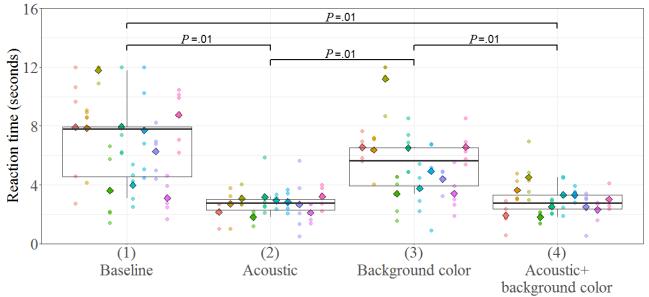
A total of 10 children and adolescents (male: n=9; age: mean 12.6 years, SD 3.5 years; range 7.3-16.3 years) participated. The participants' diagnoses were bilateral spastic CP (n=5; Gross Motor Function Classification System I-IV and Manual Ability Classification System I-II), sensory-motor neuropathy (n=1), epilepsy (n=1), congenital hemiplegia (n=1), anti–N-Methyl-D-aspartate receptor encephalitis (n=1), and intracranial hemorrhage (n=1). The RTs are shown in Figure 5. They differed significantly between the conditions (χ^2_3 =26.2; *P*<.001). Pairwise comparisons revealed that the RT was

significantly longer (P=.01) in conditions without the acoustic feedback signal (conditions 1 and 3) than in conditions that included the alarm sound (conditions 2 and 4). RT tended to be longer (P=.06) in the baseline condition (1), where only the velocity was reduced, compared with the background color condition (3). RTs in conditions 2 and 4 did not differ (P=.99).

Although none of the participants missed responding in any acoustic feedback signal trial, 14% (7/50) of responses in total were missed in the baseline condition of only velocity reduction, whereas 6% (3/50) were missed in the background color condition.



Figure 5. Boxplots of the reaction times for each feedback mode (1-4). In the baseline condition, only the speed of the avatar was reduced. In the other conditions, velocity reduction was combined with an additional feedback signal, that is, an acoustic alarm or a change of the background color. The colors represent individual participants. The small circles show the reaction time of each individual trial, whereas diamonds show the mean reaction time over all 5 trials per participant.



Feedback signal

Feasibility Trial

The ICP was piloted in 11 sessions with healthy participants; 5 children and adolescents with impaired SVMC were recruited,

and their characteristics are shown in Table 2. One participant (ID 2) stopped the study after two sessions owing to the premature end of rehabilitation because of the COVID-19 pandemic.

Table 2. Characteristics of participants in the feasibility study (n=5).

ID num- ber	Age (years)	Sex	Diagnosis	SVMC ^a total (points)	SVMC target joint (points)	System	Target joint or muscle group ^b	Involuntary move- ment
1	7.8	Female	Bilateral spastic CP ^c , GMFCS ^d III	5 ^e	0 ^e	sEMG ^f	Ankle dorsiflexion	Ipsilateral knee exten- sion
2	13.0	Male	Bilateral spastic CP, GMFCS II	8 ^e	0 ^e	ArmeoSenso	Knee flexion and extension	Trunk flexion and ex- tension
3	12.7	Female	Bilateral spastic CP, GMFCS III	7 ^e	1 ^e	sEMG	Knee extension	Contralateral knee ex- tension
4	12.5	Female	Traumatic brain in- jury	16 ^e	1 ^e	sEMG	Ankle dorsiflexion	Contralateral ankle dorsiflexion
5	16.1	Male	Unilateral spastic CP, MACS ^g III	20 ^h	2 ^h	ArmeoSenso	Shoulder abduction and adduction	Ipsilateral elbow flex- ion and extension

^aSVMC: selective voluntary motor control; SVMC total: total Selective Control Assessment of the Lower Extremity (SCALE) score (maximum of 2 points per joint; total of 20 points) or Selective Control of the Upper Extremity Scale (SCUES; maximum of 3 points per joint; total of 30 points); SVMC target score: SCALE or SCUES item scores for the target joint that was practiced with the game.

^bRefers to the target joint when the ArmeoSenso system was used and to the target muscle group when the electromyography-based system was used. ^cCP: cerebral palsy.

^dGMFCS: gross motor function classification system (it standardizes the classification of gross motor function, emphasizing the trunk control and walking ability of children with cerebral palsy [32]. Level 1 means that children perform all the activities of neurologically intact children of the same age, allowing for slight limitations in speed and quality of movements. Level 5 means that children exhibit difficulties in head and trunk control in most positions or in achieving any voluntary control of movement at all).

^eSelective voluntary motor control assessed with the Selective Control Assessment of the Lower Extremity.

^fsEMG: surface electromyography.

^gMACS: manual ability classification system (it classifies how children with cerebral palsy handle objects in daily activities [33]. Level 1 means that the child can handle objects easily and successfully, whereas children at level 5 do not handle objects at all).

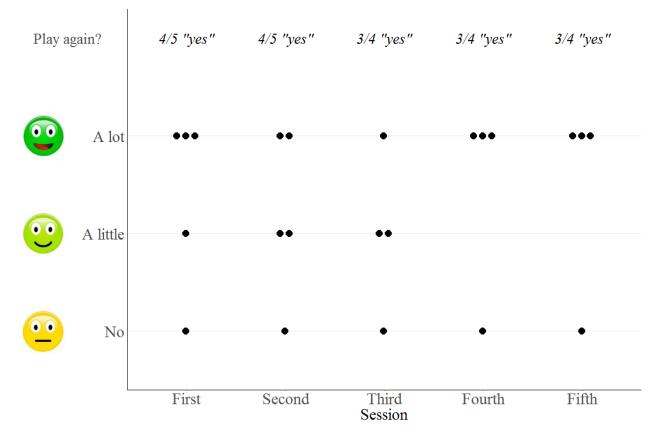
^hSelective voluntary motor control assessed with the Selective Control of the Upper Extremity Scale.

In one case, the ArmeoSenso was favored (ID 5) and also once, the participant and therapist clearly preferred the electromyography-based system (ID 1), because steering the game with the ArmeoSenso proved to be challenging in the case of a small active range of motion. No comparison of systems was possible for the other participants. In two cases, because the unilateral ArmeoSenso system is not able to track mirror movements (IDs 3 and 4), we could only use the sEMG system; in the third case, the patient withdrew (ID 2), but the motion capture system was working reliably until then.

It took more time than expected to set up the ICP until game control functioned reliably, because we encountered difficulties in conducting and standardizing the calibration. Recalibration was necessary more frequently than expected, because problems occurred with steering. Participants were actively playing for 18.3 (SD 5.4) minutes per session on average (range 9.8-30.4 minutes) with training time increasing over the course of the study (15.8 minutes in first session vs 20.3 minutes in fifth session).

Only one participant answered having experienced "no fun at all" (ID 5), while having "a lot of fun" represented the majority of answers. ID 5 remained uninterested over all sessions, whereas two that were a little skeptical in the beginning became more enthusiastic over time (Figure 6). None of the participants reported any discomfort or harm.

Figure 6. Participants' ratings of enjoyment. Scores indicated how much they liked the game and whether they would like to play it again. Only sessions with the more appropriate system are shown.



Discussion

Principal Findings

This study describes the development of an ICP to specifically enhance SVMC in children and adolescents. The game-based intervention trains movement control while simultaneously providing feedback to reduce involuntary movements. We designed the game environment based on the favorite game features that children reported in a survey. Subsequently, we tested various feedback conditions to identify the auditory signal as the modality that patients perceived the fastest. An ensuing investigation of usability revealed that children enjoyed the game despite some technical issues.

Motivating Game Features

Interestingly, the features mentioned most frequently, strategic gameplay, and having multiple options depend on each other. If a game provides many options, the player needs a strategy to succeed, and vice versa, players can only develop a strategy if they are provided with more than one option. These features are comparable with the interdependent construct choice and interactivity, which are considered key principles of game design to increase motivation [24]. Strategic gameplay was also one of the motivators of video games for therapy mentioned by children with hemiparesis in a focus group [34]. Furthermore, variability, challenge, and competition were identified as common elements that increased motivation in a study investigating the effect of several ICP environments on motivational behaviors in children with CP [35]. Although



variability was not a specific response in this study, the features of multiple options, power-ups, and character evolution introduce variability and help to avoid the fact that a game looks the same every time it is played.

Multiple options were incorporated into the game design in several ways. The game did not follow one particular trajectory with the game avatar but allowed different ways through the environment. Furthermore, players could choose the level to play and which challenge to tackle on their own. Presenting three challenges for each level forced the player to develop and use varying strategies to fulfill each of them. Finally, we included power-ups, the possibility to personalize the game character, and varied the visual appearance of the game with a thematic design of the worlds.

Feedback Modalities

Unlike common simple RT tasks, this study investigated a dual-task situation. While participants focused on collecting coins and avoiding obstacles, the feedback signals had to attract their attention. The game already provided many visual inputs, which might have complicated the detection of other visual stimuli (such as reducing speed or changing background color) due to overloading visual perception [36]. In particular, during parts of the game with many obstacles, the visual load could have been high. Although the game sounds and background music were not relevant for playing the game, the alarm sounds were easy to distinguish. The RTs and their variability were considerably lower in conditions with an auditory feedback signal than in conditions with only visual signals. This suggests that the alarm sound had the highest contrast to the game environment and attracted attention most easily.

Feasibility Trial

On the basis of most participants expressing moderate-to-high enjoyment and no discomfort, the ICP intervention can be considered acceptable. One child's spontaneous comment ("I cannot reach this [next] world with only one more session, can I come more often?") revealed that the design of the game environment created long-term motivation and engagement. These results confirm that game-like interventions can lead to high levels of compliance and motivation [37]. Increased fun and interest in the game-based intervention was also shown in a study directly comparing conventional ankle dorsiflexion training with an ICP protocol [38]. High levels of motivation increase the time dedicated to an intervention and would thereby contribute to the success of a therapy, which depends on adherence over an extended period. We can only speculate why one participant did not like the ICP based on our observations during the training sessions. The target movement proved rather difficult for this participant, and the ICP did not allow control of the game by the compensatory movement pattern he usually used. This frustrated him, and it seemed that he was not motivated to practice something challenging in general. Lower levels of motivation to persevere in challenging situations have already been reported in children with CP [39]. We have to be aware of such personal reactions and need to seek solutions to prevent frustration, resulting in loss of compliance.

Some issues encountered with the game calibration interfere with the practicability of the ICP. The time needed to solve these issues automatically reduced the active training time because the overall duration of sessions was determined by the clinic schedule. Moreover, the occurrence of technical problems sometimes seemed to coincide with lower levels of enjoyment. Difficulties arose during the first sessions and resolved during later sessions. This also finds reflection in a longer active training period during later sessions. Further measures are needed to increase the active training time because we think that 15-20 minutes is a rather low amount of training during sessions lasting 40 minutes. Adult patients with stroke engaged in physical activity for 60% of the time during a physical therapy session [40]. Activity rates during technology-assisted rehabilitation were higher than those during conventional therapy [41]. However, we must acknowledge that exploiting the game features we included to increase motivation and engagement (ie, choice, challenges, and personalization) took time. Moreover, by selecting a single target joint, our intervention was very specific, and the active time was fully dedicated to train one particular movement. At the same time, this might cause children to need more breaks because switching between different tasks for a change was not possible.

The comparison of hardware systems (game controllers) did not reveal a clear favorite but showed that both systems were required. The use of the sEMG system was obligatory to address mirror movements during training because ArmeoSenso cannot track contralateral movements. The sEMG system was also superior in the case of a small active range of motion, where motion tracking with ArmeoSenso failed. However, ArmeoSenso was particularly useful for recording trunk movements, where the selection of one representative muscle would be difficult. These findings further strengthen our view of an individualized approach to improving SVMC in children and adolescents with upper motor neuron lesions.

Limitations

With the survey in the first part of our study, we only assessed the subjective preferences of children and adolescents about game features, assuming that the preferred game elements are motivating. However, it would require a longitudinal study in which these features were systematically manipulated to investigate their influence on long-term engagement.

A limitation of the investigation of feedback modalities is that the game was played with the arrow keys and not with the intended way of steering through muscle activation or joint movement. Nevertheless, we would not expect the results to be different because both steering modes require coordination of one's movement according to what is displayed in the game. Using the arrow keys might have shortened RTs (for all feedback modalities), as this mode of control is likely more common and therefore less challenging than controlling a game by body movements.

Although the overall aim was to develop an intervention for patients with reduced SVMC due to an upper motor neuron lesion, we recruited children with various diagnoses undergoing neuro-orthopedic rehabilitation for the first two subprojects, as we considered these research questions unrelated to SVMC. An

advantage of investigating a more general population of children undergoing rehabilitation is the higher generalizability of the results to the ICP design for other pediatric patient groups.

We could not evaluate the preliminary effectiveness of the ICP to determine its appropriateness, although we had intended to do so with an assessment integrated with the ICP, similar to a previously developed assessgame [42,43]. Difficulties in standardizing the calibration prevented comparability between sessions or after recalibration. We are planning a single-subject research design study to evaluate the effectiveness of the game in improving motor control and reducing the occurrence of involuntary movements compared with regular multimodal rehabilitation in children and adolescents with impairments in SVMC. After showing effectiveness in a clinical setting, a future plan could be to implement the intervention in a home-based setting. It would also be interesting to investigate whether

potential improvements in SVMC are meaningful to children and translate to improvements in activities of daily life.

Conclusions

This study revealed that strategic gameplay and having multiple options are favorable and likely motivating features of games for children and adolescents undergoing rehabilitation. This indicates that they prefer to choose their own strategies among several options to influence the course of a game. We incorporated these findings in the design of an ICP to train SVMC, as well as the finding that an acoustic warning signal was perceived more quickly than the other modalities that we tested. Feasibility testing revealed that participants enjoyed playing, but some technical issues impeded user experience and should be addressed to optimize practicability. The results of this study could be considered by designers of other interactive computer games if long-term engagement of children, such as during a rehabilitation period, is needed.

Acknowledgments

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Authors' Contributions

AF conceived the study, performed measurements, conducted the analysis, and wrote the initial draft. JWK conceived the study and performed the measurements. AK conceived the study, was responsible for game software development, and performed measurements. HJAVH supervised the project and acquired funding. All authors critically reviewed the manuscript and agreed with the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Video of the game. This shows the avatar being navigated through the game environment, collisions with obstacles, and the effects of a power-up.

[MP4 File (MP4 Video), 22803 KB - games_v9i3e26028_app1.mp4]

Multimedia Appendix 2 List of all answers during the interview. [PDF File (Adobe PDF File), 276 KB - games_v9i3e26028_app2.pdf]

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Abbreviations

CP: cerebral palsy ICP: interactive computer play RT: reaction time sEMG: surface electromyography SVMC: selective voluntary motor control VR: virtual reality



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Original Paper

Perspectives on the Gamification of an Interactive Health Technology for Postoperative Rehabilitation of Pediatric Anterior Cruciate Ligament Reconstruction: User-Centered Design Approach

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Abstract

Background: Pediatric and adolescent athletes are a large demographic undergoing anterior cruciate ligament reconstruction (ACL-R). Postoperative rehabilitation is critical, requiring patients to complete home exercise programs (HEPs). To address obstacles to HEP adherence, we developed an interactive health technology, *interACTION (iA)*, to monitor knee-specific rehabilitation. *iA* is a web-based platform that incorporates wearable motion sensors and a mobile app that provides feedback and allows remote monitoring. The Wheel of Sukr is a gamification mechanism that includes numerous behavioral elements.

Objective: This study aims to use a user-centered design process to incorporate behavioral change strategies derived from self-management theory into *iA* using the Wheel of Sukr, with the aim of influencing patient behavior.

Methods: In total, 10 athletes aged 10-18 years with a history of ACL-R were included in this study. Patients were between 4 weeks and 1 year post–ACL-R. Participants underwent a 60-minute triphasic interview. Phase 1 focused on elements of gaming that led to high participation and information regarding surgery and recovery. In phase 2, participants were asked to *think aloud* and rank cards representing the components of the Wheel of Sukr in order of interest. In phase 3, the patients reviewed the current version of *iA*. Interviews were recorded, transcribed, and checked for accuracy. Qualitative content analysis segmented the data and tagged meaningful codes until descriptive redundancy was achieved; next, 2 coders independently coded the data set. These elements were categorized according to the Wheel of Sukr framework. The mean age of participants was 12.8 (SD 1.32) years, and 70% (7/10) were female. Most participants (7/10, 70%) reported attending sessions twice weekly. All patients were prescribed home exercises. Self-reported HEP compliance was 75%-100% in 40% (4/10), 50%-75% in 40% (4/10), and 25%-50% of prescribed exercises in 20% (2/10) of the participants.

Results: The participants responded positively to an app that could track home exercises. Desirable features included exercise demonstrations, motivational components, and convenience. The participants listed sports specificity, competition, notifications, reminders, rewards, and social aspects of gameplay as features to incorporate. In the Wheel of Sukr card sort exercise, motivation was ranked first; self-management, second; and growth, esteem, and fun tied for the third position. The recommended gameplay components closely followed the themes from the Wheel of Sukr card sort activity.

Conclusions: The participants believe *iA* is a helpful addition to recovery and want the app to include exercise movement tracking and encouragement. Despite the small number of participants, thematic saturation was reached, suggesting the sample

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was sufficient to obtain a representative range of perspectives. Future work will implement motivation; self-management; and growth, confidence, and fun in the *iA* user experience. Young athlete ACL-R patients will complete typical clinical scenarios using increasingly developed prototypes of the gamified *iA* in a controlled setting.

(JMIR Serious Games 2021;9(3):e27195) doi:10.2196/27195

KEYWORDS

IHT; pediatric; sports medicine; ACL; orthopaedics; rehabilitation; health technology; gamification

Introduction

Background

Anterior cruciate ligament (ACL) injury can lead to pain, knee instability, and variable disability level, from reduced participation in sports to more severe limitations in activities of daily living [1,2]. ACL reconstruction (ACL-R) is the sixth most common orthopedic surgical procedure in the United States [3]. The goals for ACL-R include restored knee stability and return to prior activities. Recent studies evaluating insurance databases have noted that pediatric and adolescent athletes (young athletes) are the largest demography of patients per capita undergoing ACL-R [4,5]. Young athletes also demonstrate higher reinjury rates following ACL-R, partly because of their high level of functional demands following surgery. Biomechanical studies note that persistent muscular weakness or dysfunction is a significant risk factor for reinjury after the patient has returned to preprocedure activities and that postoperative rehabilitation is critical in reducing these negative outcomes [6,7].

Rehabilitation—specifically restoration of motion, optimizing muscular strength, and improving neuromuscular control—is demonstrably important in optimizing the quality of life of young athletes and function following ACL-R [6-8]. Adequate rehabilitation requires patients to complete prescribed exercises daily, primarily in the form of home exercise programs (HEPs)

[9]. Unfortunately, due to lack of education, communication, and oversight, many patients do not fully understand or appreciate the importance of their HEP [10]. Particularly, in a young athlete population, low rehabilitation adherence is a common and critical obstacle in ACL-R recovery [8,11]. Inadequate rehabilitation can result in poorer clinical outcomes, including reduced quality of life, increased pain, and increased chances of reinjury [12-14]. Commonly reported barriers to rehabilitation adherence in the ACL-R population include fear of pain or reinjury, low self-motivation (self-efficacy) or exercise level, and a feeling of low patient control have been cited as common barriers faced by patients following ACL-R [13].

In response to these obstacles, our group developed an interactive health technology (IHT) called *interACTION (iA; Elizur)*, to prescribe and monitor home exercises for knee-specific rehabilitation. *iA* is a web-based rehabilitation platform that incorporates wearable motion sensors with a mobile device app, using real-time motion tracking to provide exercise biofeedback to the patient and log HEP performance metrics for remote clinicians (Figure 1). Through these mechanisms, *iA* helps to bridge the gaps in current physical therapy practices by allowing remote monitoring of HEP compliance and performance. *iA* has been evaluated in both healthy controls and adult patients with total knee replacement, which established a proof of concept of the technology [15].

Figure 1. *interACTION* (*Elizur*) platform components: (A) wireless motion sensors attached to the knee of a patient; (B) screenshots from the current version of the mobile app; (C) screenshot from the current version of the clinician portal. iA provides real-time exercise feedback to the patient and logs performance metrics for remote clinicians to allow home exercise program monitoring.

The interACTION Platform



Similar to many IHTs, *iA* in its current form is not grounded in models of behavioral change that may translate to a prolonged influence on patient behavior. IHTs founded on theoretical models of behavioral intervention, supported by technology, have been shown to promote exercise adherence more

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for the incorporation of numerous behavioral elements (ie, JMIR Serious Games 2021 | vol. 9 | iss. 3 |e27195 | p.185

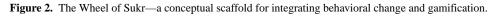
effectively [16-18]. The Wheel of Sukr is a proposed mechanism to introduce behavioral intervention concepts into IHTs. The

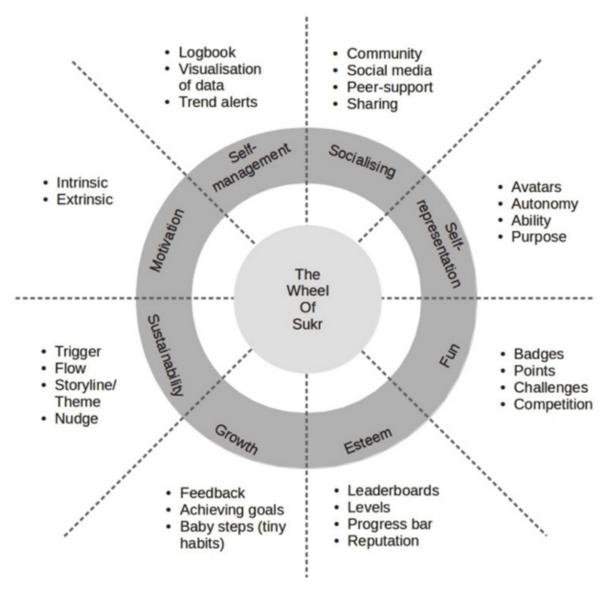
Wheel of Sukr (Figure 2), which was initially described in its

application to diabetes self-management, provides a structure

motivation, self-management, fun, and sustainability) into a game-like experience of an IHT [19]. This process of IHT *gamification* introduces behavioral intervention concepts through techniques typically used in game development [20]. It seeks to insert concepts such as engagement, reward, and incentive into the IHT platform to better engage patients and affect

behavioral change [21]. Adolescent athletes typically note prolonged (6-12 months) recovery following ACL-R as a hurdle to rehabilitation adherence, so the focus of Wheel of Sukr on sustainability was felt to be of relevance to this patient cohort [11].





Objective

The objective of this study is to use a user-centered design process to incorporate behavioral change strategies derived from self-management theory into the *iA* platform using the Wheel of Sukr gamification framework [19]. With the implementation of gamification on the *iA* platform, we hope to better engage young athlete ACL-R patients to improve their adherence to postoperative rehabilitation programs and subsequently improve their recovery. Self-reported questionnaires focus on patient adherence and barriers to adherence are also recorded to help characterize this patient population and to inform the development of behavioral change strategies.

Methods

Patient Recruitment

Young athletes aged 10-18 years with a history of ACL injury and surgical reconstruction were included in this study. Patients were identified for study inclusion by reviewing the electronic medical records at our institution. All patients were between 4 weeks and 1 year from the ACL-R before their consideration for study participation. Concomitant procedures, such as meniscal repairs and chondroplasties, performed at the time of ACL-R did not exclude participation but patients undergoing multiple-ligament reconstructions were excluded. Eligible patients were contacted by a research coordinator, at which time

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a thorough description of the study was presented, and informed consent was obtained from the patient or guardian.

Patient Information

After the participants were enrolled and informed consent was obtained, their age, sex, site of surgery (right or left), surgical procedures performed (including concomitant procedures), and date of surgery were recorded from the electronic medical record. On their interview date, participants were presented with a set of self-reported questionnaires, which were completed by either the participant or their proxy (parent or legal guardian). The questionnaire included demographic questions as well as the Exercise Adherence Rating Scale 10 items (EARS-10), General Self-Efficacy (GSE) scale, Tampa Scale for Kinesiophobia (TSK), and Numeric Pain Rating Scale (NPRS). The EARS-10 assesses adherence to prescribed HEPs by asking participants to answer questions about their exercise adherence and attitudes toward exercise.

GSE measures a participant's perceived self-efficacy. Scores predict the self-perceptions of self-efficacy. The participants rated their perceived self-efficacy, and higher self-efficacy was correlated with emotion, optimism, and better health outcomes. The TSK assesses fear of movement, fear of physical activity, and fear avoidance. A score <37 is classified as *low fear*, and a score >37 is classified as *high fear* [22].

Descriptive statistics were used to summarize patient demographics and the results for the EARS-10 GSE, TSK, and NPRS. The Pearson correlation coefficient (r) was calculated between these patient-reported outcome measures and was interpreted as follows: 0-0.1, negligible; 0.1-0.3, weak; 0.3-0.7, moderate; 0.7-1.0, strong.

Interview Process

The patient interviews were performed in private rooms in a clinical research suite, which served as a controlled environment to simulate outpatient medical encounters. The participants took part in a single individual interview with three distinct phases, as described below. The audio of participants was recorded throughout the entirety of their interviews.

Phase 1 followed a standardized, semistructured script, with open-ended questions designed to facilitate conversation with a specific focus on: (1) identifying critical elements of existing gaming experiences (ie, sports, video games) that lead to high levels of participation (adherence) and (2) eliciting experiential information regarding their knee surgery and subsequent physical therapy.

In phase 2, participants were presented with a series of cards, each presenting an aspect of game play designed to promote continued interest and participation. Each card displayed an individual component and a description of the Wheel of Sukr methodology. The language was altered to the appropriate reading level of the participants. The participants were prompted to *think aloud* as they reviewed these cards and were prompted to rank the cards in order of importance in maintaining interest in a game. The final card rankings of the participants were

recorded. The card sort was followed by a brief semistructured survey to elucidate the motivations behind the card sort results.

Finally, for phase 3, participants were presented with the current version of the *iA*. Participants were again prompted to *think aloud* as they had experienced the device. The participants were then presented with a brief semistructured survey to determine their overall opinion of the current device, elicit suggestions for improvement, and identify any gamification changes that should be implemented.

Phase 1 of the interviews was performed by an experienced facilitator with extensive background in qualitative research methods from the Qualitative Research Core at the University of Pittsburgh Center for Research on Healthcare Data. Phases 2 and 3 of the interviews were performed by a study research assistant, as they did not require the same level of experience with qualitative interview facilitation as the first phase. The interviews were audio recorded, transcribed, checked for accuracy, and transferred to ATLAS.ti (ATLAS.ti Scientific Software Development, GmBH) for coding.

Qualitative Data Analysis

A qualitative codebook was developed by the phase 1 interviewer using an inductive approach and shared with the study team to ensure that it captured key concepts that were of interest to the investigators. Once the codebook was finalized, 2 Qualitative Research Core coders used ATLAS.ti to independently code the full data set and to reconcile any coding differences. The interviewer or primary coder then conducted a content analysis using the coded data [23]. The resulting content analysis was confirmed by the secondary coder in the form of investigator triangulation.

Additional Data Analysis

The research team assisted in developing the best ways to display, represent, interpret, triangulate, and summarize the qualitative findings to achieve a fully integrated description [24]. These elements were categorized according to the Wheel of Sukr framework and translated into elements relevant to improving the design of iA to increase ACL-R patient engagement.

Results

Overview

A total of 10 interviews were conducted during the fall of 2019. Participants ranged in age from 11 to 15 years (mean 12.8, SD 1.32 years). Participant demographics are presented in Table 1. All 10 participants completed all three phases of the interviews.

Results of the EARS-10, GSE, and TSK questionnaires are presented in Table 2. The median value for the EARS-10 questionnaire was 26, with values ranging from 6 to 36. The median self-efficacy rating was 31.5, participants reported values ranging from 21 to 40, with 40 being the maximum value on the scale. Participants were divided evenly between low and high fear on the kinesiophobia scale. The median rating was 37.5 with ratings ranging from 19 to 44.



Table 1. Participant demographic information (N=10).

Demographics	Values
Gender, n (%)	
Male	3 (30)
Female	7 (70)
Age (years), mean (SD)	12.8 (1.32)
ACL ^a graft, n (%)	
Quadriceps tendon	1 (10)
Iliotibial band	1 (10)
Other procedures, n (%)	
Left knee arthroscopy	1 (10)
Lateral meniscal repair	1 (10)
Medial and lateral meniscal repair	1 (10)
Surgery date, n (%)	
February-April 2019	2 (20)
May-July 2019	5 (50)
August-October 2019	3 (30)
Time since surgery (months), n (%)	
0-2	2 (20)
2-4	3 (30)
4-6	3 (30)
>6	2 (20)
PT ^b start date, n (%)	
March-May 2019	2 (20)
June-August 2019	5 (50)
September-November 2019	2 (20)
Not recorded	1 (10)
PT duration, n (%)	
3 months	1 (10)
Ongoing	9 (90)
PT frequency, n (%)	
Once every 2 weeks	1 (10)
Once a week	1 (10)
Twice a week	6 (60)
Once or twice a week	1 (10)
Thrice a week	1 (10)
HEP ^c format, n (%)	
Verbal	7 (70)
Hard copy	7 (70)
Mobile app	2 (20)
HEP completed (%), n (%)	
25-50	2 (20)
50-75	4 (40)

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Demographics	Values
75-100	4 (40)

^aACL: anterior cruciate ligament.

^bPT: physical therapy.

^cHEP: home exercise program.

Table 2. Patient-reported outcomes of Exercise Adherence Rating Score, General Self-Efficacy score, and Tampa Scale of Kinesiophobia (TSK) listed
by participant. Participants divided into low fear and high fear categories based on results of TSK tabulation.

Participant	EARS-10 ^a score	GSE ^b scores	TSK ^c score	
1	25	36	19 ^d	
2	21	31	39	
3	21	36	37	
4	17	24	37	
5	34	30	38	
6	27	31	44	
7	36	39	29	
8	33	40	42	
9	6	21	35	
10	36	32	42	

^aEARS-10: Exercise Adherence Rating Scale 10 item; median score 26 (range 6-36).

^bGSE: General Self-Efficacy; median score 31.5 (range 21-40).

^cTSK: Tampa Scale of Kinesiophobia; median score 37.5 (range 19-44).

^dValues in italics denote low-fear patients (defined as Tampa Scale of Kinesiophobia score ≤37).

NPRS scores showed moderate rates of postoperative pain, which improved with the start of physical therapy and study enrollment (Table 3). The median pain rating postoperatively was 4, with postoperative pain ranging from 0 to 7. Pain at the

start of physical therapy ranged from 0 to 6, with a median value of 2. Pain in the 24 hours before the interview was low, with a median score of 0 and a range from 0 to 2.

Table 3. Numeric Pain Rating Scale responses, demonstrating mild-to-moderate postoperative pain that improved during and following physical therapy (N=10).

Pain rating scale responses	Participants, n (%)
Pain with surgery	
None	2 (20)
Mild	4 (40)
Moderate	4 (40)
Severe	0 (0)
Pain during physical therapy	
None	2 (20)
Mild	7 (70)
Moderate	1 (10)
Severe	0 (0)
Pain in the last 24 hours	
None	8 (80)
Mild	2 (20)

Pearson correlation coefficients were calculated for patient-reported outcomes. The correlation between EARS-10 and GSE was 0.79, indicating a strong correlation. Another

strong correlation was found between the NPRS surgery outcome and the TSK, with a value of 0.74. Both these correlations had a significant *P* value. All other *P* values were

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not significant. The r value for NPRS at the beginning of PT (Table 4). and EARS-10 was calculated as -0.46, a moderate correlation

 Table 4. Pearson correlation coefficients between patient-reported outcome measures. Strength of correlation increases as the r value approaches 1.

	GSE ^a	TSK ^b	NPRS ^c -surgery	NPRS-physical therapy	NPRS-24 hours
EARS-10 ^d					
r	0.792	0.101	-0.257	-0.456	0.173
P value	.006	.78	.47	.19	.63
GSE					
r	e	-0.207	-0.227	-0.280	0.345
P value	_	.57	.53	.43	.33
TSK					
r	—	—	0.741	0.1284	0.277
P value	—	—	.01	.72	.44

^aGSE: General Self-Efficacy Scale.

^bTSK: Tampa Scale for Kinesiophobia.

^cNPRS: Numeric Pain Rating Scale.

^dEARS-10: Exercise Adherence Rating Scale 10 item.

^eNot applicable.

Phase 1: Semistructured Interview

Injury and Surgical Recovery Experience

The participants typically injured their knees while playing a sport. Basketball was the most common sport, with other injuries occurring during soccer, lacrossing, skiing, and baseball. Participants described their surgical experience as *not bad* or said that it was tough at first and got better over time. Most patients did not complain of pain. Those who mentioned pain said they used counter pain medicine when they felt pain. As one patient explained:

Um, it was difficult, but it got easier along the way...Um, I wasn't in that much pain after surgery. Um, I took Tylenol if I had any pain.

Experiences in Postoperative Physical Therapy

Most participants attended all physical therapy sessions. Those who missed a session were missed because of being sick or having another appointment. One participant reported at the time of their interview that they had finished their physical therapy 1 month prior. When asked about their physical therapy experience, participants described that their therapy started out easily and progressively became more challenging:

Um well at first I just started like trying to bend my knee a little bit more and do some easier exercises and then it got like a little bit harder and...the exercises were like more difficult...at first it was super easy, and we didn't do a lot of stuff but then we started doing more stuff and it like got more challenging.

All participants were prescribed home exercises by their physical therapists. For the most part, they completed their home exercises. Others who missed a day of home exercise said they

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did not feel like it, they forgot, or were busy, which was consistent with responses on the EARS-10. Most said that their physical therapist did not monitor their home exercises, instead citing their parents as monitors. A few mentioned that while at a physical therapy session, the therapist would ask about their home exercises. Most also said that it would have been beneficial if their therapist monitored their home exercises. Select responses included:

Yeah I feel like it could be more uh motivating too...Um because the patient would know that the physical therapist could tell if you were doing your exercises or not and then they obviously wouldn't want the physical therapist to know that they're not doing them

Uh, because I feel like if he would have monitored it, um, they would have known where I was quicker, to help reach my goals.

The most common reason that the participants wanted to continue therapy was to improve their knee function and return to activities. Select responses include:

Just to regain-to go back to sports mainly; that's the main reason why I go, but also just to regain, like, stability in my knee.

Well, I wanna get back to sports as fast as I can and I wanna have my leg be as strong as before.

Others mentioned acceptance that they did not have a choice when it came to performing physical therapy during recovery and that the progress they were making was motivation to continue:

Yeah I-I didn't really have a choice. [laugh]...Because like if I didn't do it then I wouldn't get better. And I'd

rather be better than be like that for all the rest of my life.

Preferred Activities and Games

When prompted to provide examples of activities requiring dedicated practice in their daily lives, the majority of participants noted that they played a sport or multiple sports. Other less commonly cited activities included musical instruments or foreign languages. The reasons cited for continued practice for these activities were varied and included: the activities are fun or enjoyable or personally motivating, encouraging physical activity, and satisfying desires for both social interaction and competition. Sample responses included, "it's just fun...being with friends and...working out," "I like playing it...competing against other teams," "also because of the team aspect...being a part of something," and "I just have inner motivation to do them, like it's something that I enjoy."

Participants cited losing interest, lacking talent or ability, losing companions or teammates, and parental influences as reasons for withdrawal from activities. Many participants noted that they would keep doing an activity that they personally no longer care about with the help of extrinsic motivators such as friends, family members, or a coach to encourage them:

Maybe I'd do something if, like, my friends were doing it.

...help from others or maybe like...someone to, someone else to motivate...probably friends, my sister, parents, a teacher, or a coach depending on what the activity is.

A few mentioned acceptance that they just have to do an activity they do not care about (most commonly school), whereas others also said they would keep doing an activity they did not care about because it keeps them active.

All participants said that they enjoyed playing games. The types of games they enjoyed were sports, board games, and videogames. Most of the participants said that sports were their favorite games to play. The reasons they played their favorite games were enjoyment, competition, social aspects, and the nature of the game—or how the game is played, and its aspects are what they like about it. When asked how frequently they would play their favorite games, some said almost every day or every day. Typically, this frequency was for sports-related activities such as practices, games, or casual play. Some others said that a few times a week, a few participants said once a week. The frequency of how often they played their favorite games depended on whether it was a sport, board game, or videogame—with sports having more frequent sessions.

Mobile Apps

Participant responses were positive when asked about using a mobile app for home exercises. They thought that an instructional component on the app would be helpful: "...if I

had that thing on my leg it would just make me feel like I'm actually doing something and it would make me feel like it's easier and it would tell me if like I need to do better or not." They also felt that the app would be motivational and help keep them accountable when it came to completing their home exercises:

that would help a lot because again the physical therapist would be able to tell. And I also feel like you would get more uh research and like knowledge out of that.

Participants also cited convenience as it would be accessible by their phone, "I think it would be really convenient especially since you have your phone on you pretty much 24/7."

Participants were prompted to list features from their favorite games that they would include in a mobile app for their physical therapy. Sports specificity was commonly cited, such as:

Like, the soccer...foot skills...what skills I could do while I'm in physical therapy and like what could possibly help.

...it would also help motivate I feel like if you were practicing for a-I mean if you were training for a particular uh like sport or event or something like that.

Other features from the participants' favorite games that they endorsed included competition, notifications or reminders, rewards, and social aspects of gameplay:

If it had notifications or like reminders set for your uh for-what you have to do and if it just explained it like thoroughly how to do each thing having like your goals maybe like a chart of how far you've gone.

Maybe if there was, like, a competitive part of it where like...you, like, have to reach this goal, then, but if, like, a little hard to reach so you have to, like, kind of push yourself out of your comfort zone to do all of the exercises.

Phase 2: Wheel of Sukr Card Sort

In the Wheel of Sukr card sort exercise, the collective top three themes were motivation, self-management, and esteem (when using the median). When using the mean, motivation was first; self-management was second; and growth, esteem, and fun tied for the third. The top three themes of each participant are presented in Table 5, along with their reported favorite games, and the reasons and motivations for playing their favorite game. We presented the data individually by participants because the participants generally did not describe the cards any further than what it already said on the cards themselves—that is, most did not provide information on why they liked a concept beyond how it was already described on the card, and thus it was not possible to derive themes from their descriptions.



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Table 5. Wheel of Sukr themes and corresponding motivation among participants. Chosen themes, favorite games, and underlying motivations listed by participant.

Participant	Wheel of Sukr themes	Favorite games	Reasons and motivations
1	MotivationFunEsteem	BaseballFootballMonopoly	• Fun and physical activity
2	GrowthFunSelf-management	 FIFA^a Fortnight Minecraft Monopoly 	• Like soccer, multiple modes of play
3	MotivationFunGrowth	Strategy gamesCard gamesSports	• Focus and thinking, being with other people
4	SustainabilityMotivationSocializing	• Videogames	• Calming and fun
5	SocializingSelf-representationSelf-management	Board games	• Fun to play with friends and family
6	MotivationEsteemSelf-management	• Team sports	• Support from team and being active
7	FunMotivationSelf-management	BasketballBoard games	• Playing with friends, competition
8	MotivationEsteemSelf-management	Monopoly	• Competitive
9	Self-managementGrowthEsteem	• Sports or hockey	• Fun to play, interesting, fast paced
10	GrowthSelf-representationMotivation	• Soccer	• Enjoy it

^aFIFA: Fédération Internationale de Football Association.

When talking about what elements or features from the cards the participants would like to see in a game, many referenced their top three. Few participants mentioned a feature of a card, not in the top three. Textbox 1 lists the example recommendations for each card theme provided by the participants.



Card Element and Example Recommendation	
Motivation	
• Position on a leaderboard	
• Reward for playing each day	
• Points for completing tasks	
• Leveling up	
• Self-management	
• Seeing daily results	
• Setting goals	
Socializing	
• Connecting to friends in the game	
• Self-representation	
Creating own character	
• Fun	
• Challenges within the game	
• Esteem	
Congratulations	
• Growth	
Complete goals	
• Increased challenge progression	
• Sustainability	
Phase 3: iA Demonstration	having the ability of a physical therapist to morprogress remotely:

Review of Current Version

Participants generally had a favorable review of the current version of the iA. Participants liked that the device would be able to show them how they are moving during their physical therapy exercises:

I like the, how it shows you how far you have to go and stuff with like the angles and stuff. It's, it looks pretty simple and I like how it has the videos and it tells you everything.

Other participants elaborated that it would help them because they would not have to wait until their next physical therapy session to get feedback about their exercises:

That's so helpful...at the beginning [my therapist] tried to set goals but I couldn't really tell if I was achieving, like, the certain angle and then...I'm type who worries about everything, so I thought that I would, like, overstretch it or something like that. So I would one hundred percent use [iA]

Overall, all participants liked the device or thought it was cool. All would like to have something like it at home for physical therapy exercises. Some participants noted that they appreciated

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I think that would be helpful. And then, maybe, like...they could send you feedback once a week or something before your next session.

Whenever a parent spoke during the demo, they commented positively about the device and app. One parent said that it would help with motivation: "I think it would definitely help motivate, you know, an athlete to, to continue to do it because, you know, a lot of 'em get depressed and stuff and don't wanna do anything." Most participants did not have negative criticisms about the device or app, but a few felt that the sensor straps were cumbersome or irritating, suggesting a sleeve or other method of fixation.

Suggestions for Future Improvement

The participants verbalized various suggestions or improvements for the device and/or app related to understanding the exercises, creating goal-motivated incentives to complete exercises, and visual additions or changes. From a usability standpoint, some suggested improved descriptions of the individual exercises, whereas others focused on improving the method of attaching the sensors to their knees. One individual suggested the inclusion of a general surgical recovery guideline:

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[some]thing where you could search up if you had a question about [your recovery]...just like if you were feeling something it'd be cool to see if it was normal. Because, like, sometimes I felt, like, a pop or something, and...I would have to wait until the next time to ask [my therapist]. But if there's, like, a way to search up something that you're feeling.

The features of gameplay that participants wished to incorporate closely followed the themes from the Wheel of Sukr card sort activity. Suggestions for improvements centered more on mobile apps and games as opposed to sports and may have been influenced by phase 2's focus on these topics. Some participants suggested the incorporation of a sport into the *iA* app, but none went further to elaborate specific ways to incorporate sports. Participants also did not specifically cite social networking capabilities as essential additions to iA, but they noted this capability to be of interest or importance in general mobile apps or games. Textbox 2 shows the suggested iA improvements separated into their respective Wheel of Sukr categories.

۷h	heel of Sukr Category (Suggested Improvement)
•	Motivation
	• Encouragement
	• Tips
	Reward or congratulations for completion
•	Self-management
	Visual progress graph or timeline
•	Socializing
•	Self-representation
	Create-a-character option with customizable extras
•	Fun
	• Earning points or prizes for completion
	• Selection of games
	Bonus points and incentives for completing exercises or improvements
•	Esteem
•	Growth
	Timeline demonstrating baseline to current progress
	Sustainability

Discussion

Principal Findings

This study is the first in a stepwise, user-centered design process to integrate behavioral theory concepts into the design of iA, a mobile IHT to prescribe and monitor home exercises for knee-specific rehabilitation following ACL-R in young athletes. Participants reported that their favorite games were sports, with many participants reporting playing multiple sports and most participants becoming injured through their sports. Participants generally reported positive experiences with PT following ACL-R, yet most thought iA and its remote monitoring would have been a helpful addition to their overall PT experience and recovery.

When considering gameplay and mobile apps, the Wheel of Sukr domains of motivation, self-management, and confidence were deemed of highest importance, by median. The top three domains were motivation, self-management, and growth, esteem,

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minu. Participants impressions of tracked their knee PT exercises were overwhelmingly positive. The participants want the app to include a feature that tracks their exercise movement for accuracy and to include features to encourage or motivate them.

On the basis of these interviews, future versions of *iA* will strive to incorporate the following components of gameplay:

- 1. Provide a connection to favorite games or activities, which are predominantly sports in this young athlete population.
- 2. Provide goal- and incentive-based biofeedback during rehabilitative workouts to provide a source of motivation, both extrinsic and intrinsic, to complete assigned tasks and expedite recovery.
- 3. Provide a reward program based on progression along an expected rehabilitation trajectory with thresholds for performance and ability to socialize with fellow users (avatars, leaderboards, etc).

4. Provide motivational and/or encouragement components (alerts, clinician feedback, background educational information, etc) that draw users into the app daily.

Having a connection to favorite games or sports would help establish interest in the app from a preexisting interest. Incorporation of sport-specific activities later in the rehabilitation process may be helpful to promote longitudinal usage of the app:

...it would obviously help the knee get better for that specific sport so you'd be ready for that sport...And it would also help motivate I feel like if you were practicing for...a particular...sport or event.

The participants wanted to know that they were doing their home exercises correctly. This feature is already present in *iA*, through real-time biofeedback provided by the wireless sensors, but in its current form, it acts as a simple counting mechanism with no gamified structure. By improving this interface, the app can show how their knees are moving and provide more motivational feedback during workouts. The participants also wanted a better sense of how their recovery progressed. Incorporating performance thresholds or milestones and rewards, allowing users to interact with peers via avatars, and integrating regular feedback from their remote clinicians will be explored in future studies. This would improve self-management capabilities and provide extrinsic sources of motivation.

A strong significant correlation was calculated between the EARS-10 survey measuring exercise adherence and the GSE survey measuring self-efficacy. This strong correlation indicates that individuals with low self-efficacy are more likely to have lower adherence to HEPs. As the average score of the GSE was 31, with a value of 40 being the maximum score and indicating the highest level of self-efficacy, the participants interviewed overall had a fairly high self-efficacy score. Confidence and self-management were both highly rated components of the Wheel of Sukr and ideas related to a high level of self-efficacy. Designing the next iteration of *iA* and taking into account the highly ranked ideals of confidence and self-management can keep those with high self-efficacy adherent to their maximum potential and engage young athletes with naturally lower self-efficacy.

A strong significant correlation between a high NPRS value postoperatively and a high rating on the TSK was calculated, suggesting that higher pain postsurgery is related to a fear of movement. This finding is consistent with those of previous studies on chronic musculoskeletal pain and kinesiophobia using the Tampa Scale [25]. Goal and incentive-based feedback, both intrinsic and extrinsic, will be implemented in future iterations of iA to keep users engaged in the early aspects of their rehabilitation despite high levels of pain. Starting the rehabilitation process out quickly postoperatively and having patients adhere to their HEP over time should decrease pain levels and kinesiophobia as the patient progresses through treatment, as patients will gain more confidence as exercises and movement become easier and less painful. In addition, direct communication from remote clinician monitoring progress can ease patient hesitation and build confidence by answering

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A moderate negative correlation was found between the EARS-10 and NPRS-PT ratings, indicating that higher pain during physical therapy is related to lower home exercise adherence. This correlation was not statistically significant; therefore, future work is needed to completely understand this relationship. The patients do not want to perform their assigned exercises on their own if they are in pain. Increasing patient adherence through motivational tools to draw users to the app daily will increase the frequency of home exercise performance and decrease pain over time as the knee begins to return to its previous level of function.

iA is an IHT designed to bridge the gap between patients and clinicians during rehabilitation for knee injuries and surgeries. The use of IHTs to promote health and manage illness has led to fundamental changes in health practices and transformed health care [26]. Qualitative studies indicate that patients have positive perceptions of IHTs and their benefits, including awareness of progress, feeling of being in control, empowered self-management, and improved patient-clinician communication [27-30]. IHTs founded on theoretical models of behavioral intervention supported by technology have been shown to promote exercise adherence more effectively than those devoid of behavioral modeling [16-18]. The Wheel of Sukr method was applied to *iA* as it is designed to affect behavioral changes for chronic conditions, and many adolescent athletes view their ACL-R rehabilitation as a long-term event and cite fatigue as a prime driver of noncompliance [11,21,31].

Limitations and Future Considerations

This study has several limitations. Given that qualitative studies emphasize exploration of participant perspectives in great depth, sample sizes tend to be small, potentially limiting generalizability. In addition, there may be bias in the sample, insofar as participants may have agreed to be interviewed because of a particular interest in the topic. However, thematic saturation was reached by the conclusion of our 10 interviews, suggesting that the sample was sufficient to obtain a representative range of perspectives and experiences. The interview responses were monitored by a quantitative data expert who determined when thematic saturation was achieved. Furthermore, our sample was diverse in terms of gender, age, and surgical procedures (concomitant procedures with ACL-R).

Gamification of iA was explored in this study to incorporate the behavioral theory concepts of gaming to improve engagement with and adherence to the iA rehabilitation platform, which can be applicable to other IHTs as well [19,21]. Moving forward, we will focus on improving the domains of motivation, self-management, and growth or esteem or fun to the iA user experience. In subsequent studies, young athlete ACL-R patients will be asked to complete typical clinical scenarios using progressively more developed prototypes of the gamified iA in a controlled laboratory setting. The usability of each gamification aspect and its ability to induce continued user engagement will be assessed objectively and subjectively. On the basis of these metrics, iA will undergo an iterative improvement process to address its current limitations.

Conflicts of Interest

MM receives royalties from Elizur, LLC, for a patent related to this manuscript. KMB receives royalties (<US \$5000 per year) from the license of iA (University of Pittsburgh Reference #04275) being further developed in this research study.

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Abbreviations

ACL: anterior cruciate ligament ACL-R: anterior cruciate ligament–reconstruction EARS-10: Exercise Adherence Rating Scale 10 item GSE: General Self-Efficacy HEP: home exercise program iA: interACTION IHT: interactive health technology NPRS: Numeric Pain Rating Scale TSK: Tampa Scale for Kinesiophobia

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Original Paper

A Personalized Home-Based Rehabilitation Program Using Exergames Combined With a Telerehabilitation App in a Chronic Stroke Survivor: Mixed Methods Case Study

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Abstract

Background: In Canada, only 11% of stroke survivors have access to outpatient and community-based rehabilitation after discharge from inpatient rehabilitation. Hence, innovative community-based strategies are needed to provide adequate postrehabilitation services. The VirTele program, which combines virtual reality exergames and a telerehabilitation app, was developed to provide stroke survivors with residual upper extremity deficits, the opportunity to participate in a personalized home rehabilitation program.

Objective: This study aims to determine the feasibility of VirTele for remote upper extremity rehabilitation in a chronic stroke survivor; explore the preliminary efficacy of VirTele on upper extremity motor function, the amount and quality of upper extremity use, and impact on quality of life and motivation; and explore the determinants of behavioral intention and use behavior of VirTele along with indicators of empowerment.

Methods: A 63-year-old male stroke survivor (3 years) with moderate upper extremity impairment participated in a 2-month VirTele intervention. He was instructed to use exergames (5 games for upper extremity) for 30 minutes, 5 times per week, and conduct videoconference sessions with a clinician at least once per week. Motivational interviewing was incorporated into VirTele to empower the participant to continue exercising and use his upper extremities in everyday activities. Upper extremity motor function (Fugl-Meyer Assessment–upper extremity), amount and quality of upper extremity use (Motor Activity Log-30), and impact on quality of life (Stroke Impact Scale-16) and motivation (Treatment Self-Regulation Questionnaire-15) were measured before (T1), after (T2) VirTele intervention, and during a 1- (T3) and 2-month (T4) follow-up period. Qualitative data were collected through logs and semistructured interviews. Feasibility data (eg, number and duration of videoconference sessions and adherence) were documented at the end of each week.

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Results: The participant completed 48 exergame sessions (33 hours) and 8 videoconference sessions. Results suggest that the VirTele intervention and the study protocol could be feasible for stroke survivors. The participant exhibited clinically meaningful improvements at T2 on the Fugl-Meyer and Stroke Impact Scale-16 and maintained these gains at T3 and T4. During the follow-up periods, the amount and quality of upper extremity use showed meaningful changes, suggesting more involvement of the affected upper extremity in daily activities. The participant demonstrated a high level of autonomous motivation, which may explain his adherence. Performance, effort, and social influence have meaningful weights in the behavioral intention of using VirTele. However, the lack of control of technical and organizational infrastructures may influence the long-term use of technology. At the end of the intervention, the participant demonstrated considerable empowerment at both the behavioral and capacity levels.

Conclusions: VirTele was shown to be feasible for use in chronic stroke survivors for remote upper extremity rehabilitation. Meaningful determinants of behavioral intention and use behavior of VirTele were identified, and preliminary efficacy results are promising.

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KEYWORDS

stroke; rehabilitation; virtual reality; video games; telerehabilitation; upper extremity; motivation

Introduction

Background

Stroke can cause chronic sequelae in the hemiparetic upper extremity, requiring long-term rehabilitation care [1]. In Canada, only 11% of stroke survivors have access to outpatient and community-based rehabilitation after discharge from inpatient rehabilitation [2]. Stroke rehabilitation can help minimize impairments and promote independence during both the acute and chronic phases of stroke [3,4]. Hence, innovative community-based strategies are needed to provide adequate postrehabilitation services to stroke survivors in the community when these resources are not available. Consequently, virtual reality (VR) exergames are a promising alternative to traditional rehabilitation services, allowing continuous access to challenging exercises [5]. When combined with a telerehabilitation app [6], a follow-up with a clinician may be provided to adjust the difficulty level of the exergames and choice of exercises, according to the stroke survivor's abilities and goals. The VirTele program-a program that combines VR exergames and a telerehabilitation app-was developed to provide stroke survivors with residual upper extremity deficits the opportunity to participate in a personalized rehabilitation program.

Motor and functional gains can be achieved during the chronic phase of stroke. However, it remains difficult to maintain these gains throughout time as they are essentially dependent on adherence to exercise guidelines and the availability of community-based resources, such as access to rehabilitation services, programs, and clinicians with stroke recovery expertise [4]. Therefore, rehabilitation programs developed for chronic stroke survivors should include strategies to encourage and motivate the use of the affected upper extremity through self-directed exercises and everyday activities [4,5]. Behavior change techniques (BCTs) were therefore incorporated into the VirTele program to empower users to continue exercising and using their upper extremities in everyday activities (eg, brushing their hair, getting dressed, and eating) [7]. Furthermore, there is increasing evidence that having a strong theoretical basis and using BCTs improves the efficacy of programs aimed at changing behaviors [7-9].

In light of current knowledge, the self-determination theory [10] was used to guide the clinician-stroke survivor interaction during videoconference sessions in the VirTele program. This theory stipulates that people tend to change their behavior when three of their needs are respected, including autonomy (the ability to organize their behavior according to their own aspirations and values), connectivity (the sense of belonging and the desire to be supported), and competencies (belief in their skills and abilities) [10]. Thus, the clinician was trained to consider these three psychological needs when interacting with a stroke survivor. In addition, BCTs (eg, 1.1. Goal setting, 1.4. Action planning, and 1.5. Review behavior goals) [7] and motivational techniques (open-ended questions, affirmation, reflective listening, and summary statements) [11] may be used to enhance stroke survivors' motivation and adherence to VirTele exercises [12,13].

As we intend to implement the VirTele program in stroke survivors' communities, factors that could influence behavioral intention and use behavior regarding the intervention must be explored. This study was conducted in the context of a larger study before starting a randomized clinical trial to inform the development of evaluation and intervention protocols [14]. The clinical trial was registered at ClinicalTrials.gov (NCT03759106).

Objectives

The objectives of this study are (1) to determine the feasibility of using a telerehabilitation app combined with an exergame for a remote upper extremity rehabilitation program in a chronic stroke survivor; (2) explore the preliminary efficacy of VirTele on upper extremity motor function, the amount and quality of upper extremity use, and impact on quality of life and motivation; and (3) explore the determinants of behavioral intention and use behavior of VirTele along with indicators of empowerment.

Methods

Overview

A case study using a mixed methods design was conducted before the start of a randomized clinical trial. A quantitative approach was used to collect feasibility and preliminary efficacy data before and after the VirTele intervention and during a 1and 2-month follow-up period. A qualitative approach was used to explore the factors that influenced the use of the technology and its impact on the participants' empowerment. This study was approved by the research ethics boards of the Center for Interdisciplinary Research in Rehabilitation of Greater Montreal (June 28, 2018).

Participant

A 63-year-old male stroke survivor (3 years) from the United States participated in this study. His upper extremity score on the Chedoke McMaster Stroke Assessment Scale indicated moderate impairment (arm stage 6). The participant was no longer receiving rehabilitation services and had an active lifestyle (swimming, walking, and fitness training). He was very comfortable with computers as he had a professional information technology background and used a computer one or more times a week.

After reading about our registered protocol at ClinicalTrials.gov, he approached our research team via email. At that time, the development and testing phases of the rehabilitation program and technology with VirTele were still ongoing. The participant was enthusiastic about playing an expert role in the study and testing the VirTele remote rehabilitation program in a setting similar to that of the proposed research study. He was eager to help identify the best way to combine telerehabilitation and videogames for home use to optimize upper extremity functional and motor recovery following a stroke. In doing so, he would assist in developing a final VirTele rehabilitation training that could be used as an intervention model for our future randomized clinical trial. Given the remote nature of the VirTele program, we were able to conduct the study with the participant remotely. The participant agreed to contribute to preliminary data collection and will not be included in future clinical trials. He provided informed consent before starting the case study, as per the Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal's institutional ethics review board.

VirTele Intervention Protocol

Overview

The participant was invited to complete a home-based, 2-month rehabilitation training program using a telerehabilitation app combined with a nonimmersive VR exergame. The equipment necessary to operate the technology properly included internet access, a computer (desktop or laptop), a video camera, and a Kinect camera. The participant already owned all the equipment except for the Kinect camera, which was sent to him. Before starting the intervention, the participant was trained on using the telerehabilitation app Reacts (Innovative Imaging Technologies and Reacts) [15] and the VR exergame Jintronix (Jintronix Inc) [16], two systems previously used by the research team.

The program included 30-minute exergame sessions 5 times per week for 2 months (approximately 20 hours) and 1-hour videoconference sessions with a clinician one to three times per week for 2 months. However, it was up to the clinician to determine the frequency of follow-up. The clinician based that decision on the stroke survivor's behavior (adherence to the exergames and use of the affected arm in daily life activities) and needs (support for exergames use and discomfort). This approach intends to maintain the participant's motivation, ensure that the exergames are adequately tailored, monitor functional use of the upper extremity, and develop strategies to increase the participant's autonomy in an effort to maintain the participant's activity level after the study ended. The clinician (DRA; physiotherapist) is part of the research team and has 4 years of experience working with a stroke population in research settings.

Exergame Sessions

We used the Jintronix-VR exergame (Jintronix Inc), which included 5 types of upper extremity games at the time (Space Race, Fish Frenzy, Pop Clap, Catch and Carry an apple, and *Kitchen clean up*) [16]. The practice involved reaching virtual target objects and moving them following a specific trajectory preselected by the clinician based on the participant's level of impairment. For example, with the Fish Frenzy task, the participant must successfully move a fish along a designated path by controlling the position of the affected hand; in the Kitchen clean up task, the participant must pick up various pieces of cutlery and dishes and put them away in the appropriate drawer or shelf. Although performing the virtual tasks, the participant can see his own virtual hand displayed on the screen in games such as Pop Clap, Catch and Carry an apple, and Kitchen clean up. In other games (Space Race and Fish Frenzy), the hand is replaced by a virtual object (fish or spaceship). The exergame platform also provides visual feedback on the game score, the remaining time to succeed in the task and the warning signal for each unsuccessful attempt, as well as auditory feedback reflecting successful or unsuccessful outcomes of the accomplished movement. The exergame sessions follow a structured training protocol with tasks of increasing difficulty using various parameters, such as the number of rounds, repetitions, time, speed, precision, and shape of objects, adjusted weekly by the clinician during videoconference meetings. Overall, the exergames were chosen based on the participant's preferences and progress.

Gameplay Overview

The game starts on a menu screen in which a predetermined program training session can be launched. After clicking start, the Kinect camera starts calibrating the initial stroke survivor's position, capturing the user skeleton with markerless motion sensors [17]. An example of the gameplay overview of the Fish Frenzy task is shown in Figure 1. Screenshots of the gameplay of the other games are provided in Multimedia Appendix 1.

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Figure 1. All phases of the Fish Frenzy task are depicted from (a) to (f). At the start of the game session, an example of the gameplay with a human model is shown on the screen. At the GO signal, the stroke survivor starts moving the fish to follow a path or catch the stars. The stroke survivor must complete the journey as fast as he can and repeat the same journey as often as possible for a predetermined period, as assigned by the clinician. The stroke survivor has to control his upper extremity when moving the fish to avoid touching the black objects surrounding the stars, which results in a loss of points. When finished, the final score is shown.

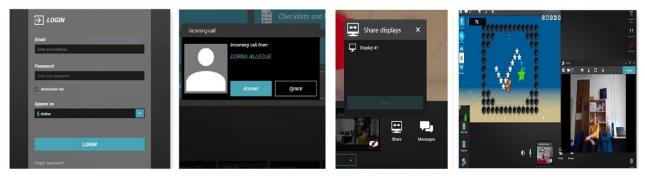


Telerehabilitation

For the telerehabilitation app, we used Reacts (Innovative Imaging Technologies Inc and Reacts) [15], which allows videoconferencing and secure sharing of participants' health information [15]. The telerehabilitation app was used for remote supervision, monitoring, and rehabilitation purposes. An algorithm design was used to run the telerehabilitation app and exergame simultaneously, allowing the clinician to see the participant performing the exercises and view the game screen simultaneously, making the VirTele program unique. The

videoconference session allows the clinician to provide the participant important instructions and advice during the games, for example, to correct their posture or their upper extremity position and observe the quality of the participant's upper extremity movements. In studies using VR systems for home-based rehabilitation [18-24], supervision is not always provided [16,18], and when it is offered, it is delivered by telephone [18,19,23] and rarely synchronized with the time when the participant is performing the games [21,24]. All phases of running the exergames and the videoconference system are shown in Figure 2.

Figure 2. All phases of running the exergames and the videoconference system simultaneously are depicted from left to right. After entering their email and password into Reacts, the stroke survivor waits for the clinician's call and then clicks on the answer button to start the videoconference session. Once the videoconference begins, they must click on the share button. After launching screen sharing, the stroke survivors may start playing the games. In this phase, the clinician can see the gameplay overview and the stroke survivor.



Motivational Interviewing

Motor and functional gains can be achieved during the chronic stroke phase; however, for long-term maintenance, rehabilitation programs should include strategies to encourage and motivate

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XSL•F() RenderX the use of the affected upper extremities through self-directed exercises and everyday activities [4,5]. Therefore, motivational interviewing based on BCTs was incorporated into the videoconference sessions to ensure that shared decision-making and empowerment were consistently integrated into the VirTele

intervention. The BCTs included were as follows: 1.1. Goal setting, 1.4. Action planning, 1.5. Review behavior goals, 4.1. Instruction on how to perform the behavior, 8.1. Behavioral practice, 6.1. Demonstration of the behavior, 2.2. Feedback on behavior, 2.7. Feedback on outcomes of behavior, 1.6. Discrepancy between current behavior and goal, 1.2. Problem solving, 2.3. Self-monitoring of behavior, 9.2. Pros and cons, 5.1. Information about health consequences, and 15.1 Verbal persuasion about capability [7]. Motivational interviewing techniques included open-ended questions, affirmation, reflective listening, and summary statements [11].

In addition to exergames, the program included supplementary daily activities to meet participants' individual goals, such as hand dexterity (eg, grasping, holding, and pinching) using the resources available within the participant's home.

Thus, many tools available through the telerehabilitation app (document sharing) and the exergame (computerized participant logs such as active time, compensation, and scores during each game) were used by the clinician for encouragement, goal setting, tracking of upper extremity use in daily activities, monitoring of exergame adherence (duration, intensity, and type), and tailoring the exergames to the participant's abilities.

In accordance with the self-determination theory [10], the clinician was trained to consider the three psychological needs when interacting with the stroke survivor by including him in every step of the decision-making process related to the treatment plan, respecting his autonomy, and valuing his skills and ability to achieve his goals.

The clinician received training in motivational interviewing before starting the intervention and used standardized interview guidelines during each videoconference session. The motivational interview guidelines were standardized to facilitate their use in further research and better monitor the use of BCTs. In that sense, predefined questions were prepared and applied concerning the stroke survivor's three psychological needs (autonomy, competence, and connectivity). The choice of questions varied depending on the stroke survivor's behavior state (total adherence or nonadherence to VirTele). The questions were provided as examples, but the clinician was free to reformulate them. Further details can be found in Multimedia Appendix 2.

Data Collection

Functional Performance and Self-reported Data

For this case study, progress was assessed remotely using the videoconference system Reacts (Innovative Imaging Technologies Inc and Reacts) at baseline, at the end of the 2-month intervention, and after a 1- and 2-month follow-up period. Performance-based measures included the Fugl-Meyer Assessment–Upper Extremity (FMA-UE) [25,26] motor function score, which captures synergy, coordination or speed, and the sensorimotor function of the upper extremity, wrist, and hand. The FMA-UE motor function score has been shown to be valid in a stroke population [27] and reliable for remote evaluation (video observation of the scale administration by an evaluator) [28]. Given the participant's distance, we tested the feasibility of administering the FMA-UE (motor function) remotely,

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without the presence of an evaluator on site with the participant. For that purpose, the score was adjusted to 60 as the reflex activity component was removed from the scale (which was retained in other studies, including on-site evaluations) [28,29].

Self-reported questionnaires included the Motor Activity Log (MAL)-30 [30,31], the Stroke Impact Scale (SIS)-16 [32,33], and the Treatment Self-Regulation Questionnaire (TSRQ)-15 [34]. The MAL is a self-reported measure that rates the quality (MAL-quality of use subscale) and frequency of use (MAL-amount of use subscale) of the affected upper extremity in 30 everyday functional tasks [30,31]. The MAL includes several versions (MAL-14, MAL-26, MAL-28, and MAL-12), which vary according to the number of items, but the original version of the MAL-30 is the most encompassing in terms of tasks and best meets our study objectives [35]. The MAL-30 demonstrated high reliability and validity in a poststroke population [36]. The impact on quality of life was determined using the SIS, a stroke-specific, self-reported health status measure consisting of 16 items. The SIS evaluates the impact of stroke on 3 dimensions: hand function, activities of daily living, and mobility [32,33]. The SIS-16 has been shown to have good reliability and validity [37]. Motivation was measured using the TSRQ, a 15-item questionnaire developed to measure treatment motivation, consistent with the self-determination theory [10]. The TSRQ captures different processes of motivation through 4 subscales: autonomous motivation, amotivation, external regulation, and introjected regulation. First, external regulation is the lowest level of the regulatory process that contributes to short-term changes [38]. During this process, the person behaves in such a way that they obtain a reward or avoid punishment; this choice is controlled by certain consequences, and they do not act according to their own wishes [38]. Second, introjected regulation describes a controlled motivation regulated by internal pressures, where a person behaves to avoid feeling guilty or proud [38]. Ultimately, autonomous motivation corresponds to the state of internalization of extrinsic motivation, where the person is in full agreement with the new changes, and their self-regulated behavior becomes autonomous [38]. Finally, amotivation describes a lack of motivation to pursue these changes.

A previous version of the TSRQ, a 13-item questionnaire, did not include the amotivation subscale, which is an important aspect to capture in our study, thus explaining our choice of the 15-item version. The TSRQ-15 has been shown to be reliable and valid across health care contexts [34], including rehabilitation [39].

The participant received the questionnaires through the telerehabilitation platform, which allows secure document sharing. Once the questionnaires were filled out, we met the participant via a videoconference to check his answers (to ensure that the questions were well understood) and ask for clarifications if necessary. This step was only taken in this case study, as we assessed the feasibility of the evaluation process, including remote questionnaire administration.

Sociodemographic variables were also collected at baseline: age, sex, civil status, years of education, primary occupation, date of stroke, time since stroke, side of stroke, and handedness.

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We also documented all physical and leisure activities (types and duration) accomplished before, during, and after the intervention.

Qualitative Data

Qualitative data were collected throughout the study using different sources (logs, videos, and email correspondence). A semidirected interview was conducted at the end of the intervention to identify the factors that influenced the behavioral intention and use behavior of VirTele and capture the participant empowerment indicators. The interview guide was developed based on the principles of the self-determination theory [10] and the Unified Theory of Acceptance and Use of Technology (UTAUT) [40]. The UTAUT highlights three direct determinants of behavioral intention (social influence, performance expectancy, effort expectancy, and facilitating conditions) and two direct determinants of use behavior (facilitating conditions and behavioral intention) of a new technology [40]. In addition, 4 moderators were described in this theory, including age, gender, experience, and voluntariness of use [40]. The UTAUT has been validated and consistently explains use behavior in various settings (research and technology) [41].

The constructs of the UTAUT [40] were used to inform the determinants that influenced the behavioral intention and use behavior of VirTele. Operational definitions were used for each theoretical construct to capture the context in which VirTele was used and better comprehend the environment-related factors. The operational definitions of the constructs are as follows: performance is defined as the degree to which a participant believes that VirTele would enhance or has enhanced their exercise performance (eg, duration, frequency, difficulty, goals, and expected outcomes) to optimize rehabilitation of the upper extremity. This definition embodies both expected and actual performance, as it aims to capture the participant's expectancy of VirTele regarding exercise performance and the actual exercise performance after using VirTele, which could impact their motivation to continue using the system. Effort is defined as the degree of ease or complexity related to VirTele use and encompasses both expected and experienced efforts. Social influence is defined as the degree to which an individual entourage agreement or disagreement may affect their use of VirTele. Facilitating conditions and obstacles are defined as the factors that may facilitate or inhibit the use of VR-telerehabilitation technology, including control of internal constraints (capacity and knowledge to use new technology) and external constraints (technical and organizational infrastructure). The self-determination theory constructs were used to inform the participant empowerment during the VirTele program.

Feasibility Data

Descriptive data relating to the VirTele rehabilitation training were documented in a standardized form at the end of each week. These data included the number and duration of videoconference sessions, adherence to the exergames (duration and frequency), technical difficulties, and adverse events (pain, falls, motion sickness, dizziness, exertion, fatigue, and headaches). These data were collected from logs completed by the clinician and from the exergame and telerehabilitation portals.

Data Analysis

Descriptive analyses were conducted for performance-based measures and self-reported data. The interview was audio-recorded, transcribed verbatim, and analyzed through the lens of the self-determination theory [10] and the UTAUT [40]. Content analysis was applied to identify the factors that influenced behavioral intention and use behavior of VirTele and significant indicators of empowerment that could result from the use of the VirTele program, including motivational strategies. The identified empowerment indicators were categorized into capacities and behaviors based on the conceptual model of patient empowerment [42]. When relevant, themes identified through the qualitative analysis were used to deepen and explain the quantitative findings.

For the scientific rigor of qualitative data, the principles of Lincoln and Guba [43] were applied. Audit trail and verification were performed to ensure confirmability. External verification by team members was applied to ensure credibility. Reliability was achieved through verification by 3 coders of a part of the data. For transferability, reflexive notes and a detailed description of the context of the intervention were provided.

Results

Functional Performance and Self-reported Data

The FMA-UE (motor function component) exhibited a significant increase in the total score from baseline (T1) to postintervention (T2; total score difference 6; Table 1), which is within the estimated minimal clinically important difference (MCID) range of 4.25 to 7.25, specifically for the upper extremity motor function component [44]. The FMA-UE total score was maintained during the follow-up period at T3 and T4 and may suggest a slight increase, although there were no significant changes beyond the postintervention results at T2 (Table 1).



Table 1. Functional performance and self-reported measures.

Outcome measures	T1	T2	Т3	T4	Score direction
Fugl-Meyer Assessment–Upper Extremity motor function (score from 0 to 60)	49	55	56	57	High score: better motricity of the affected upper extremity
Motor Activity Log (score from 0 to 5)					
Amount of use	1.53	2.45	2.72	3.26	High score: higher frequency of use of the affected upper extremity
Quality of use	1.43	2.29	2.65	2.95	High score: better quality of movement of the affected upper extremity
Stroke Impact Scale (score from 0 to 100)					
Hand function	0	25	25	50	Low score: high impact on quality of life
Mobility	75	71.43	64.28	64.28	Low score: high impact on quality of life
Activities of daily living	68.75	71.87	87.5	84.37	Low score: high impact on quality of life
Treatment Self-Regulation Questionnaire					
Autonomous motivation (score from 0 to 42)	42	42	42	42	High score: high level of autonomous motivation
Introjected regulation (score from 0 to 14)	8	8	2	5	High score: high level of introjected motivation
External regulation (score from 0 to 28)	6	10	4	8	High score: high level of external motivation
Amotivation (score from 0 to 21)	3	3	3	4	High score: high level of amotivation

The total score on the MAL–amount of use increased to 2.45 at T2, close to the score of 2.5 (Table 1), predicting 50% or greater perception of recovery in the affected upper extremity (based on a scale of 0% to 100% of SIS–section perceived recovery) [45]. During the follow-up period, improvement in the amount of use scale was maintained and exceeded the score of 2.5 at T3 and T4. The change in the MAL–quality of use at T2 (total score difference 0.86) was not clinically relevant (MCID is between 1.0 and 1.1 [31]) but was significantly different from baseline at T3 (total score difference 1.22) and T4 (total score difference 1.52; Table 1).

The SIS revealed improvements in hand function and activities of daily living dimensions with a meaningful difference from baseline to T4 (Table 1), exceeding both the MCID range of 9.4 to 14.1 [33]. There was no improvement in the SIS mobility dimension, with a decreasing tendency over time (Table 1).

The TSRQ showed a high score on the autonomous motivation subscale (score=42/42), which was maintained during the follow-up period at T3 and T4. The amotivation subscale showed a low score (score=3/21) from baseline to the follow-up period at T3 and increased by 1 point at T4 (score=4/21). The external regulation subscale showed an increase in score from baseline (T1) to postintervention (T2; score from 6 to 10/28), followed by a decrease at T3 (score=4/28) and an increasing tendency at T4 (score=8/28). The introjected regulation subscale showed a moderate score (score=8/14), which was maintained from baseline to postintervention T2 and decreased during the follow-up period.

Qualitative Data

Determinants of Behavioral Intention and Use Behavior of VirTele

Consistent with the UTAUT, we identified four major determinants from the directive content analysis, namely,

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performance, effort, social influence, facilitating conditions, and obstacles.

Performance

Regarding performance, the participant raised many relative advantages of VirTele compared with standard therapy (exchange of messages, videoconference, follow-up by the clinician, no limited time of therapy, time to reflect, correct, and discuss with the clinician) and perceived an improvement in arm functional performance and impact on daily activities, including making his bed, putting socks on, doing laundry, and shopping.

Effort

As for effort, the participant was very comfortable using VirTele and reported only minor issues related to the audio and video being cut off, which he resolved himself. Effort was highly moderated by participants' previous experiences with information technology. In fact, the participant's background in information technology facilitated his VirTele use and management of the issues he encountered.

Social Influence

Concerning social influence, it was important for the participant to share his VirTele experience with his friends and family, and receiving positive feedback encouraged him to continue using the technology.

Facilitating Conditions and Obstacles

The qualitative results suggest that the participant believed that he had the necessary knowledge to use VirTele but raised potential factors that could influence the long-term use of the technology: the lack of control of technical infrastructures (internet access, quality of internet service [high speed], and the method to modify the exergames) and organizational infrastructure (access difficulty to VR at the individual level

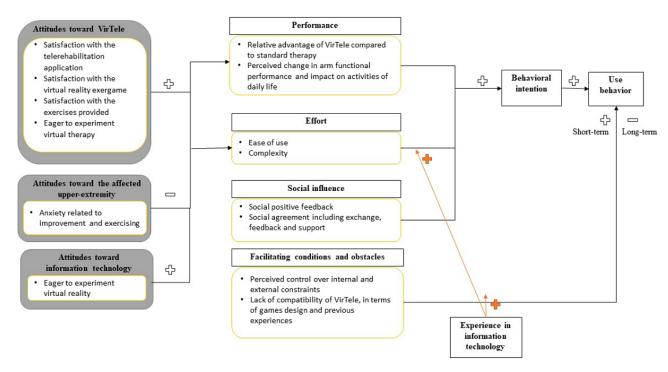


and limited health system resources). In addition, the participant reported a lack of compatibility of VirTele with needs in terms of game design (choice of avatar and background color) and previous experience (interoperability).

In addition to the pre-established determinants of the UTAUT, three new constructs emerged, including attitudes toward VirTele (satisfaction with the telerehabilitation platform, satisfaction with the exercises provided during the intervention, and satisfaction with the VR exergames), attitudes toward the affected upper extremity (anxiety related to upper extremity improvement and exercising), and attitudes toward information technology (eager to experiment with VR).

A model of how these four determinants and attitudinal factors interact with behavioral intention and use behavior is presented in Figure 3.

Figure 3. Factors that influence behavioral intention and use behavior of VirTele.



Empowerment

Of the eight videoconference sessions, two sessions focused on motivational interviewing. The first one was conducted after the participant reported discomfort to find a strategy to overcome the problem and motivate him to gradually resume the exercises. The second one was conducted 2 weeks later to maintain his adherence to the exercises using different motivational techniques such as goal planning, exploration of ambivalence, valuation, and reflective listening. In the other six sessions, the clinician usually started the videoconference with remote supervision of the participant's performance, adjustment of the difficulty level of the preselected games, and finally ended with motivational interviewing. During the videoconference sessions, the participant took an active role and participated in every decision related to his rehabilitation program, including the choice of games, difficulty level, and strategies to improve daily life activities.

Relevant empowerment indicators were identified and categorized into capacities and behaviors. Detailed descriptions of these indicators are provided in Textbox 1.



Textbox 1. Description of empowerment indicators in terms of capacities and behaviors.

Description of indicators in terms of capacities and behaviors

Attitudes

- High expectation of improvement
- Motivation to continue exercising despite the difficulties
- Willingness to communicate and exchanges ideas of exercises modalities
- Willingness to participate in patient support or advocacy groups

Self-awareness

- Importance of exercise
- Continue exercising despite difficulties
- Awareness that recovery may require long and hard work
- Perceived personal control of health and health care
 - Limited access to health care services
 - Frustration because of lack of access to health services
- Sense of meaning and coherence about health condition
 - No complaints about the functional stage attained and gratefulness
- Health literacy
 - Comprehension of the neuroplasticity phenomenon and its role in stroke recovery
- Self-management of own health care
 - Using a keyboard instead of a touching screen to exercise fingers
 - Management of time between autonomous game sessions, supervised sessions with a clinician, and fitness program
- Participation in decision-making
 - Discussion of the exercise's parameters with the clinician
 - Discussion of the difficulties encountered and related solutions
- Self-empowerment
 - Use the internet to collect information and support from other survivors and get other perspectives
 - Use the internet to collect information about other virtual reality-based rehabilitation and contact clinician
 - Participation in a course given at the rehabilitation school at Université de Montreal (Montreal, Canada) as a speaker to share his VirTele experience with students and clinicians

Feasibility Data

Adherence to the VirTele Program

During the 2-month intervention, the participant completed 48 sessions of 33 hours and 15 minutes of active games and 8 videoconference sessions with a clinician. As the participant was very comfortable with the technology and used the exergames more than expected, the clinician did not feel the need to meet with him more than once a week. During the fourth

week, no meeting occurred, and the meeting was rescheduled during the fifth week (which included 2 meetings).

The 48 sessions included 6 supervised game sessions with a clinician and 42 autonomous game sessions. The time spent on each game and the number of repetitions are listed in Table 2. The participant was encouraged to play the games five times a week. However, he was free to repeat game sessions whenever he wanted.

Table 2.	Time spent and th	e total number of repetitions	achieved in the exergames.
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Exergames	Active time playing the game (hours)	Total number of repetitions ^a	
Fish Frenzy	4.48	2581	
Catch and Carry an Apple	3.8	2418	
Kitchen Clean Up	2.083	674	
Pop Clap	11.116	10,304	
Space Race	11.76	14,364	
Total	33.25	30,341	

^aReflects the number of successful tasks or movements completed during a game.

During the first month of VirTele, the participant was afraid of using his upper extremity in daily life activities (fear of dropping objects, difficulty in using upper extremity, or pain) and was only manipulating virtual objects during the exergames. Nonetheless, during the second month, the participant demonstrated more frequent use of the affected upper extremity to assist the healthy hand in carrying out a task, for example, drinking from a glass using the help of a finger of the affected hand and using the affected upper extremity to answer the phone (with a touch screen). The clinician encouraged and praised the participant in achieving these small steps to maintain his motivation to continue practicing, even after the end of VirTele.

Technical Challenges and Adverse Events

The participant quickly became familiar with the VirTele technology, including the use of the exergame and the telerehabilitation app. The noninteroperability of the exergame software with the participant's computer (iMac, Apple) and his unfamiliarity with Windows operating systems did not prevent him from finding a solution to make the game work. In fact, the participant managed to divide his computer (iMac, Apple) hard drive into 2 parts to run Windows 10 and use the exergame.

Similarly, the participant encountered difficulties with the internet connection (video or sound cut off during the videoconference or poor connection) and log in process. However, he always managed to find a solution to each problem, for example, reset the modem or router, restart the apps, or reset the password, as he mentioned:

I didn't have any problem in setting, as well as using and from time to time, when there is an update...when the system said: "wrong password", I can reset the password and everything...remember we had a little bit of an issue with the audio, I was trying to put us in a video conference on my computer but it didn't work and I tried and tried and finally I said fine I will use my iPad. It is a small screen but still on the iPad.

Overall, the participant appreciated exercising with the exergame and had suggestions to better enjoy the game experience. For example, he preferred seeing his own hand or an image of a realistic hand on the screen, instead of the glove or the spaceship, and he was more drawn to realistic scenes than fictional scenarios (coloring stars with a pen instead of catching stars with a fish).

No adverse events occurred during the first few weeks of intervention. However, the participant reported an increased

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feeling of heaviness in the affected upper extremity during the fourth week of the intervention. The clinician in charge suggested that the participant used stretching postures at the beginning and end of the games to prevent discomfort. These were demonstrated during the videoconference sessions and relieved discomfort.

Discussion

Principal Findings

We addressed three objectives in this case study: (1) determine the feasibility of using a telerehabilitation app combined with an exergame for a remote upper extremity rehabilitation program in a chronic stroke survivor; (2) explore the preliminary efficacy of VirTele on upper extremity motor function, amount and quality of use, impact on quality of life and motivation; and (3) explore the determinants of behavioral intention and use behavior of VirTele and indicators of participant empowerment.

Adherence to VirTele, Technical Challenges, and Preliminary Efficacy Results

During the 2-month intervention, the participant demonstrated complete adherence to VirTele, completing 48 sessions or 33 hours and 15 minutes of active games, surpassing the minimum 20 hours planned for the program. A minimum of 15 hours is suggested for an intervention aiming at a moderate improvement of activities related to daily living following a stroke [46]. The 48 sessions included six supervised game sessions with a clinician and 42 autonomous game sessions. In addition to the exercises provided, the participant participated in eight videoconference sessions with a clinician for monitoring and empowerment purposes.

Although the participant encountered some technical challenges related to interoperability, internet connection issues (interruption of the video or sound, poor connection), and the login procedure (forgotten password), he was able to find a solution and use both the exergame and the telerehabilitation app throughout the 2 months. Furthermore, the participant suggested some improvements for the avatar and background, which he felt would render the game more meaningful. In addition, he was more drawn to realistic scenes and avatars, which is consistent with the findings of a previous study that indicated that players preferred simulated real-world games [47]. The sense of presence in a virtual environment or the degree to which an individual perceives the environment as real may affect the participant's engagement and motivation [48,49].

Thus, it is important to consider certain elements, such as the background, avatar design, and the scene's realism, when developing a VR system for rehabilitation use [48]. Fortunately, the lack of these elements did not decrease the participant's compliance with or commitment to performing the exercises, given that he spent 11 hours using the Space Race game.

Regarding the combined use of a telerehabilitation app and an exergame, the results of this case study suggest that the VirTele intervention and study protocol could be feasible with stroke participants, although it is important to ensure that it will be accessible to participants who may be less motivated and technologically savvy. Moreover, the participant appreciated the follow-up by the clinician when playing the exergames and described this room for maneuver in VirTele as the time to reflect. In fact, while the clinician was supervising, the participant was able to identify his errors during the exercises (compensatory movements), discuss the solutions, adjust the difficulty level as needed, and correct his posture and upper extremity movements. This may have prevented him from reproducing a pathological pattern of movement when playing alone. The participant exhibited clinically meaningful improvements at T2 in the motor function dimension of the FMA-UE and the hand function dimension of the SIS. Not surprisingly, there was no improvement in the SIS mobility dimension, which addresses the impact of stroke on lower extremity mobility, further indicating the impact of the intervention on upper extremity motor function. The FMA-UE (motor function) and the SIS (hand function) scores were maintained at T3 and T4, followed by a relevant increase in the SIS score (daily living activities), suggesting maintenance of motor gains throughout time, contrary to the findings of a previous study using VR exergames without supervision and a motivational approach [6].

During the follow-up period, there was a meaningful change in the MAL–amount of use subscale, suggesting more involvement of the affected upper extremity in daily activities, along with a meaningful improvement in the SIS activities of daily living dimension at T3 and the SIS hand function dimension at T4. These results suggest that a transfer pattern occurred between the virtual and daily life activities, as the participant showed meaningful improvements in daily life activities and amount of use of the upper extremity following 2 consecutive months after completing the VirTele program.

Although we had predetermined that 20 hours of active games within the VirTele program should be performed, the participant decided to do more (33 hours and 15 minutes). A much higher number of repetitions may have positively affected the upper extremity motor function. In fact, a meta-analysis of 20 randomized clinical trials, including 2686 stroke patients (acute, postacute, and chronic), supports the presence of a dose-response relationship between intense practice (therapy time ranged from 132 minutes to 6186 minutes) and better outcomes [50]. However, it is important to note that all users may not use VirTele at this level of intensity. More research is required to determine the amount of time required to obtain optimal results.

The MAL-quality of use subscale showed no change in movement quality at the end of the program but exhibited a

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meaningful improvement during the follow-up period. In fact, during the 2-month training, the participant did not use his affected hand sufficiently during daily life activities (pain and fear) and was mostly manipulating virtual objects during the exergame, with no force or touch feedback, which may have limited the integration of somatosensory information that contributes to motor learning [5]. During the follow-up period, the participant stopped using the exergame and was more involved in daily life activities, more frequently using his upper extremity to manipulate real-life objects, which involves somatosensory feedback that may favorably affect the movement quality of the affected upper extremity [5]. These results highlight the necessity of transferring virtual activities to real-life activities to avoid a potential gap in somatosensory information affluence.

Participant Motivation

The participant exhibited a lot of enthusiasm from the day he contacted our research team and demonstrated a high level of autonomous motivation (score=42/42) throughout the entire intervention, which may partly explain the high level of adherence to the VirTele rehabilitation program. The TSRQ showed a low level of external regulation, meaning that the participant made autonomous choices regarding his use of VirTele and completion of the exercises and was not influenced by certain consequences ("I want others to approve of me") [5] or pressure ("I feel pressure from others to do so") [34]. However, the external regulation score increased from 6 to 10 during the VirTele intervention. This could have possibly resulted from the desire to satisfy the research team or the clinician, leading to short-term changes in the participant's behavior (eg, better adherence to VirTele and higher motivation), improving upper extremity motor scores. However, the long-term maintenance of motor gains involves continuous adherence to exercises (after the end of VirTele) and maintaining motivation despite the lack of external factors (eg, encouragement by the clinician).

Similarly, the TSRQ showed a medium level of introjected regulation (score=8/14), meaning that the participant partially introjected and self-identified with the values linked to the VirTele rehabilitation program. This suggests that the participant possibly integrated the potential benefits of the exercises with his affected upper extremity and identified aspects of the VirTele program that could match his own values and beliefs, potentially affecting the long-term behavioral use of the technology.

Determinants of Behavioral Intention and Use Behavior of VirTele

Performance, effort, and social influence were meaningfully weighed in the behavioral intention use of VirTele. The relative advantages of the VirTele program compared with standard therapy and the perceived improvement in daily life activities facilitated the use performance of the VirTele program. The participant's level of comfort with the technology positively influenced the effort determinant. The additional constructs of the UTAUT model were not identified as direct determinants of behavioral intention or use behavior. According to Venkatesh et al [51], attitudinal constructs may indirectly affect behavioral

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intention and use behavior through performance and effort constructs.

In fact, the participant's attitude toward VirTele, the affected upper extremity, and information technology indirectly influenced behavioral intention through a positive and negative impact on effort and performance determinants. Owing to the participant's experience in information technology, he may have been more sensitive to some aspects of the exergame design (eg, avatar and background) and the operating system within the technology, although these aspects did not affect his compliance with the VirTele program.

Empowerment Indicators

The participant demonstrated considerable empowerment on the behavior and capacity levels, which may have positively affected his adherence to the VirTele rehabilitation program and explain the meaningful improvement in many clinical outcomes. The self-determination theory was used to inform the VirTele program by identifying the main constructs that target the desired behaviors (increase in adherence to the VirTele program and increased use of the affected upper extremity in daily life activities) and providing the means for developing component intervention techniques such as motivational interviewing. Health behavior change literature mentions numerous advantages of applying theory to interventions [52-54], including stronger effects [52], which may corroborate the findings of our study.

Other components of the VirTele program that may have also contributed to the participant's empowerment include the autonomous access to a personalized training program, the motivational aspect of VR exergames (eg, augmented feedback and challenging exercises), shared decision-making using the combination of VR and telerehabilitation, health counseling, and the ability to get real-time feedback during direct or web-based supervision (promoting the desired behavioral result). The extent to which the different VirTele program components played a role in the improvements observed in the clinical outcomes or empowerment indicators is still unclear.

Study Limitations

First, the FMA-UE results should be carefully interpreted, as the remote administration of the scale without the presence of an evaluator on site with the participant has not been validated in the literature. However, the FMA-UE (motor function) results in this case study were consistent with the self-reported findings (SIS and MAL) and provided an indication of the affected upper extremity motor function pattern during the intervention. The literature lacks a scale that remotely assesses the motor function of the arm in stroke survivors and is extremely relevant to the current need for telerehabilitation interventions.

Second, the participant was already highly motivated when he started the intervention. This may have naturally increased his adherence to the VirTele rehabilitation program and, consequently, favor his clinical outcomes. However, this level of adherence may not be representative of all participants.

In addition, with only 1 participant, it is difficult to capture all the factors that could influence the behavioral intention and use behavior of VirTele, such as technology familiarity, motivation, and previous experiences. The findings gathered so far are limited to the participant's own experiences, thereby limiting their transferability to other contexts.

The participant was also very comfortable with the technology and easily handled the technical difficulties that occurred during the intervention. This may not represent future users, although the participant's input during the development phase allowed the team to address potential future technological issues. This is crucial because it is highly likely that many participants affected by a stroke would be older and possibly less comfortable with new information technologies [55].

Finally, we cannot predict how well other participants would manage technical problems or how comfortable they would be with the technology used in the VirTele program. The technical difficulties are considered a direct determinant factor of intervention adherence and may influence a participant's willingness to use the technology. Technical problems should indeed be considered as a part of technology use, and end users should be technically (where to click and what this signal means) and emotionally (do not panic, you do not need to be frustrated, you did nothing wrong, and that is not your fault) prepared to better manage various situations. Accordingly, a video and informative pamphlet, including simple, concise instructions on how to open and use the exergames and videoconference platform, could be prepared to support VirTele use among future participants.

Future Research

It is important to explore the extent to which technological knowledge and experience play a role in using the latest technology. In addition, further research is needed to explore the role of shared decision-making and empowerment in exercise program adherence and progression and behavior modification for upper extremity use.

The data collected so far may not be representative of stroke survivors aged 63 years. However, the feasibility and preliminary efficacy results are promising and support the use of the VirTele rehabilitation program and have contributed to improving the intervention and study methodology. Further studies are warranted to corroborate these preliminary findings and test the feasibility and efficacy of VirTele in a diverse stroke population.

Conclusions

The results of this case study suggest that it is relevant to continue investigating the use of exergames provided by telerehabilitation to improve upper extremity motor function and enhance the upper extremity quality and amount of use in activities of daily living.



Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1 Screenshots of the Jintronix exergames. [PDF File (Adobe PDF File), 1104 KB - games v9i3e26153 app1.pdf]

Multimedia Appendix 2 Guideline for motivational interviewing in the study. [PDF File (Adobe PDF File), 59 KB - games_v9i3e26153_app2.pdf]

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Abbreviations

BCT: behavior change technique FMA-UE: Fugl-Meyer Assessment–Upper Extremity MAL: Motor Activity Log MCID: minimal clinically important difference SIS: Stroke Impact Scale TSRQ: Treatment Self-Regulation Questionnaire UTAUT: Unified Theory of Acceptance and Use of Technology VR: virtual reality

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Original Paper

Feasibility of Virtual Reality Audiological Testing: Prospective Study

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Related Article:

This is a corrected version. See correction statement: https://games.jmir.org/2021/4/e34994

Abstract

Background: It has been noted in the literature that there is a gap between clinical assessment and real-world performance. Real-world conversations entail visual and audio information, yet there are not any audiological assessment tools that include visual information. Virtual reality (VR) technology has been applied to various areas, including audiology. However, the use of VR in speech-in-noise perception has not yet been investigated.

Objective: The purpose of this study was to investigate the impact of virtual space (VS) on speech performance and its feasibility to be used as a speech test instrument. We hypothesized that individuals' ability to recognize speech would improve when visual cues were provided.

Methods: A total of 30 individuals with normal hearing and 25 individuals with hearing loss completed pure-tone audiometry and the Korean version of the Hearing in Noise Test (K-HINT) under three conditions—conventional K-HINT (cK-HINT), VS on PC (VSPC), and VS head-mounted display (VSHMD)—at –10 dB, –5 dB, 0 dB, and +5 dB signal-to-noise ratios (SNRs). Participants listened to target speech and repeated it back to the tester for all conditions. Hearing aid users in the hearing loss group completed testing under unaided and aided conditions. A questionnaire was administered after testing to gather subjective opinions on the headset, the VSHMD condition, and test preference.

Results: Provision of visual information had a significant impact on speech performance between the normal hearing and hearing impaired groups. The Mann-Whitney *U* test showed statistical significance (P<.05) between the two groups under all test conditions. Hearing aid use led to better integration of audio and visual cues. Statistical significance through the Mann-Whitney *U* test was observed for -5 dB (P=.04) and 0 dB (P=.02) SNRs under the cK-HINT condition, as well as for -10 dB (P=.007) and 0 dB (P=.04) SNRs under the VSPC condition, between hearing aid and non-hearing aid users. Participants reported positive responses across almost all items on the questionnaire except for the weight of the headset. Participants preferred a test method with visual imagery, but found the headset to be heavy.

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Conclusions: Findings are in line with previous literature that showed that visual cues were beneficial for communication. This is the first study to include hearing aid users with a more naturalistic stimulus and a relatively simple test environment, suggesting the feasibility of VR audiological testing in clinical practice.

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KEYWORDS

hearing loss; virtual reality; speech performance; real-world performance; hearing; audiology

Introduction

Hearing loss is a major health concern for the global society due to its negative consequences on individuals' lives. These consequences include, but are not limited to, communication, employment, cognitive decline, social participation, and quality of life [1-5]. Hearing loss primarily affects communication, and for those who are diagnosed with sensorineural hearing loss, a prescription of hearing aids is typically the first step of the aural rehabilitation process [6]. Hearing aids amplify sounds and provide various features (ie, noise reduction) to substantially mitigate the negative consequences of hearing loss by improving audibility. However, even with these advancements, there is a gap between clinical assessment and real-world performance [7-13], such as the wearer's complaint of persistent hearing difficulties in noisy situations [14-17].

One contributing factor for this issue could be limitations of current measurement tools. Taylor [18] mentioned difficulties in constructing a laboratory environment that closely replicates real-world settings and in measuring individuals' unique auditory environments. In clinical practice, aided threshold and speech perception testing is often performed to assess the benefits provided by hearing aids. Aided threshold testing involves presenting warbles tones (250 Hz to 8000 Hz) through a loudspeaker in the sound field [19]. The patient is asked to respond (ie, "say yes or press the button") when he or she hears the tone, even if the tone is soft. Speech testing is also performed in the sound field with one or more loudspeakers [19]. Words and sentences can be used as test materials and the patient is asked to listen and repeat words and sentences back to the tester. Some outcome measures include noise and multi-talker conditions to simulate real-world auditory environments, but they lack an important piece of information that people use for communication: visual cues. In real-world conversations, nonverbal cues, such as lip movements, are readily available and their significant influence on speech perception has been demonstrated in previous studies [20-25]. Summerfield [21] examined changes in the accuracy of phonetic perception in noise depending on the amount of visual information given to 10 listeners with normal hearing (NH). The participants heard a total of 125 sentences with 100 keywords and repeated the keywords under various conditions. Participants' overall speech performance was the best when they were able to see the whole face of the speaker (65.3%), followed by the lips (54.0%), the four points (30.7%), nothing (22.7%), and a circle (20.8%). A more recent study investigated the speech perception performance of 77 NH participants who were divided into five age groups under three conditions: auditory only, visual only, and audiovisual. The highest accuracy rate was observed for

the audiovisual condition, followed by the auditory-only and the visual-only conditions [26]. Benefits of audiovisual integration are well noted in literature and, yet, there are no audiological evaluation tools that use visual cues. Thus, even with well-programmed devices and good test results, hearing aid wearers often do not perceive this benefit in the real world. This mismatch reduces device satisfaction and can ultimately result in discontinuance of hearing aid use [7-9,11-13,27,28]. The MarkeTrak survey conducted in 2000 by Sergei Kochkin reported poor benefit as one of the top 10 reasons for not using hearing aids [27]. Results from previous studies emphasize the need for closing the gap between clinical assessment and real-world performance.

With the emergence of the fourth industrial revolution, researchers and industries have been putting in efforts to fuse technologies and health care. Among these technologies, virtual reality (VR) has been applied not only to gaming but to education and health care. There are five key components of VR systems: virtual space (VS), immersion, interactivity, creators, and users [29]. To be more specific, there is an imaginary place, VS, and through interaction and immersion, individuals feel more present, or connected, to the VS. VR's biggest strength is that auditory and visual information are provided simultaneously to generate realistic environments. There are studies showing the efficacy of VR in certain areas, such as pain management, stroke rehabilitation, and chronic subjective tinnitus [30-34]. For audiology, VR has been researched for sound localization, but research into the effect of VS on speech performance has been sparse [35-37].

Ahrens et al [37] tested the sound localization ability of 10 NH listeners under eight conditions involving blindfolding, a head-mounted display (HMD) headset, virtual and real environments, loudspeakers, acoustic or visual stimuli, and a simulated laser pointer. The results revealed that the headset had a negative impact on individuals' sound localization ability, as differences in interaural time and levels, which are important cues for sound localization, were larger when wearing the headset. Azimuth and elevation errors decreased when the source locations were visible to the participants in both the virtual and real environments. Sechler et al [38] explored the potential use of VR in sound localization testing among bilateral cochlear implant users. A total of 12 NH listeners and four bilateral cochlear implant users performed sound localization testing in a VR environment that was created for the study. A total of 13 sound cues were presented and the participants selected where they heard the sound cues in the VR environment. Bilateral cochlear implant users completed testing under first implant-only, second implant-only, and both implants conditions. Comparing the localization performance, individuals

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with NH showed better performance than bilateral cochlear implant users as to response time, left or right discrimination, percent correct, and root mean square error. Better sound localization performance was observed under the implants condition and the first implant–only condition. Overall, both studies suggest VR's potential to be employed in clinical audiology.

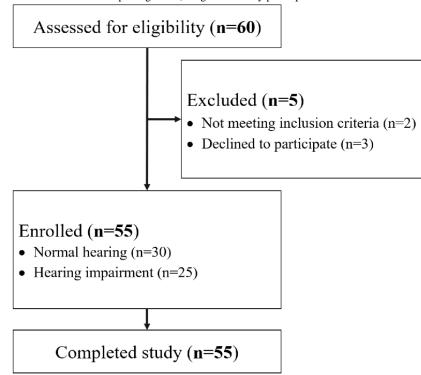
The purpose of this study was to investigate the impact of VS on speech-in-noise performance and its feasibility as a viable instrument for speech testing in clinical practice. Findings from this study will shed light on VR's potential to overcome the limitations of current assessment tools and, ultimately, to be utilized in clinical practice, which is an unexplored territory in the field of audiology.

Methods

Participants

The sample size was determined based on previous research examining reaction time and accuracy differences under auditory-only and visual-only conditions among individuals with and without autism [39]. The resulting sample size was 45, using Stata version 14 (StataCorp LP) for power set at 0.9 and α set at .0167 (corrected for multiple comparison). A total of 30 individuals with NH and 25 hearing impaired (HI) individuals were enrolled in the study (Figure 1). The NH group had average pure-tone thresholds below 25 dB hearing level (HL), with an asymmetry in hearing thresholds below 10 dB across 250 Hz, 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, and 8000 Hz. The HI group had average pure-tone thresholds above 25 dB HL, with an asymmetry in hearing thresholds below 10 dB across the testing frequencies. For the HI group, 10 individuals were hearing aid users. Individuals who were unable to communicate and understand television at a distance of 1 meter and those with neurological and mental disorders were excluded from the study. All experimental procedures were approved by the regulations set by Samsung Medical Center's Institutional Review Board and were carried out in accordance with approved guidelines. An informed consent document was obtained prior to testing from the participants. Informed consent was also obtained from actors to publish the images in an online publication.

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) diagram of study participation.



Conventional Pure-Tone Audiometry

Following the 2005 American Speech-Language-Hearing Association guidelines [40], conventional pure-tone audiometry was performed in a sound booth using a GSI 61 audiometer (Grason-Stadler) and TDH-39 headphones (Telephonics).

Virtual Space

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A café was created as a VS with the assistance of the Samsung Changwon Hospital VR Lab using the Samsung 360 Round VR camera (Samsung Electronics Co). The film was then edited using commercial editing tools from Adobe Systems: Adobe Premiere Pro, Adobe After Effects, and Adobe Audition (2018-2019 versions). A café was selected as an environment as it is one of the most common places within which individuals have trouble hearing [41,42]. A scenario for the VS where the user is having a one-on-one conversation with a conversational partner who speaks sentences from the Korean version of the Hearing in Noise Test (K-HINT), while other "customers" are talking in the background, was designed (Figure 2). The conversational partner recorded the K-HINT sentences.

Figure 2. A screenshot of the virtual space. The "conversational partner" is speaking sentences from the Korean version of the Hearing in Noise Test (K-HINT), while the "customers" are talking in the background.



K-HINT

The K-HINT, developed by Sung Kyun Moon and his colleagues at Ajou University and the House Ear Institute, is widely used in Korea as a speech-in-noise test [43], with a listen-and-repeat task. The K-HINT consists of 12 lists with 20 sentences per list. The K-HINT sentences were used for the study with a presentation level of 65 dBA (A-weighted dB). Each list was broken down into two sets in order for the participants to complete all test conditions: (1) conventional K-HINT (cK-HINT); (2) VS on PC (VSPC), where the VS was displayed on a monitor; and (3) VS head-mounted display (VSHMD), where the VS was displayed on the HMD at -10, -5, 0, and +5dB signal-to-noise ratios (SNRs). For VSPC and VSHMD conditions, the same VS was displayed and all participants had 10 seconds to familiarize themselves with the virtual environment. The test conditions were randomized for each participant. Percent-correct scores were calculated based on the number of sentences that were repeated back to the tester correctly among 10 sentences. The hearing aid wearers used their own hearing aids to complete testing under unaided and aided conditions. No adjustments were made to the participants' hearing aid settings, as the authors wanted to simulate as natural an environment as possible. Testing was performed in a semianechoic chamber with sentences being presented through a loudspeaker in the front. Making the testing more realistic, café noise was obtained from YouTube and normalized to the average level of the sound file using Cool Edit Pro 2.1 (Syntrillium Software Corporation). Then, sound levels of speech as well as the café noise were measured using a sound level meter for the four SNRs. The noise was presented from speakers located at 45, 135, 225, and 315 degrees for all test conditions. A Samsung Notebook Odyssey laptop and a Samsung Odyssey VR headset with controllers (Samsung Electronics Co) were used to display the VS. The Samsung Odyssey laptop was used, as testers can see the screen that participants are seeing during the VSHMD condition. This allows individuals who are unfamiliar with VR technology to easily complete the task with assistance from the tester. A practice test was run before the experiment to familiarize the participants with the listen-and-repeat task in the VS.

Questionnaire

A questionnaire was administered after testing to evaluate various aspects of testing (Table 1). The questionnaire contained four domains: HMD headset, VSHMD condition, tests, and cK-HINT versus VSHMD. Items regarding the headset consisted of physical comfort and weight of the device, audiovisual synchronization, and sound quality of the recorded K-HINT sentences. In terms of the VSHMD condition, immersiveness, listening effort, degree of reality reflection, need for VR to be incorporated into audiological testing, adequacy of the VS, structure of the test, and interestingness were evaluated. For questions about immersiveness and listening effort, hearing aid users completed these questions twice for unaided and aided conditions. Participants also chose the most preferred test method and the test that required the greatest amount of listening effort, encouraged hearing aid use, and assessed communication difficulties better in the tests domain. The last domain compared the cK-HINT and VSHMD conditions. Participants were asked to write down strengths and weaknesses of the two conditions. In terms of differences between the two conditions, participants had an option to choose multiple responses among immersiveness, reality reflection, convenience, and others. If they chose others, they were asked to provide specific responses. Questions in the HMD headset and VSHMD condition domains were answered using the 10-point Visual Analogue Scale (VAS) with the following respones: 0 (poor, strongly disagree, or extremely heavy), 5 (neutral), and 10 (excellent, strongly agree, or extremely light). The tests domain contained multiple-choice questions. Participants had to choose from the following response options: cK-HINT, VSPC, and VSHMD.



Table 1. Questionnaire items

Domain and question No.	Question	
HMD ^a headset		
1	How is the physical comfort of the device?	
2	How heavy is the device?	
3	Does the visualization (café) match well with the audio?	
4	How is the sound quality?	
VSHMD ^b condition		
5	Without hearing aids: How immersive was the virtual space? Did you feel like you were in a real café?	
5-1	With hearing aids: How immersive was the virtual space? Did you feel like you were in a real café?	
6	Without hearing aids: How much effort did you have to spend to understand speech?	
6-1	With hearing aids: How much effort did you have to spend to understand speech?	
7	How much did the virtual space (café) reflect reality?	
8	Does the virtual reality technology need to be used for clinical testing?	
9	Was the café an appropriate place to use as the virtual space?	
10	Was the test structured to be easily understood?	
11	Was the test interesting?	
Tests		
12	Which test do you prefer the most?	
13	Which test required the most amount of effort for listening?	
14	Which test would encourage hearing aid use?	
15	Which test would assess communication difficulties better?	
cK-HINT ^c versus VSHMD co	ondition	
16	Describe any differences between conventional testing (without visual cues) and the VSHMD (visualization through the headset).	
17	Describe strengths and weaknesses of conventional testing (without visual cues) and the VSHMD (visualization through the headset).	

^aHMD: head-mounted display.

^bVSHMD: virtual space head-mounted display.

^ccK-HINT: conventional Korean version of the Hearing in Noise Test.

Statistical Analysis

Statistical analysis was performed using SAS version 9.4 (SAS Institute Inc). Nonparametric tests were used, as our results did not pass the normality test. To compare K-HINT performance based on test conditions in each group and SNRs, the Friedman test was performed. The primary outcome was individuals' K-HINT performance, and the availability of visual cues was the exposure of interest in this study. To compare K-HINT performance between the groups, the Mann-Whitney *U* test was used. A *P* value of less than .05 was considered to be statistically significant.

Results

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Participant Characteristics

The age range of the participants was 18 to 75 years old. The mean age of the NH group was 29.7 years (SD 10.4), while the mean age of the HI group was 53.0 years (SD 14.0). The NH

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group's pure-tone averages were 6.3 dB in the right ear and 5.5 dB in the left ear. The HI group had pure-tone averages of 49.2 dB in the right ear and 47.2 dB in the left ear. A total of 10 participants in the HI group were hearing aid users, with pure-tone averages of 56.5 dB and 54.2 dB in the right and left ears, respectively. Non-hearing aid users in the HI group had pure-tone averages of 37.0 dB and 34.9 dB in the right and left ears, respectively.

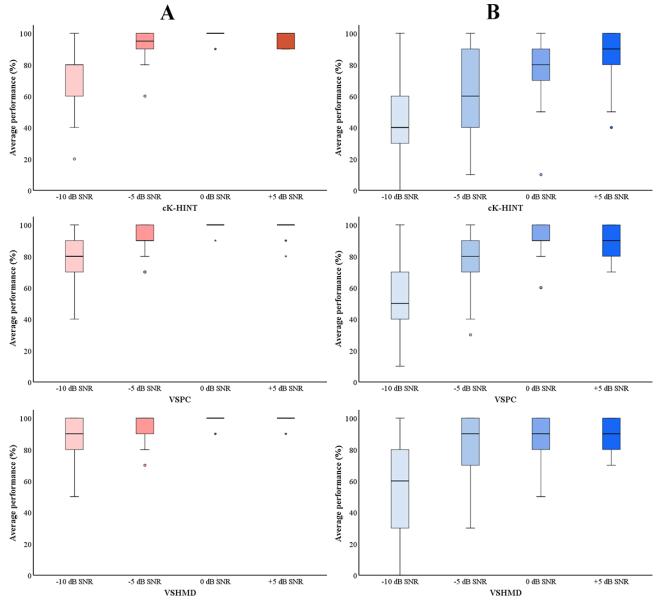
K-HINT Performance Between the NH and HI Groups

Comparison of the K-HINT performance of both groups under all test conditions is illustrated in Figure 3. For hearing aid users, their percent-correct scores for the aided conditions were used for comparison. Both groups performed better when visual cues were available. The Friedman test was performed for each group to examine whether provision of visual signals was beneficial. Statistical significance was observed for -10 dB SNR in the NH group (*P*=.004) and for -10 dB (*P*=.01), -5 dB (*P*=.01), and 0 dB (*P*=.045) SNRs in the HI group. Group comparison

using the Mann-Whitney U test showed statistical significance (P<.05) between the two groups under all test conditions, with

P values ranging from .001 to .004. Overall, NH listeners showed better speech-in-noise performance than the HI group.

Figure 3. Statistical analysis of the groups' average speech performance. Pink bars (A) indicate normal hearing group's performance. Blue bars (B) indicate hearing impaired group's performance. The horizontal lines within the shaded bars represent the median values, the shaded bars represent the IQRs, the error whiskers represent the highest and lowest points, and the circles and stars represent outliers and extreme outliers, respectively. cK-HINT: conventional Korean version of the Hearing in Noise Test; SNR: signal-to-noise ratio; VSHMD: virtual space head-mounted display; VSPC: virtual space on PC.

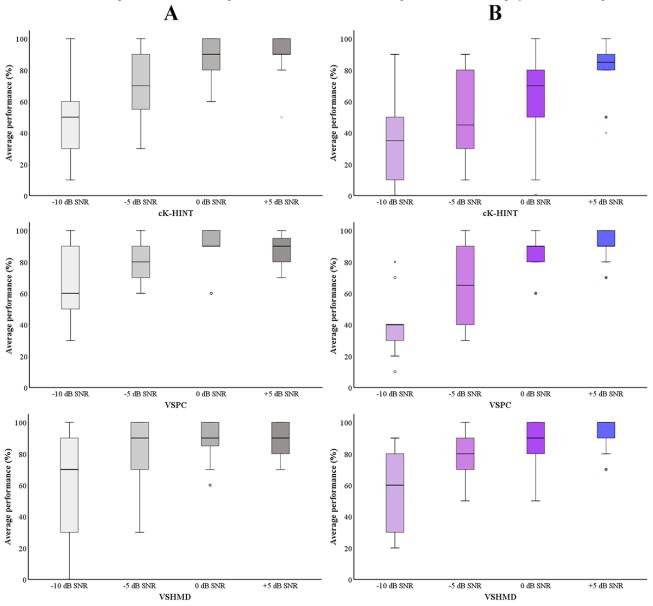


VR K-HINT Performance Between Hearing Aid Users and Non–Hearing Aid Users in the HI Group

The K-HINT performance of hearing aid and non-hearing aid users is shown in Figure 4. Hearing aid users' aided scores were used for performance comparison. Higher average percent-correct scores for non-hearing aid users indicate that they understood speech better in noise than hearing aid users. This is consistent with non-hearing aid users' and hearing aid

users' pure-tone audiometry data: non-hearing aid users had better audiometric thresholds across the testing frequencies, except at 4000 Hz and 8000 Hz in the left ear. The Mann-Whitney U test revealed statistical significance at -5 dB (P=.04) and 0 dB (P=.02) SNRs under the cK-HINT condition and at -10 dB (P=.007) and 0 dB (P=.04) SNRs under the VSPC condition between the non-hearing aid users and hearing aid users.

Figure 4. Statistical analysis of the groups' average speech performance. Gray bars (A) indicate non–hearing aid users' performance. Purple bars (B) indicate hearing aid users' performance. The horizontal lines within the shaded bars represent the median values, the shaded bars represent IQRs, the error whiskers represent the highest and lowest points, and the circles and stars represent outliers and extreme outliers, respectively. cK-HINT: conventional Korean version of the Hearing in Noise Test; SNR: signal-to-noise ratio; VSHMD: virtual space head-mounted display; VSPC: virtual space on PC.

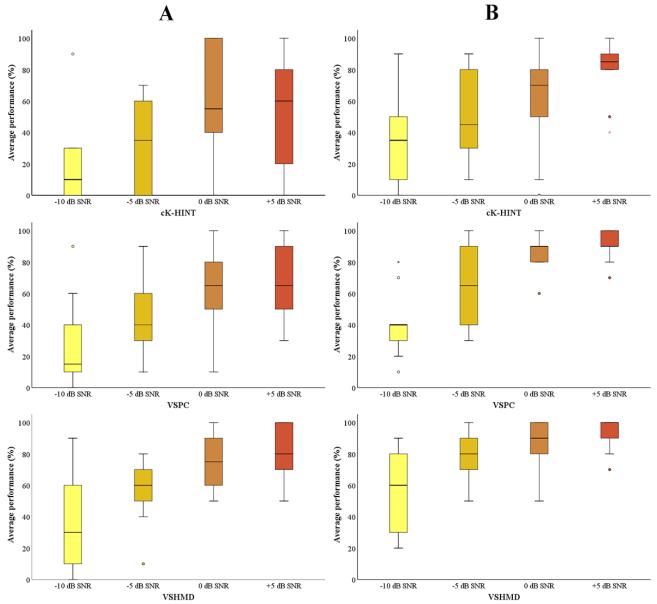


Hearing Aid Users' Unaided and Aided VR K-HINT Performance

Figure 5 displays hearing aid users' K-HINT performance with and without their hearing aids. The results are in line with previous studies showing that speech-understanding-in-noise performance is better with hearing aids. Statistical significance was also observed for +5 dB SNR under the cK-HINT condition (P=.02); -10 dB (P=.04), -5 dB (P=.02), and +5 dB (P=.02) SNRs under the VSPC condition; and -10 dB (P=.04) and -5 dB (P=.002) SNRs under the VSHMD condition through the Wilcoxon signed-rank test.



Figure 5. Statistical analysis of hearing aid users' average performance of the Korean version of the Hearing in Noise Test (K-HINT) in unaided (A) and aided (B) conditions. The horizontal lines within the shaded bars represent the median values, the shaded bars represent the IQRs, the error whiskers represent the highest and lowest points, and the circles and stars represent outliers and extreme outliers, respectively. cK-HINT: conventional Korean version of the Hearing in Noise Test; SNR: signal-to-noise ratio; VSHMD: virtual space head-mounted display; VSPC: virtual space on PC.



Questionnaire

The groups' subjective opinions on the headset, the VSHMD condition, listening effort, and presence in the VS were gathered through a questionnaire (Figure 6). For the HMD headset, the following items were evaluated: physical comfort when wearing the device, weight of the device, synchronization between audio and visual information, and sound quality of the recorded sentences. The VAS was used to rate the items, with 10 being *strongly agree* or *excellent*. Responses for all items, except for the weight of the device, were positive toward the system; the headset was heavy, but was comfortable to wear and had excellent sound quality and audiovisual synchronization. The degree of reality reflection, need for VR to be used in clinical testing, adequacy of VS, test structure, and interestingness regarding the VSHMD condition were also evaluated. The VAS was used to rate the items, with 10 being *strongly agree* or

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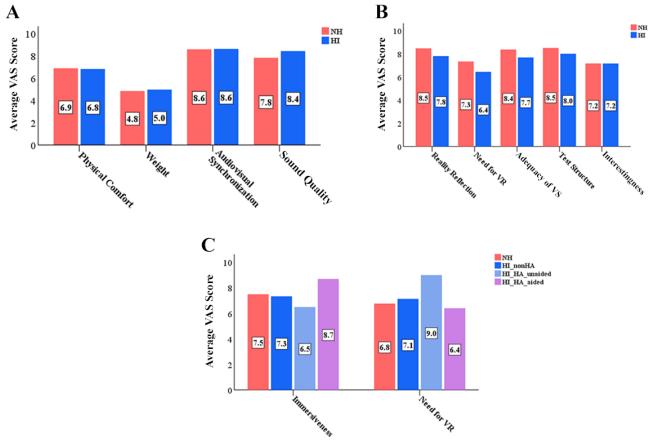
excellent. The results revealed that reality simulation through the VS was excellent, and participants felt that the testing was interesting. The café was an appropriate place to use as the VS. The test structure, in which participants completed practice runs and then experimental tests, was considered good as well. The necessity of VR in audiology was high. Lastly, immersion and listening effort were investigated. Since the hearing aid users completed testing under unaided and aided conditions, the amount of listening effort required for these conditions was evaluated twice. Responses from NH listeners and non-hearing aid users were similar to each other across all items; the Wilcoxon signed-rank test showed no statistical differences for immersion (P=.36) and listening effort (P=.49) for the NH and HI groups. For hearing aid users, scores were higher for immersion and lower for listening effort with hearing aids, implying that integration of auditory and visual information through hearing aids and visual cues have a positive impact on

speech understanding in the presence of noise. Significant differences for immersion (P=.047) and listening effort (P=.04) between the unaided and aided conditions were also observed through the Wilcoxon signed-rank test.

Both groups preferred tests that contained visual cues; 50% (15/30) and 32% (8/25) of the participants in the NH and HI groups, respectively, selected VSHMD. VSHMD was also selected the most by the groups as a test that better-assessed

communication difficulties (67% [20/30] of the NH group and 52% [13/25] of the HI group) and encouraged hearing aid use (50% [15/30] of the NH group and 44% [11/25] of the HI group). The cK-HINT, which did not provide any visual information, required the greatest amount of listening effort, as reported by the NH (22/30, 73%) and HI (20/25, 80%) groups. A total of 97% (29/30) of participants in the NH group and 88% (22/25) of participants in the HI group showed willingness to complete the test if available in clinical practice.

Figure 6. (A) Questionnaire results regarding the head-mounted display (HMD) headset. Pink bars represent average responses from the normal hearing (NH) group and blue bars represent average responses from the hearing impaired (HI) group. A value of zero (0) on the Visual Analogue Scale (VAS) indicates *extremely heavy* or *poor*, while 5 indicates *neutral* and 1 indicates *extremely light* or *excellent*. (B) Questionnaire results for the virtual space head-mounted display (VSHMD) condition. Pink bars represent average responses from the NH group and blue bars represent average responses from the HI group. (C) Questionnaire results for the VSHMD condition regarding the amount of perceptual presentation in the virtual space (VS) and effort excerted to understand speech in noise. Pink bars indicate average responses from the NH group, while blue, sky blue, and purple bars indicate average responses from non–hearing aid (nonHA) users, hearing aid (HA) users in the unaided condition, and hearing aid users in the aided condition, respectively. VR: virtual reality.



Differences Between the cK-HINT and VSHMD Conditions

Simulation of reality and immersion were the main differences reported by the groups. For this question, individuals were able to select more than one option. A total of 63% (19/30) and 83% (25/30) of participants in the NH group selected immersion and simulation of a real-world environment, respectively, as differences between the conditions. For the HI group, 72% (18/25) and 52% (13/25) of participants selected immersion and reality simulation, respectively, as differences between the conditions. Other responses included "test is interesting," "being able to concentrate during testing," and "visual cues (ie, lip movements) were available." This adds value to VR's strengths and participants' subjective responses regarding test preference

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and tests that better promote hearing aid use and assess hearing problems.

Strengths and Weaknesses of the cK-HINT and VSHMD Conditions

A substantial majority of the participants reported that the cK-HINT would be a better assessment tool for measuring auditory performance because it did not provide any visual cues: they only had auditory information to understand speech. Convenience of testing was another strength of the condition, as it did not require additional devices for the participants to wear. Weaknesses of the condition, on the other hand, included boredom, no provision of visual information, unrealistic testing environment, and noise. Since no visual cues were presented as part of this condition, participants thought that the test would

not be able to accurately assess their real-world speech-in-noise performance. For the VSHMD condition, both groups reported the following strengths: less effort to hear, excellent audio and visual quality, excellent reality reflection, feeling present in the environment, and increased concentration during testing. Utilizing visual cues during testing helped the participants exert less effort to understand speech in the presence of noise. Excellent audio and visual quality and reality reflection allowed them to feel present in the VS during testing. However, the headset was heavy to wear, which the participants thought could possibly affect the test results. In terms of weakness, they mentioned that individuals who are not familiar with the HMD system might have difficulty performing the test (ie, wearing the device and navigating through the test) and that visualization provided as part of this condition might distract individuals.

Discussion

In our study, speech recognition improved with the provision of visual information, regardless of the presence of hearing loss. Hearing aids facilitated better speech recognition with lower listening effort for hearing aid wearers. All of these findings are consistent with previous literature [44-49]. After summarizing participants' subjective responses, we saw that the quality of the VS was excellent, which was demonstrated by high scores for audiovisual synchronization, audio quality of the recorded sentences, immersion, and the amount of reality reflected in the VS. A café was an appropriate place to use as the VS. Participants were interested in the new testing method (ie, VSHMD), and a high percentage of participants showed inclination toward completing the test once available in clinic.

Our study is meaningful in terms of diversity of participant characteristics, a relatively simple test environment, and a more naturalistic stimulus. Most studies utilizing VR for speech performance recruited individuals with NH and HI [36,50-52] and involved a test setup that may be difficult to establish in clinical settings. For example, in Salanger et al [50], 40 children and 8 young adults with NH were enrolled in the study. Acoustic treatments (ie, acoustic wall and ceiling tiles) and objects (ie, chalkboards) were included to create a VR 3D classroom. Video recordings of the talkers, which were less naturalistic, were presented to the participants. Hendrikse et al [51] also recruited 14 young NH listeners for localization and speech performance testing with animated characters as test stimuli. A 16-loudspeaker array and a projector were used to present auditory and visual stimuli, and a metal frame covered by a cloth was used to reduce environmental sounds, light, and room reflections [51]. Setting up such test environments in clinical practice may be challenging, as they require a number of loudspeakers, large space, and other necessary materials for the creation of a realistic environment. Our study, on the other hand, is the first study to include hearing aid users with a more naturalistic stimulus and a potentially more implementable test setup for clinical practice. The VS presented in this study was created using a real café and actors instead of avatars. The testing was performed using a relatively fewer number of loudspeakers (five) and, yet, the results were comparable to that obtained in previous studies.

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Incorporation of visual information into speech testing can be beneficial for both patients and professionals. Since communication entails visual and auditory information, this type of testing could assess communication difficulties in conjunction with speech recognition performance more accurately. Patients would be more engaged in testing since the test is more interesting, as reported on the questionnaire. For hearing aid users, reality-reflected test results could foster realistic expectations, ownership of hearing loss, and better optimization of the devices. This would lead to increased satisfaction toward the device and reduced hearing aid return and discontinuance rate. If hearing aid wearers experience higher device satisfaction and perceived hearing aid benefit, the number of clinic visits for further adjustments would also decrease, which can be a critical issue for individuals who live far away from hospitals and clinics.

Although a VS is shown to be beneficial for speech recognition in noise in this study, ample work is still needed to address some limitations of our research. Each K-HINT list was broken down into two separate lists so that hearing aid users could complete tests under unaided and aided conditions. It is highly likely that phoneme distribution was affected during this process and, therefore, test materials with more sentence lists need to be used for subsequent studies. The weight of the headset also needs to be improved. The authors believe that it is crucial to not only examine the effect of visual cues on speech performance but to test the device that will be used, as it could be one of many factors that professionals and patients would consider before employing and performing the test in clinics. The weight of the system was reported to be heavy on the questionnaire and was mentioned as a weakness of the VSHMD condition. Use of a lighter device could possibly address this concern. Another concern was that individuals who are unfamiliar with the HMD system might have difficulty performing the test. Designing user interfaces that are easy to use and providing tester assistance regarding the HMD system before and during testing could address the issue. It is also worth mentioning that in-depth investigation as to the amount contributed by each sensory modality for speech-in-noise performance is necessary. Gonzalez-Franco et al [53] examined the impact of selective attention on individuals' speech perception when visual and auditory cues were asynchronous. Two speakers were simultaneously speaking sentences, and participants were asked to recall the "target CALL," which consisted of eight words ("Arrow," "Baron," etc), and to remember the content of the target sentences under four conditions (ie, synchronized visual and audio cues; auditory only with no visual information; asynchronized visual and audio cues, in which the target speaker's lips matched the audio of the other talker; and asynchronized visual and audio cues, in which the target speaker's lips did not match any talker's audio). Participants were able to identify the "target CALL" more accurately when auditory and visual information was synchronous. In terms of remembering the content of the sentences, more errors were observed with asynchronous information, especially when the target speaker's lips matched the audio of the other speaker, demonstrating the dominance of visual cues [53]. Measuring one's reliance on each sensory system might allow researchers to recognize whether a test containing visual cues reflects one's

speech performance in a real environment; if one's communication is actually interfered with by visual signals occurring naturally in real life and the test scores are poor, this might mean that the test is reflective of his or her real-world performance. In addition, vision screening was not performed prior to testing. Although the authors made sure all participants were able to clearly see the VS for the VSHMD condition, as the rationale behind the experiment is visual and auditory input representing real-world conditions, it is necessary to include vision screening. There is a possibility of different hearing aid settings affecting the HI group's speech performance. As mentioned earlier, the authors did not make any changes to the hearing aid settings because those are the settings that are used by hearing aid users in the real world. However, some features, such as noise reduction, might have influenced the results of the HI group. It is worth noting that in-depth investigations regarding the actual impact of VR audiological testing in clinical practice is necessary. For example, the Technology Acceptance Model is commonly used for implementation-focused research to examine user acceptance of information technology by

evaluating individuals' willingness to use technology, perceived ease of use, and so on [54]. It is important to not only compare performance but also assess end-user acceptance of VR audiological testing to fully understand how VR audiological testing works and compares to other testing methods. Further studies with larger sample sizes, a larger variety of participant characteristics, and correlational analysis between speech performance with visual cues and standardized hearing aid questionnaires would be beneficial. Development of sentences that are appropriate for the VS and examination of their effect would be valuable in taking a step forward toward the development and standardization of reality-reflecting test methods and materials. In sum, we hope our findings open up opportunities for future studies and support the necessity of VR in being utilized in the field of audiology. It might still be challenging to set up a test environment that closely resembles individuals' everyday listening environments and to accurately evaluate one's unique hearing difficulties and needs. However, VR audiological testing would be another way for professionals to serve diverse clinical populations more competently.

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Conflicts of Interest

None declared.

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Abbreviations

cK-HINT: conventional Korean version of the Hearing in Noise Test
dBA: A-weighted dB
HI: hearing impaired
HL: hearing level
HMD: head-mounted display
K-HINT: Korean version of the Hearing in Noise Test
NH: normal hearing
NRF: National Research Foundation of Korea
SNR: signal-to-noise ratio
VAS: Visual Analogue Scale
VR: virtual reality
VS: virtual space

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VSHMD: virtual space head-mounted display **VSPC:** virtual space on PC

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Review

Serious Game Design and Clinical Improvement in Physical Rehabilitation: Systematic Review

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Abstract

Background: Serious video games have now been used and assessed in clinical protocols, with several studies reporting patient improvement and engagement with this type of therapy. Even though some literature reviews have approached this topic from a game perspective and presented a broad overview of the types of video games that have been used in this context, there is still a need to better understand how different game characteristics and development strategies might impact and relate to clinical outcomes.

Objective: This review assessed the relationship between the characteristics of serious games (SGs) and their relationship with the clinical outcomes of studies that use this type of therapy in motor impairment rehabilitation of patients with stroke, multiple sclerosis, or cerebral palsy. The purpose was to take a closer look at video game design features described in the literature (game genre [GG], game nature [GN], and game development strategy [GDS]) and assess how they may contribute toward improving health outcomes. Additionally, this review attempted to bring together medical and game development perspectives to facilitate communication between clinicians and game developers, therefore easing the process of choosing the video games to be used for physical rehabilitation.

Methods: We analyzed the main features of SG design to obtain significant clinical outcomes when applied to physical rehabilitation of patients recovering from motor impairments resulting from stroke, multiple sclerosis, and cerebral palsy. We implemented a PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) database-adjusted electronic search strategy for the PubMed, IEEE Xplore, and Cochrane databases.

Results: We screened 623 related papers from 2010-2021 and identified 12 that presented results compatible with our inclusion criteria. A total of 512 participants with stroke (8 studies, 417 participants), cerebral palsy (1 study, 8 participants), and multiple sclerosis (2 studies, 46 participants) were included; 1 study targeting the elderly (41 participants) was also included. All studies assessed motor, sensory, and functional functions, while some also measured general health outcomes. Interventions with games were used for upper-limb motor rehabilitation. Of the 12 studies, 8 presented significant improvements in at least one clinical measurement, of which 6 presented games from the casual GG, 1 combined the casual, simulation, and exergaming GGs, and 2 combined the sports and simulation GGs.

Conclusions: Of the possible combinations of game design features (GG, GN, and GDS) described, custom-made casual games that resort to the first-person perspective, do not feature a visible player character, are played in single-player mode, and use nonimmersive virtual reality attain the best results in terms of positive clinical outcomes. In addition, the use of custom-made games versus commercial off-the-shelf games tends to give better clinical results, although the latter are perceived as more motivating and engaging.

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KEYWORDS

serious games; physical rehabilitation; systematic review; physical impairment; game design; game characteristics; stroke; multiple sclerosis; cerebral palsy

Introduction

Background

The concept of serious games (SGs) emerged with Abt in 1970. The author described SGs as games that "have an explicit and carefully thought-out educational purpose and are not intended to be played primarily for amusement," therefore referring to an innovative approach to education in its various forms [1]. Initially referring to board and card games, the proposed concept endured, adapting itself to the technological advances taking place worldwide, ensuring that it is still applicable in the computer age that characterizes the twenty-first century [2]. In parallel, SG applications emerged into other fields that embodied other objectives and purposes [3]. For example, SGs have been used for a wide range of health care purposes: from education of medical personnel to health monitoring, health management, and rehabilitation [4]. Specifically, SGs in physical rehabilitation aim to provide an intervention context for reacquisition, recovery, or maintenance of the self's physical faculties (ie, motor and sensorial functions) to ensure the quality of life (QoL) of patients. It usually encompasses post-stroke rehabilitation (both upper limb and lower limb), balance and gait training, orthopedic rehabilitation, and stimulation of physical activity for patients suffering from pathologies such as cerebral palsy, multiple sclerosis, or Parkinson [4-6]. Thus, the SG definition/applications grew broader, now referring to any video game that aims to convey some sort of message or input-be it knowledge, a skill, or something else-to the players, while preserving the characteristics that makes it be accepted and categorized as a video game [3,4].

On the design and development perspective, a video game-be it serious or not-can take several paths; therefore the array of variables that need to be considered is vast [7]. In this sense, game design elements, such as the game genre (GG), game nature (GN) [5,8,9], and game development strategy (GDS) are necessary to develop, deploy, and implement a video game. The GG encompasses sports, simulation, role-playing games, fighting, shooting, strategizing, etc [9]. Moreover, the design of a video game also refers to GN features [7], such as player perspective-taking (first-person perspective [1PP] third-person perspective [3PP]), game-play mode (multiplayer vs single player), type of scenery/in-game environment (realistic, fantasy-themed vs simple), the presence/absence of playable characters, and the level of immersion applied to the use of immersive or nonimmersive virtual reality (VR). From the GDS perspective, some studies have used custom-made SGs [10-17]—games that were tailored and developed specifically for the study in question-while others have opted for a direct-to-consumer approach by resorting to commercial off-the-shelf (COTS) titles [18-21], such as those available for the discontinued Nintendo Wii [22].

Past studies have tried to understand how game design elements can influence both game enjoyment and player engagement different points view: from of from а commercial/entertainment/general perspective [23-25], from a gamification perspective [26], or in terms of SGs targeting education [27]. One of the main and most studied applications of SGs in health care is the education and training of medical personnel [28]. Being 1 of the sole medical application areas for SGs that has been systematized in terms of, for example, the video GG, it has been demonstrated that for this purpose, the GG that is used the most is simulation, once it answers the specific needs of professional training [28,29]. Although the impact of simulation games for medical education has been quantified before by Cook et al [30] and Cheng et al [31], there is little to no research done (concerning outcome influence) for purposes other than education. In addition, Hookham and Nesbitt [29] analyzed several SGs used for education, including that of budding health care professionals. Their study proved that for these purposes, simulations and puzzles are the most common genres, since they are the video GGs that best suit the needs that the SG tries to cover [29]. However, although they have systematized information of this nature of SGs for education, to the best of our knowledge, there are no studies that analyze the game design elements (GG, GN, GDS) in games applied in the context of health care when the consumer is the patient instead of a professional in training. From the systematic content analysis of games for health presented by Lu and Kharazzi [8] as well as from the taxonomy proposed by Rego et al [5], we can get an overall picture of the use of these distinct genres in the context of health care. Lu and Kharazzi [8] present an overview of SGs developed specifically for health care between 1983 and 2016. Of the 1553 systematized games, 580 targeted cognitive training, while only 60 targeted physical activity and 5 addressed strokes. Of the analyzed games, the 3 predominant genres were puzzle, casual game, and simulation. Despite the thorough systematization of SGs applied to health care and their various aspects concerning the GG, GN and GDS, this review does not present any sort of conclusion that attempts to relate those aspects to clinical outcomes and/or patient improvement.

Altogether, even though several studies have adopted the SG approach to targeting physical rehabilitation, assessing the clinical efficacy and relevance of using video games [10-21], the relationship between intrinsic game design characteristics and clinical outcomes still needs to be further developed. This gap of knowledge has been previously pointed out, not only in the health care field, but also in relation to SGs and their many possible applications [32,33] Thus, there is a need to systematize studies that have achieved improvements by applying SGs for physical rehabilitation in order to find patterns and links between SG design (GG, GN, and GDS) and clinical improvement.

Objectives

This systematic review aims to identify, evaluate, and summarize the features of SG design (GG, GN, and GDS) that significantly improve patient outcomes in physical rehabilitation. In this sense, we provided a qualitative synthesis that attempts to understand which video GG, GN features, and GDS may carry a link to attain significant clinical outcomes. To achieve our aim, we mapped both the characteristics of game design and the clinical outcomes. Specifically, we aimed to answer the question of what features of the game would be most relevant to improving clinical outcomes or may contribute to clinical intervention success.

Methods

Databases and Search Strategy

This systematic survey included papers written in English, published from 2010 to 2021, identified using the PubMed, IEEE Xplore, and Cochrane databases. We searched the titles, abstracts, and keywords of database entries using the following

Textbox 1. Selection criteria for systematic literature review.

Inclusion criteria

- Papers that include game-based physical rehabilitation
- Papers that detail the aspects of the design of the applied video game
- Papers that detail the aspects of the design of the applied video game
- Papers that feature any sort of clinical test and present clear qualitative results of performance measures
- Other papers relevant to the research question

Exclusion criteria

- Papers that mention serious game (SG) design applied to cognitive rehabilitation
- Papers that mention an SG but do not specify the design of the game
- Papers that do not quantify the performance measures of the participants
- Papers that do not use control groups
- Books, theses, and published posters

Data Extraction

We followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) [34] guidelines for data extraction. The collected data comprised the study (authors, year of publication, study design, number of participants), sample information (gender, age, clinical information), game characteristics (ie, GN, GG, GDS), measures and clinical assessment information, and intervention characteristics (eg, number of rehabilitation sessions per week, session duration, total number of rehabilitation sessions). The primary outcome measure for this review referred to the clinical measurements (measurements, results, statistical significance), which were systematically extracted.

keywords: "serious games" AND "stroke" OR "cerebral palsy"

OR "multiple sclerosis" OR "physical rehabilitation." Search

results from each database were merged and sorted for removal

of duplicates. Afterward, titles and abstracts were screened

The obtained results were screened according to the selection

criteria (Textbox 1). Papers were included if they featured a

clear description of game-based physical rehabilitation with

specific descriptions of the game used in terms of its nature,

featured the clinical test of the game on humans with control

groups, and included quantitative results of performance measures. Non-peer-reviewed material, books, theses, and

published posters were excluded. Additionally, studies were excluded if they (1) described the use of SGs for cognitive

rehabilitation, (2) did not mention the design of the video game

used for rehabilitation, (3) merely described prototypes without

any actual clinical test, (4) had no quantitative results or had

results assessed only qualitatively, (5) did not use control groups,

according to their relevance to the research.

Inclusion and Exclusion Criteria

or (6) did not have accessible full text.

Given that the primary objective of this review was to access the relevant information regarding the relationship between game characteristics and the clinical outcomes of the respective studies, the selected papers were primarily organized and analyzed in terms of their GG, GN, and GDS aspects. The definition used for each game characteristics is presented in Table 1.

Table 1. Definition of each video GG^a found in this review [9].

Vieira et al

Video games characteristics	Description		
Health and wellness, fitness, exergaming	Video games that are also a form of exercise and that rely on technology that tracks body movement and (or) gestures.		
Casual games	This category includes games that feature simple game play and objectives, including drag-and drop games or point-and-click games.		
Simulation	Games that aim to closely simulate aspects of a real or fictional reality. They seek to provide enjoyment through re-enactment.		
Sports	Games that simulate the sporting experience. They focus on the experience of playing the sport or on the strategy behind the sport.		
Game perspective (1PP ^b /3PP ^c)	The player camera angle/perspective. Games can be presented to the user either in 1PP or 3PP. In 1PP, the player experiences and interacts with the game through the playable character/avatar's eyes, that is, the game action is observed the same way the user would experience the real world, which gives the player a sense of "being" the character (eg, <i>Overwatch</i>). In 3PP, the player is distanced from the game's action by allowing them to control a playable character or avatar that they can see (eg, <i>New Super Mario Bros</i>) [35].		
Game-play mode (single player/multiplayer)	Refers to whether the game is single-player (only one user can play the game at a time) or multi- player (allows for different users to play the game at the same time and interact with each other) [36].		
Presence of visible playable characters (yes/no)	Refers to whether the user has to control an avatar or a character in order to play the game. Playable characters are often linked to the game perspective. When a game presents a first-person approach, the playable characters/avatars are often omitted—they are there, but since the player is seeing the game world through their eyes, the actual characters are not seen. However, third-person point-of-view (POV) games generally allow the player to control a specific character/avatar that they can keep track of at all times [35,37].		
Presence of a story (yes/no)	Whether the game play invites the player to follow a story.		
Type of scenery/in-game environment (realistic/fan- tasy/simple)	Refers to the aesthetics of the background image/3D setting used in the game. Realistic scenerie depict situations, locations, etc, that can be found in the real world. Fantasy determines that the scenery represents locations that are not an imitation of direct reality. Simple environments denote that there is no actual scenery, and the game takes place on top of single-color backgrounds with no associated imagery, often relying on geometric shapes, hence without any specific sense of aesthetic.		
Level of immersion applied to the use of VR ^d (immersive/nonimmersive)	Immersion can be described as the sensation the player experiences as being part of the virtual world promoted by the game, that is, the involving nature of game play [38,39]. In this specific context (applied to VR), nonimmersive VR denotes a system where the interaction between environment and player is achieved through the use of a mouse or a joystick, putting some distance between player and game, while immersive VR implies the use of tools that are connected to the human body (eg, head-mounted display) in order to interact with the game [40].		

^aGG: game genre.

^b1PP: first-person perspective.

^c3PP: third-person perspective.

^dVR: virtual reality.

Data Synthesis and Analysis

The screening process was completed by the authors. The papers were selected by title and abstract if they met the inclusion criteria. If so, full-text papers were obtained for closer inspection. Any disagreement concerning whether to include a specific study was discussed with all the authors.

Assessment of Quality

To assess the quality of the papers, we used the code "Quality of the Studies" by Connolly et al [41]. Each of the 12 papers included in this review was given a quality score using a 3-point Likert scale (3=high; 2=medium; 1=low) based on 5 questions, for example, *How appropriate is the research design for addressing the question or subquestions of this review (with a higher weighting for inclusion of a control group)?*; see more

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in Connolly et al [41]. After scoring each paper, the mean score and mode were calculated (mean 13.42, SD 0.64; mode=12), with scores ranging between 12 and 15 points. Following Connolly et al [41], we used the mode as a cutoff point to determine which papers should be included in this study in order to increase the probability of more methodologically robust evidence. Thus, papers with a score of 12 or more were included.

Results

Paper Selection Process

The search conducted resulted in 623 papers, including 15 papers identified through recursive analysis (excluding duplicates). After removing duplicates, 412 papers with unique titles were identified and reviewed. After title screening, 202

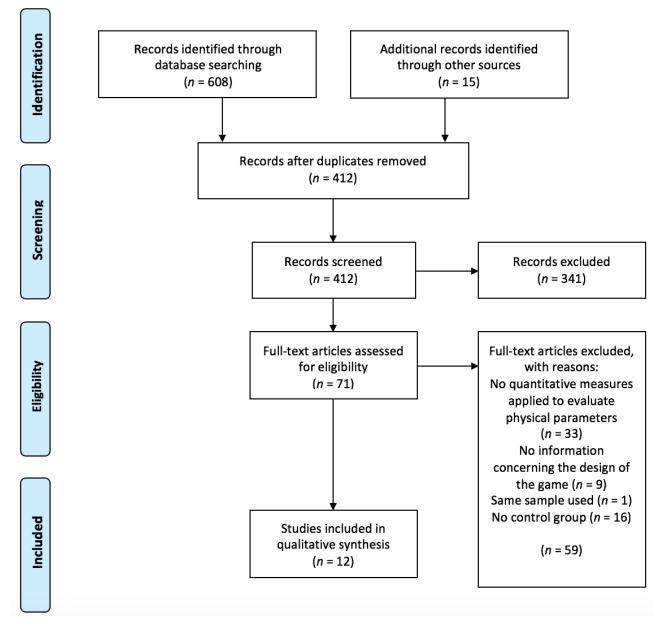
assessment. All of the 12 papers ranked 12 or more in the quality

assessment (see Multimedia Appendix 1 for results) and were

finally included in this systematic review (see Figure 1).

papers were excluded. Another 139 were excluded after abstract review for not meeting the inclusion criteria. A comprehensive review of 71 full-text papers was conducted, 59 of which were excluded. As a result, 12 papers were selected for quality

Figure 1. Article selection process for the systematic literature review.



Regarding the organization of the studies, it is important to note that the cases analyzed in this review sometimes present more than one game mode (eg, sometimes the player can pick whether they want to play the game in 1PP or 3PP, and sometimes, they can play it solo or opt for a multiplayer function instead). When this happened, we selected the option that differentiated the game from other titles (eg, if the multiplayer function was available, even if not always used, the game was considered a multiplayer game). Additionally, in situations where COTS games were used, if there was any reference to the games not being played in full (eg, only certain features of the game were explored for therapy purposes), we solely considered the aspects that were, in fact, used in those studies. A table featuring a summary of the general characteristics of each study, displaying

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the pathology, rehabilitation goals, GDS, GG, GN, nature of intervention, evaluation measures, qualitative results, and quantitative results, is included in the supplementary materials of this paper (Multimedia Appendix 2).

Studies and Sample Characteristics

Of the 12 papers, 7 were randomized controlled trials [11-15,17-21] and quasi-experimental controlled studies or pre /posttest designs [10,16]. A total of 512 participants (from all age groups) were included in this review, who had pathologies such as stroke (8 studies, 417 participants), cerebral palsy (1 study, 8 participants), and multiple sclerosis (2 studies, 46 participants); 1 study targeting the elderly (41 participants) was also included. The ages of the participants ranged from 18 to more than 85 years (estimated mean age ~59 years). For the

stroke cases, the time after stroke went from 1 month up to over 2 years, although most of the patients in the sample were within the first semester after stroke. For the multiple sclerosis cases, the elapsed time since the disease was diagnosed went from 2 years up to over 20 years.

Intervention Characteristics

All studies featured physical therapy sessions with durations varying from 25 minutes to 1 hour. The weekly frequency of the treatment was also flexible, ranging from twice a week to every day. The duration of the studies varied from 5 days to 10 weeks, and the number of sessions went from 5 up to 42.

Measures and Clinical Assessment

To relate the clinical outcomes with the characteristics of the games used, it was necessary to create a classification for the clinical outcomes of the 12 studies presented in this review. Given that the studies were conducted with distinct experimental settings and patients, we proposed to classify the studies into two groups: studies that presented at least one significant improvement in their clinical measurements and studies that presented no significant improvement in any of the clinical measurements. All studies included in the review assessed the domain of motor, sensory, and functional functions, resorting to measures such as the 6-minute walk test (6MWT), the Wolf Motor Function Test (WMFT), the Box and Block Test (BBT), the Nine-Hole Peg Test (9HPT), the 10-meter walk test, the Tinetti test, the Timed Up & Go Test, the Dynamic Gait Index, the Berg Balance Scale (BBS), the Fugl-Meyer Assessment Upper Extremity Scale, Timed Chair Stands, the Purdue Pegboard Test (PPT), and the Action Research Arm Test. Additionally, some studies measured general health outcomes (eg, physical and psychological well-being, QoL, perception of health, cognition, emotion, communication, social participation, perception of pain) by using the Multiple Sclerosis Impact Scale, the EQ-5D visual analogue scale (EQ-VAS), the Short-Form 12 Health Survey, the Stroke Impact Scale (SIS), the visual analogic scale (VAS), and the Functional Independence Measure (FIM). These outcomes were occasionally presented as secondary outcomes [10,11,13,20]. Still other studies [11,20] assessed compliance or satisfaction outcomes (eg, the Client Satisfaction Questionnaire). The BBT (to measure unilateral gross manual dexterity), SIS, and VAS measures were used in 3 to 4 studies. In this review, interventions with games were essentially used for motor rehabilitation of the upper limbs [10-15,18,20,21].

Study Scope, Clinical Improvements, and Session Characteristics

Of the 12 studies, 8 (66.6%) presented significant improvements in at least one of the clinical measurements.

Taking a closer look at studies that had significant outcomes, arm function improvements were found by Saposnik et al [21] in the WMFT and Jonsdottir et al [13] in the 9HTP and BBT. Bruno et al [17] found significant clinical improvements in terms of gait and balance in the BBS and Tinetti test, while meaningful improvements in terms of aerobic capacity and endurance were found by Bower et al [14] in the 6MWT, as well as transfers and mobility improvements in the FIM. In the

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study by Norouzi-Gheidari et al [15], improvements were found in terms of activities of daily living in the Motor Activity Log–Quality of Movement, while Popović et al [12] attained improvements in patient motivation in the intrinsic motivation inventory and therapy time tests and movement smoothness and speed in the modified drawing test. In the study by Cuesta-Gómez et al [11], improvements in terms of coordination, speed of movement, and fine and gross upper-limb dexterity were found in the 9HPT, BBT, and PPT, along with the grip strength measure. Bortone et al [16] found improvements in terms of kinesiological assessment.

In the 8 studies that showed clinical improvement, 4 (50%) aimed at poststroke upper-limb rehabilitation [12,14,15,21], 2 (25%) aimed at upper-limb rehabilitation of multiple sclerosis-derived conditions [11,13], 1 (12.5%) aimed at improvement of general body balance in patients of advanced age [17], and 1 aimed at rehabilitation therapy of children with cerebral palsy [16].

In addition to the previously presented 8 studies, the remaining 4 of the 12 studies (33.3%) presented no significant improvement in any of the clinical measurements [10,18-20]. Of these 4, 3 (75%) studies aimed at poststroke upper-limb rehabilitation [10,18,20] and 1 aimed at poststroke general body balance rehabilitation [19].

Concerning the sample and study characteristics of each study, in the 8 studies that showed clinical improvements, except for 2 studies (1 that accounted for 41 patients with a mean age of 81 years [17] and 1 that accounted for 8 patients with a mean age of 10.13 years [16]), all other 6 studies experimented on adult patients with an overall mean age of 59 years (min=42.2, max=61.3). The mean study duration was 3.9 weeks (min=5 days, max=10 weeks), with the session frequency varying from 2 to 5 sessions per week and the session duration ranging from 25 minutes to 1 hour. Studies that did not show clinical improvements (4 of 12, 33.3%) experimented on adult patients with an overall age ranging from 33 to 81 years. The mean study duration was 3.67 weeks (min=2 weeks, max=6 weeks), with the session frequency varying from 3 to 7 sessions per week and the session duration ranging from 45 minutes to 1 hour.

Game Genre

Of the 8 studies that presented clinical improvements in at least one of the measures, 6 (75%) studies presented their games as being from the casual game genre [11-14,16,17]; 1 (12.5%) of those studies combined the casual game genre with the simulation and exergaming genres [13]. The remaining 2 (25%) studies presented their games as being from the sports genre combined with the simulation genre [15,21].

All the 4 studies that did not show any sort of significant clinical improvement presented their games as being from the sports genre; 1 study combined sports with the simulation genre [10], 1 with simulation and casual games genres [18], and 1 with the exergaming genre [19].

Game Nature

Of the 8 studies that showed clinical improvements, regarding the game player's perspective, 1 (25%) study [17] presented a

3PP game, while all others opted for 1PP games, 3 of which also presented a playable character [14,15,21]. All 8 studies opted for single-player games, and with exception of 1 game [16], which used a fully immersive VR strategy, all others opted for nonimmersive VR. The visual style and type of scenery (or game aesthetics) of the games were fairly distributed among the 3 possible subcategories, with 2 (25%) studies describing their games' aesthetics as simple [11,15], 3 (37.5%) as real [12,13,21], and 3 as fantasy [14,16,17].

Of the 4 studies that did not show any sort of significant clinical improvement, regarding the game player's perspective, with the exception of 1 (25%) study that presented a 1PP game [10], all others (75%) opted for 3PP games [18-20]. All 4 (100%) studies presented a playable character. In addition, 3 (75%) studies opted for single-player games, while 1 opted for a multiplayer approach [10]. With the exception of 1 game [10], which used a fully immersive VR strategy, all others opted for nonimmersive VR. The visual style and type of scenery of the games tended toward real aesthetics in 3 (75%) studies, with 1 (25%) study describing the employed game as having fantasy-type scenery [10].

Of the 12 games analyzed, none invited the player to follow a story during the playthrough.

Game Development Strategy

Of the 8 studies that showed clinical improvements, 7 (87.5%) used custom-made games [11-17], while 1 (12.5%) opted for a COTS game [21]. Of the 4 studies that did not attain any significant clinical improvement, 1 (25%) used a custom-made game [10], while 3 (75%) opted for COTS games [18-20].

Discussion

Principal Findings

Although video games can belong to several different GGs, this review suggests that the casual genre seems to be linked to a higher chance of obtaining significant clinical outcomes (eg, movement speed, upper-limb function and dexterity, gait, balance) when the game is used for physical rehabilitation. From a GN perspective, games using 1PP, played in single-player mode and using nonimmersive VR, seem to be linked to positive clinical outcomes (eg, coordination, movement speed, upper-limb function, gait, balance, motivation). It is also important to mention that 1PP games can frequently be associated with the use of nonvisible playable characters, an aspect that was also linked to studies reporting significant clinical outcomes. Concerning the type of scenery/in-game environment, since the results were well distributed throughout the different possibilities (simple, real, fantasy), it was not possible to discern whether a video game's visual aesthetic is directly linked to significant clinical outcomes. Although it is possible to attempt and draw conclusions in terms of game perspective, game-play mode, and level of immersion applied to the use of VR, it is not possible to conjecture with regard to how the presence of a story might influence the propitiousness for obtaining significant clinical improvements, considering no SGs abridged in this review featured one in their design. Additionally, this review shows that although both COTS and

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custom-made SGs can be used for physical rehabilitation, a higher percentage of the custom-made SG studies presented significant clinical results linked to patient improvement. Such findings can prove useful for health care professionals by aiding their process of choice upon needing to select a video game approach as a physical rehabilitation therapy method, which, in turn, can potentially result in a better experience for patients, as well as positive clinical outcomes.

Game Genre

With regard to the GG and its relationship with clinical outcomes, the genre that showed the best results was casual games. As explored previously, a casual game can be described as any sort of video game that requires the player to complete single and simple tasks that are generally not linked to stories or any other form of longer game play. In addition, it does not require any previous knowledge of or background and experience in playing video games-the player learns how to play right away, and once the mini-game is completed, the playthrough of the game is finished. Casual games seem to be popular in rehabilitation as they include simple game-play types, such as drag-and-drop (the player is expected to simulate the act of grabbing a virtual object-using the mouse cursor, for example—and then dragging it across the screen to a specific location to trigger an action or outcome) or point-and-click (games centered around the action of moving the cursor to a specific point on the screen and then clicking or pressing a button to trigger an action) [42]. Some of the casual games found in this review involved the virtual playout of quotidian situations or tasks-a strategy that has already been demonstrated to achieve positive clinical outcomes [20].

In addition to answering rehabilitation needs, another interesting factor behind casual games is the development time. Being rather simple in terms of game play and short in terms of game length—the experience they offer aims to be simple and easy to understand, while still perceived as entertaining—when compared to games of other genres, casual games take a considerably lower amount of time to be designed, developed, and presented to consumers, which allows for thinner budgets without sacrificing game or aesthetic design quality [43]. This answers the premise of the minimum viable product (MVP), which refers to a product version that is used to collect validated learning from potential customers and users with the minimum amount of development effort, therefore saving time and cost resources [44].

Game Nature

With regard to the GN, aspects such as game perspective, game-play mode, the presence of a story, and the presence of playable characters can highly influence the gaming experience, from the levels of motivation to the levels of experienced immersion upon game play [45,46].

In terms of physical rehabilitation, previous studies have proved that opting for 1PP enhances the sense of embodiment experienced by the user during playtime, therefore permitting better clinical outcomes and results [47,48]. This result is also supported by the cases analyzed in this review, which shows that the majority of the 1PP games portray positive clinical

outcomes. This particular perspective is often found in the casual game genre, which matches the previous findings concerning GGs. Additionally, when games do not feature an option that allows the player to toggle between 1PP and 3PP, 1PP games are often linked to the absence of visible avatars/playable characters [49] (also commonly found in casual games), which also appears to be related to positive clinical outcomes, which is another aspect that favors casual games over other video GGs in this specific context. With this in mind, if we take another look at the concept of MVP, and since the use of 1PP implies that the player character/avatar is not visible, it is relevant to note that this works in favor of reducing production costs; if the playable character is not visible, there is no need to create human-like avatars or human-like movement animations.

Between single-player and multiplayer games, single-player titles were dominant. Moreover, the single study that used a multiplayer game did not present any significant clinical outcome. In addition, nonimmersive VR was preferred over immersive VR. This can possibly be attributed to the problems (such as motion sickness) that are still prevalent in this sort of approach, mostly related to a high degree of undesired latency [50,51], and also to the year when the studies took place. Immersive VR is only becoming something rather ordinary now, while nonimmersive VR video games have already been around (commercially) for decades.

In terms of the type of environment, there was no clear relationship between the type of aesthetics used in the games and the clinical outcomes of the studies. Although in SGs targeting education, it has been proved that a fantasy setting seems to attain better learning outcomes [52], this review found no clear evidence of 1 type of setting working better than another, considering that all possible categories (real, simple, fantasy) found in the games analyzed in this review were displayed evenly in the significant-positive-outcome group.

This review does not allow any specific conclusions on how the presence/absence of a story can influence the significance of outcomes, considering that no game was said to have a story that the player must follow during the game's playthrough. This finding is curious, considering that when users buy games for their own entertainment without any serious purposes in mind, a large chunk of these consumers pick the games according to whether the video game's plot "strikes their fancy." In this sense, and even if games belonging to, for example, the casual genre, do not necessarily need a story to still be perceived as fun, every game can benefit from a good, gripping, and well-written story. With this in mind, and if the presence of a story plays such a big role in terms of play/game enjoyment, it comes across as crucial to look at it more closely, even when the game's objective is targeting physical rehabilitation [53]. Thus, a larger number of cases with video games featuring stories would be needed to be able to discern their relevance in terms of therapeutic functionality and motivation/compliance enhancement.

Game Development Strategy

The custom-made games showcased in this review presented significant clinical outcomes, making them undoubtedly promising as an approach to physical rehabilitation.

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Additionally, the obtained clinical outcomes also proved that custom-made SGs can be as functional as traditional rehabilitation approaches [11-17].

COTS games did not appear to result in any significant clinical improvements among the participants, although they are often perceived as fun by the users. This can be explained because COTS games were originally designed not as a therapeutic tool but as a form of entertainment: they are expected to be perceived as fun by their players, and their main purpose is to entertain. This may also play a role in how patients perceive the form of treatment they are offered, considering that a large number of the population knows and associates COTS franchises (Nintendo, for example) to a form of entertainment, or even a toy, and not something potentially clinically beneficial [54]. When studies resort to COTS games, they use Nintendo Wii games. These require the player to move around and, therefore, execute the needed motions for rehabilitation. Moreover, it might be potentially interesting to observe that some custom-made games presented in these papers were developed for Microsoft Kinect. Nevertheless, the differences in terms of how movement is captured and tracked between Nintendo Wii (tracking of the wireless joystick) and Microsoft Kinect (tracking of the full body) should not be disregarded. The Nintendo Wii joystick (wiimote) makes it easy for the player to cheat the necessary movement, since the device does not register the exact position of the player but just where the remote is located [4]. This does not happen in Microsoft Kinect, since the entire body is constantly tracked, not just the spatial position of the joystick. From this analysis, we can argue that the body movement and gestures performed while playing COTS games are only an approximation of the actual therapeutic movement required by clinical guidelines-hence, the low clinical effectiveness when compared to custom-made games.

Despite the presence of significant clinical outcomes in custom-made SGs, it has been highlighted that there is a need to make SGs more fun to further enhance motivation. Jonsdottir et al [13] pointed out that patients perceive more improvements when playing Wii games (COTS) than when playing games specifically designed for therapy (even if, clinically, that did not turn out to be the case). This opens up the possibility to go beyond the basic notion of custom+-made games and develop the final product to the taste and preference of the patient.

The concept of taking into account patient interests and introducing them as part of the game design elements is an idea that has already been used [55]. Moreover, this will allow custom-made games to conceptually grow closer to COTS games by providing their players with content that is of their interest, stimulating feelings of fun and entertainment that are typically associated with the experience of playing COTS video games.

Likewise, knowing that custom-made casual games can attain the same type of significant outcomes as traditional therapy, it becomes particularly advantageous to look at this approach as a way of monetizing physical therapy, while providing better access to rehabilitation to a larger number of patients. Since a single game can answer the needs of many patients with the same kind of disability, the time lapsed from the moment the

investment is made until it being repaid in full is considerably short: SGs are expected to get a high return on investment [54].

However, if we want to take a look at how COTS games can potentially thrive and cross over with the GN elements previously analyzed, it is important to think about the avatar customization options often found in COTS games. When a video game uses avatars that aim to represent the player, it is important that the user identify with them. COTS games already try to tackle this issue by frequently offering avatar customization options, allowing the user to design their character according to their preferences in order to ease the process of identification with the avatar, create empathy, and promote a sense of embodiment [47,48].

It is also important to mention that although using COTS games for physical rehabilitation may, at first, seem like a great way to avoid the production costs of developing and deploying custom-made SGs, COTS games do not prove to be as effective as the games purposefully developed to be used in therapy, therefore making the investment in custom-made SGs worth it if it they are bound to result in better health outcomes for their users.

Limitations

The main limitation of the present review has to do with the possible lack of accuracy in placing the games described in each study inside a specific genre, since, occasionally, the data provided in the papers included in this review concerning the design/game play of each game were scarce, making it hard to clearly pinpoint the exact genre of the game. Additionally, since this review only found and analyzed 12 relevant papers, which, in turn, only featured 4 distinct GGs, there is no way of knowing whether casual games are indeed the best approach, since the largest slice of the GG panoply was not represented in this review. The same happened with some of the GN features, such as the presence of a narrative, the game-play mode, and the type of scenery/in-game environment—with the information found

in the papers included in this review, it is not possible to pinpoint any conclusive findings.

Conclusions

This review had the objective to provide some insight into what kind of video games seem to work better for physical rehabilitation in terms of GG and GN characteristics. The review and analysis presented here were able to infer important discussion and conclusions on this topic, informed by actual quantitative and qualitative clinical results. As looking at rehabilitation from an SG design point of view is a perspective that is still little explored or formalized, to achieve more robust conclusions, it is necessary for the community to also present and discuss in detail the game design–related aspects of clinical studies.

Nevertheless, this review allows us to conclude that when speaking about SG development strategies, custom-made titles are able to attain better, significant clinical outcomes compared with COTS games since they are designed with therapy-specific movements in mind, therefore not opening the doors to cheating or being perceived as a form of entertainment or a toy.

Of the genres featured in the papers included in this review, casual games obtained the best clinical outcomes in terms of significance (6 of 8, 75%, attained significant results). If we delve even deeper and take a look at how GN features may influence outcomes, both 1PP video games as well as video games that did not feature a visible playable character were behind in significant clinical outcomes. As previously explored, these two features generally go hand-in-hand: if a game is played from the user's point of view, then it is to be expected that the player does not "see" the character/avatar they are controlling. Likewise, this contributes toward reducing production costs and development time, making this approach feasible not only from a clinical outcomes' perspective but also from an economic point of view.

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Conflicts of Interest

None declared.

Multimedia Appendix 1 Quality assessment results. [DOCX File , 15 KB - games v9i3e20066 app1.docx]

Multimedia Appendix 2 Summary of included studies' information. [DOCX File , 51 KB - games v9i3e20066 app2.docx]

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Abbreviations

1PP: first-person perspective **3PP:** third-person perspective 6MWT: 6-minute walk test 9HPT: Nine-Hole Peg Test **BBS:** Berg Balance Scale **BBT:** Box and Block Test **COTS:** commercial off-the-shelf FIM: functional independence measure **MVP:** minimum viable product PPT: Purdue Pegboard Test PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses QoL: quality of life **RTT:** received therapy time SIS: Stroke Impact Scale VAS: visual analogic scale VR: virtual reality WMFT: Wolf Motor Function Test

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Review

The Making and Evaluation of Digital Games Used for the Assessment of Attention: Systematic Review

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Abstract

Background: Serious games are now widely used in many contexts, including psychological research and clinical use. One area of growing interest is that of cognitive assessment, which seeks to measure different cognitive functions such as memory, attention, and perception. Measuring these functions at both the population and individual levels can inform research and indicate health issues. Attention is an important function to assess, as an accurate measure of attention can help diagnose many common disorders, such as attention-deficit/hyperactivity disorder and dementia. However, using games to assess attention poses unique problems, as games inherently manipulate attention through elements such as sound effects, graphics, and rewards, and research on adding game elements to assessments (ie, gamification) has shown mixed results. The process for developing cognitive tasks is robust, with high psychometric standards that must be met before these tasks are used for assessment. Although games offer more diverse approaches for assessment, there is no standard for how they should be developed or evaluated.

Objective: To better understand the field and provide guidance to interdisciplinary researchers, we aim to answer the question: How are digital games used for the cognitive assessment of attention made and measured?

Methods: We searched several databases for papers that described a digital game used to assess attention that could be deployed remotely without specialized hardware. We used Rayyan, a systematic review software, to screen the records before conducting a systematic review.

Results: The initial database search returned 49,365 papers. Our screening process resulted in a total of 74 papers that used a digital game to measure cognitive functions related to attention. Across the studies in our review, we found three approaches to making assessment games: gamifying cognitive tasks, creating custom games based on theories of cognition, and exploring potential assessment properties of commercial games. With regard to measuring the assessment properties of these games (eg, how accurately they assess attention), we found three approaches: comparison to a traditional cognitive task, comparison to a clinical diagnosis, and comparison to knowledge of cognition; however, most studies in our review did not evaluate the game's properties (eg, if participants enjoyed the game).

Conclusions: Our review provides an overview of how games used for the assessment of attention are developed and evaluated. We further identified three barriers to advancing the field: reliance on assumptions, lack of evaluation, and lack of integration and standardization. We then recommend the best practices to address these barriers. Our review can act as a resource to help guide the field toward more standardized approaches and rigorous evaluation required for the widespread adoption of assessment games.

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KEYWORDS

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cognitive assessment; attention; serious games; gamification; systematic review; mobile phone

Introduction

Attention

From crossing the street to composing a tweet, functioning as a human always requires people to take in information, process it, and respond accordingly. Whether in the lab or in the world, detecting stimuli and responding to them, both consciously and unconsciously, involves many cognitive functions. One of these important cognitive functions is *attention*, which Kahneman describes as "a label for some of the internal mechanisms that determine the significance of stimuli" [1].

These *internal mechanisms* of attention can be divided into multiple types. Common areas of attention include selective attention (how people attend to relevant information and ignore irrelevant information), divided attention (when people attend to multiple things at once), and sustained attention (the ability to focus on something for a continuous amount of time) [2,3].

There are also models of attentional control that describe the difference between involuntary and voluntary attention. Attentional control is related to inhibition, shifting, and updating. Inhibition involves preventing irrelevant stimuli from impairing performance, shifting refers to the allocation of attention to whatever is most relevant at the time, and updating is how people encode new information into working memory [4].

Assessment of Attention

Measuring and understanding attention and attentional control are important, as attention is a major cognitive function that influences human development and mental health. Furthermore, as attention is related to a variety of cognitive deficits (eg, attention-deficit/hyperactivity disorder [ADHD] [5] and dementia [6]) and abilities (eg, reading [7]), an accurate measure of attention can help assess and diagnose a number of common disorders.

Measuring attention, and other aspects of cognition such as memory and perception, is often done using *cognitive tasks*. A common approach is to present participants with stimuli and ask them to respond in different ways, while measuring their reaction time and accuracy (ie, how quickly they attend to stimuli and if they respond in the way intended). Research on attention has often relied on specific cognitive tasks, such as the Eriksen flanker task [8] and the Posner cueing task [9], which have been fundamental to the study of attention. More recent cognitive tasks continue to advance the knowledge of attention. For example, the dot probe task demonstrates that people with anxiety preferentially attend to threatening stimuli [10], and attentional blink tasks support the idea that attentional resources are limited [11].

Cognitive assessment tasks have specific standards that must be met before they are widely used, especially in clinical settings. They are expected to have certain psychometric properties, such as validity (how well they measure what they claim to measure), reliability (how consistent the test is), sensitivity (how well they identify true positives), and specificity (how well they identify true negatives).

Digital Games for the Assessment of Attention

Although cognitive assessment tasks are standardized and highly used, they do have some limitations. They can be expensive, as many require trained experts to administer the tasks [12]. They are boring and repetitive, which can cause difficulties with recruitment for research and with patient cooperation for clinical use [13]. The data collected by these tasks can be unreliable, as participants might not be fully engaged and often exert suboptimal effort [14,15]. They also lack ecological validity [12,16]; therefore, they may not be indicative of how these cognitive skills affect daily functioning. To address these limitations, researchers have started to integrate elements from computer and video games into cognitive tasks for assessment.

Games have the potential to improve the quality and quantity of collected data by increasing participants' engagement in the moment (better data) and by engaging many more people over longer periods (more data) [17]. For example, using a game called *Sea Hero Quest* [18], researchers were able to collect spatial navigation data from over 4.3 million people, which would be near impossible with a traditional paper-based task or even a standard digitized assessment. However, although assessment games can be very successful, they do not always improve participant enjoyment. Vanden Abeele et al [19] noted the importance of game *quality* when developing assessment games. In fact, studies have shown that some game elements are associated with lowered enjoyment compared with traditional tasks [13,17].

Game elements can also hinder the assessment properties of a task. Cognition is complicated, and traditional tasks are heavily studied before researchers can be confident that they measure what they claim to measure in a consistent way (issues of validity and reliability). Even a small change in a task must be studied to understand its effects [20].

The use of games to measure cognitive processes related to attention poses unique issues. Through their use of graphics, stimuli, and visual feedback, games inherently manipulate the player's attention, which has been shown to be problematic when using games for assessment. For example, Wiley et al [17] found that participants responded more quickly but also less accurately to a dot probe task when points were awarded for faster, correct responses. Other features could also manipulate attention; for example, increasing narrative suspense has been linked to a narrowed attentional focus [21]. In go/no-go games, using *gamelike stimuli* such as cartoon characters has resulted in decreased performance compared with standard tasks, possibly because it is more difficult to differentiate between complicated graphical stimuli than simple colored shapes [13].

Attention can also interact with games based on individual differences. A study by Delisle and Braun [22] found that game elements can normalize the performance of individuals with ADHD. They designed a task to resemble a fast-paced video game and found that the presence of game elements improved the performance of participants with ADHD more than that of non-ADHD participants. This unequal effect on performance implies that a game designed to assess ADHD could, ironically, be rendered unable to discriminate effectively. Other individual

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differences may also affect the data, such as differences in age, gender, and game-playing experience. Studies have shown that action video game players demonstrate visual search advantages [23]; such a difference may be emphasized by using a game to measure attention. Similarly, older adults or people with little gaming experience may perform poorly on a game, not because they have lower attention abilities but because they are less familiar with computers and games.

This Research

There has been considerable research interest in the use of gamification (ie, the use of game elements in nongame contexts [24]) on cognitive tasks, which has been synthesized in several review papers [25,26]. However, the focus of much of this synthesis research has been on the gamification of training and intervention [26], with less systematic exploration of the efficacy of games for assessment. Although games for training and assessment are often grouped together, recent research suggests that gamification may not be the best approach for assessment [17]. Although cognitive tasks are standardized and have been heavily researched, serious games for assessment are diverse, and there is no field-wide standard for how they should be developed. Our systematic review seeks to explore the different approaches to using games for assessment, particularly for assessing attention, which can be complex. In comparison to other systematic reviews, we provide two unique contributions: First, we look beyond gamification to other approaches for developing assessment games. Second, we review the methodology of developing and evaluating serious games for assessment, rather than just the end product. We aim to provide a guide for interdisciplinary researchers on the development and evaluation of assessment games. Our main research question is: How are digital games used for the cognitive assessment of attention made and measured?

Methods

Eligibility Criteria

Our eligibility criteria required each included paper to be published before March 1, 2021, a peer-reviewed journal article or conference proceeding, primary research (ie, not a literature review or background article), and written in English.

In addition, each paper needed to include a *digital game* used for the *assessment of attention-related processes* that could be used *remotely*. For this criterion, we used the following definitions:

- Digital game: As there are many ways to define a *game*, we chose to follow the original researchers' intentions. If the authors of a paper referred to an assessment as a *game*, *gamified*, or some other variation, we included the paper.
- Attention: We included papers related to attention and attentional control. Figure 1 presents the detailed list of the cognitive processes included.
- Assessment: We were interested in studies that sought to measure attention, for purposes of either detection or diagnosis, research, or monitoring cognitive changes. Studies focused on treatment, training, or interventions were excluded, as were studies on educational and work assessments (eg, assessing for employee selection or how well a concept was learned).
- Remote: As the goal of digitizing assessment is often to increase its scale, accessibility, and reach [27], we included only papers where the game could potentially be deployed remotely, using only a computer, tablet, or phone. Studies that required specialized hardware (eg, a Microsoft Kinect, gaming controllers, and any custom hardware) were excluded, although studies with commonly used devices (eg, a mouse, headphones, and keyboard) were included. Though the ability for studies to be deployed remotely depends on more than available hardware, for this review we did not exclude studies without the requisite software.

Figure 1. Included and excluded cognitive functions for the eligibility criteria in our review.

Included cognitive functions]	Excluded cognitive functions	
Attention and attentional control	Perception and processing speed	Memory	Executive functions and decision-making
 Selective attention Divided attention Visual attention Sustained attention Inhibition Shifting Updating Orienting 	VisualAuditoryTemporal	 Working memory Long-term memory Autobiographical memory Visuospatial memory (including spatial navigation) Prospective memory 	 General knowledge Learning Problem solving Deductive reasoning Decision-making Intelligence Creativity Planning Etc.



Information Sources and Search Strategy

We searched the titles and abstracts of papers across several databases, chosen for their relevance to games user research and psychology: ACM Digital Library, IEEE Xplore, PubMed, PsycINFO, Scopus, and Web of Science. Our keywords were used in a search string adapted to the requirements of each database but generally followed the same format. In addition, where possible, we added the requirement that the returned records be articles published in English. We set no lower time limit but did require that the included papers be published before March 1, 2021. To facilitate other potential systematic reviews, we cast a wide net with our search terms and included other cognitive processes. For example, for Scopus, the search strings were as follows: TITLE-ABS ((gamif* OR game OR games) AND (cognit* OR neuropsych* OR assessment OR memory OR executive function OR attention* OR impulse control OR processing speed OR inhibition OR anxiety OR depression)) AND DOCTYPE (ar).

Study Records and Data Management

To screen the final set of records for our inclusion criteria, we used Rayyan, a web-based system developed for conducting systematic reviews [28].

The first author screened the titles and abstracts of all records for obvious exclusions, such as papers that referenced physical games and sports, as opposed to digital games. The first 2 authors screened the remaining papers, made final decisions, and resolved conflicts through discussion.

As a final quality check, we also screened the first 100 results from Google Scholar using the search string: ((gamif* OR game OR games) AND (attention*)).

Data Items and Synthesis

Our main research question for this systematic review is: How are digital games used for the cognitive assessment of attention made and measured? We also had follow-up questions related to the evaluation of the game's efficacy and engagement: how effective are the games for accurate assessment? and how effective are they in terms of participant engagement?

To conduct the review, we gathered data related to a list of questions for each paper using a spreadsheet. We listed the specific area of attentional control the study focused on (eg, selective and divided), the population examined (eg, children and older adults), and the sample size of the study.

We also listed a number of details about each assessment, including its intended purpose, a general description of the assessment, and if it was focused on a specific disorder (eg, ADHD, dyslexia, or dementia). We were also interested in how each assessment was measured, particularly how it was evaluated, if it was compared with any traditional cognitive tasks or a clinical diagnosis, and any results from the evaluation.

We listed details about gameplay, giving a general description of each game and listing any game mechanics used (eg, points, narrative, and avatars). We also noted how the game was developed (eg, gamification of a task, custom game, and existing commercial game), the expertise of individuals involved in its development (eg, health care professionals and game designers), any evaluation of the game and the results (eg, enjoyment and immersion), and the authors' motivation for using a game.

The first 2 authors collected the data from each paper in a spreadsheet, with each author responsible for half of the papers. The first author then reviewed each paper and the spreadsheet to ensure uniform data collection. These data then informed the qualitative synthesis presented in our results. The wide range of methods used in the included papers precluded any meta-analysis or meaningful quantitative analysis. At most, we provided the summary statistics. We intended for this review to provide an overview of how research is conducted in the field and focus on the methodology of each paper.

Results

Search Results

Our initial search was conducted in December 2019, with an updated search conducted in March 2021 to include any new publications. The two searches resulted in a set of 91,968 records. We used Mendeley Reference Management software, which automatically deleted 38,179 duplicate records. We then manually deleted remaining 4424 duplicates, resulting in a final set of 49,365 records to review.

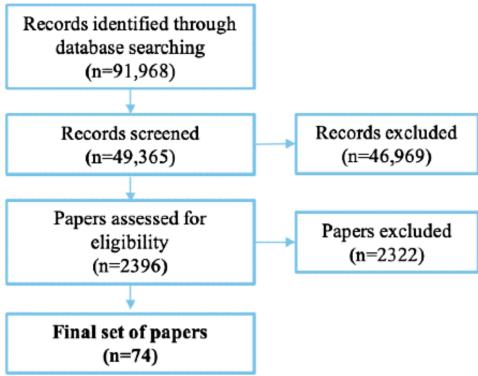
The first author's initial screening excluded 46,969 records. These exclusions were made quickly based on brief searches through titles and abstracts. For example, many records referenced *the Olympic Games* or *game* as in animal game.

The first 2 authors then reviewed the remaining 2396 papers in more detail and excluded a further 2326 papers. At this stage, common exclusions included papers that addressed cognitive processes other than attention [29], papers that used virtual reality or other specialized hardware [30], and papers that focused on interventions and training [31].

A total of 78 papers were selected for analysis; however, we were unable to obtain the full text of 4 papers from any digital library, interlibrary loan, or attempting contact with the authors, leaving a final set of 74 papers for the review (Figure 2).



Figure 2. Flowchart of included and excluded records in our review.



Summary of Included Studies

The full details of the papers included in this review can be found in Multimedia Appendix 1 [13,17,32-103] (general details of each study) and Multimedia Appendix 2 [13,17,32-103] (assessment and game details of each study).

Publishing Formats and Dates

The 74 papers in our review were published in journals from a variety of fields (based on the journal descriptions). Of these

74 papers, 33 (45%) papers were from psychology and medical publications, 26 (35%) papers were from interdisciplinary publications, 13 (18%) papers were from computer science publications, and 2 (3%) were from education publications (Table 1).

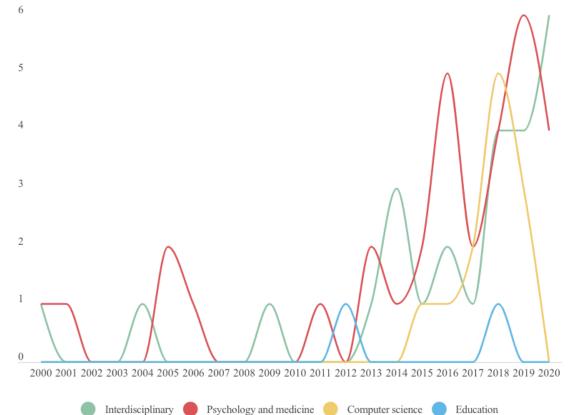
The earliest study in our review was from 2000. Most papers were published in the late 2010s, with 14 papers published in 2018 and 13 in 2019 (Figure 3). Two papers were published in the first 2 months of 2021, before the upper time limit for inclusion in this review.

Table 1. References to all included papers according to publication field.

Field	Reference
Interdisciplinary	[13,17,32-55]
Psychology and medicine	[56-88]
Computer science	[89-101]
Education	[102,103]



Figure 3. Number of included papers according to publication year and field.



Study and Participant Characteristics

The selected papers included 40,154 participants, with sample sizes ranging from 5 to 16,233 participants.

The majority of studies (35) focused on children, with 12 papers focusing on older adults and 25 on a general adult population. In addition, 2 papers had participants from across the human life span, with both children and adults of all ages.

Although the majority of papers (34) looked at a general population, 3 main disorders were also studied: 16 papers on dementia and general cognitive impairment, 11 on ADHD, and 7 on dyslexia. Furthermore, 6 papers examined other disorders (ie, schizophrenia, substance abuse, aggression, multiple sclerosis, Down syndrome, Zika virus disease, Parkinson disease, and Huntington disease).

The papers studied many different aspects of attention and attentional control: inhibition (25 papers), sustained attention (23 papers), visual attention (19 papers), selective attention (14 papers), switching (9 papers), updating (7 papers), divided attention (6 papers), orienting (2 papers), and attentional bias (1 paper). Furthermore, 23 papers measured multiple types of attention. In addition, 5 papers did not specify what type of attention was measured nor could it be inferred from the information in the papers.

Why Are Digital Games Used for Assessment?

The papers in our review listed several reasons for using a game to assess cognition: to address the limitations of traditional tests (32 papers), to increase participant motivation (22 papers), to engage children (18 papers), and because of previous research

(7 papers). In addition, 7 papers listed multiple reasons, whereas 7 papers did not list a motivation for using a game.

The most common reason for using a game was to improve motivation and engagement (22/40, 55% with a general population; 18/40, 45% specifically geared toward children). For example, Thirkettle et al [38] created an app that gamified a battery of cognitive tests, specifically with the goal of encouraging repeated play. Dibbets et al [85] sought to study task switching in children but realized that traditional tasks require participants to be literate. Thus, they developed the Switch Task for Children, which does not require a reading response and presented it as a game to "appeal to young children."

In total, 32 papers used games to address the limitations of traditional assessments, as they can be costly in terms of time and resources, require special expertise, lack ecological validity, and cannot be widely deployed. For example, Brown et al [49] collected data from over 16,000 users using a smartphone app that gamified several tasks. Tong et al [70] created a *whack-a-mole* game for delirium screening in emergency departments, noting that it would be particularly useful to have an automated cognitive test given the busy and demanding nature of emergency rooms.

How Are Digital Games Used for Assessment Made?

Overview

Our review found three different approaches to developing games for assessment purposes: gamifying cognitive tasks (33 papers), creating custom games based on theories of cognition (37 papers), and exploring potential assessment properties of

commercial games (4 papers). One study used both a gamified task and a commercial game.

Gamification

Gamifying a traditional cognitive task is a common approach for making a game for assessment. This approach involves adding points, graphics, and other game elements to a traditional task. Typically, these tasks are digitized (if they are not already), and then the game elements are layered over the top of the basic task. As an example of gamification from our review, Johann and Karbach [59] created a series of gamified tasks for children, all based on the story of a magic kingdom where an evil wizard must be defeated. One task was a go/no-go task, where the stimuli were dragons of different shapes and colors. Correct responses advanced a progress bar and earned participants magic power points. This example uses points, graphics, and themes to gamify the task, but any one game element or combination of elements can be used for gamification. For example, Lumsden et al [13] created a stop signal gamified task using only points and another variation using only thematic graphics. On the other end of the spectrum, Ryokai et al [36] used many game elements in their multiple object tracking (MOT) game for children, including a theme, graphics, music and other sound effects, dynamically adjusted levels, and feedback.

Custom Games

Another popular approach is to create a custom game based on theories of cognition or other previous research. For example, several papers in our review created games to detect dyslexia based on theories of visual-spatial attention [55,89,96,100]. As another example, McKanna et al [32] created *21 Tally*, described as "blackjack played in two dimensions," based on theories of divided attention.

The custom games in our review are diverse, ranging in appearance and complexity. Some are fairly similar to gamified tasks in their simplicity and approach. For example, although Chesham et al [50] did not gamify a specific task, their custom game looks and feels like a gamified task, with very simple designs and mechanics; in fact, they called it a *taskified game*. Other custom games, such as the *EVO* game by Anguera et al [56], are more akin to a commercial game. *EVO* was designed specifically to resemble a commercial action video game, with a focus on "high-level art, music, feedback and storylines."

These custom games are also diverse in their development. Some games are very literature- and hypothesis-driven, whereas others offer less rationale for their design. For example, Rauschenberger et al [100] created *MusVis*, a game to detect dyslexia using language-independent methods. They based their design choices on the visual and auditory processing abilities of individuals with dyslexia. On the other hand, some papers in our review did not offer a clear rationale for how they designed their custom game and why they expected it to work.

Commercial Games

Four papers used preexisting commercial games. In these cases, the games were not created by the researchers; rather, the researchers explored the potential assessment properties of a game. For example, Intarasirisawat et al [92] used Tetris, Fruit

Ninja, and Candy Crush Saga to investigate how touch gestures in popular games might relate to performance on traditional cognitive tasks. In their study, participants were asked to play games and complete traditional paper-based tasks. A bivariate analysis then revealed correlations between commercial games and tasks.

As another example, Houghton et al [52] used Crash Bandicoot to study motor control and sequencing among boys with and without ADHD, under low and high working memory and distractor conditions. The goal of the study was to compare how boys with ADHD performed in an ecologically valid, highly motivating environment (a computer game) compared with a standard laboratory environment.

How Are Digital Games Used for Assessment Measured?

Evaluation of the Assessment Aspect

Overview

As digital games have not been traditionally used for cognitive assessments, they need to be evaluated for their relation to cognition; for example, researchers may want to know whether people with and without ADHD display different mouse behaviors [102] or if scores on a gamified go/no-go task correlate to correct responses on a traditional go/no-go task [51,59,62,69].

Our review found three approaches to evaluating the assessment aspect of games: comparison to a traditional task (31 papers), comparison to a clinical diagnosis (14 papers), and comparison to knowledge of cognition (11 papers). An additional 4 papers compared game results with both a traditional task and a clinical diagnosis, and 1 study used both clinical diagnoses and comparisons to normative data. Of these papers, we further identified 4 that used machine learning to evaluate assessment. Thirteen papers did not evaluate the assessment aspect of the game.

Comparison to a Traditional Task

The most common approach to evaluating the assessment aspect of a game is to compare the results of a game with the results of an established cognitive task. For example, if the scores from a game are designed to measure response inhibition, researchers may want to compare those scores with those from a go/no-go task. If the patterns of responses are similar, it is likely that the game measures response inhibition in a similar way to a go/no-go task. This process is what Chicchi Giglioli et al [51] followed when evaluating their game, *EXPANSE*, which gamified the dot probe task, go/no-go task, Stroop task, trail making task, and Wisconsin Card Sorting Test. Participants were asked to complete both the standard tasks and game-based versions.

Although this process offers the most direct comparison between tasks and their gamified components, of the 33 papers that gamified a traditional task, only 14 evaluated the game by comparing it with the task.

Custom and commercial games may also be compared with traditional tasks. For example, Tong et al [69] created a

whack-a-mole game designed to measure response inhibition. Although this game was not based on a specific task, it calculated correlations between performance on the game and performance on a standard Stroop task, which also measures response inhibition. Similarly, Baniqued et al [57] had participants play 20 commercial casual games, as well as a battery of cognitive tasks, and examined the relationships between how participants performed on the games and the tasks.

Comparison to a Clinical Diagnosis

Another approach to evaluation is to compare the results of a game with a clinical diagnosis or questionnaire. For example, if a game is designed to measure selective attention, researchers may want to look at how scores on the game differ between children with and without ADHD. As children with and without ADHD typically display different patterns of selective attention, the game can be assessed to determine if it discriminates between children with and without ADHD. If game performance differs between the 2 groups, it may be measuring selective attention. Alternatively, it may be picking up on some other feature of cognition that differs between children with and without ADHD; therefore, this approach needs to be used carefully.

If the intent of the game is to diagnose ADHD, it matters less *why* it works than *if* it works. Most of the games in our review used this evaluation approach for situations in which diagnosis was the goal. For example, Peijnenborgh et al [34] demonstrated that their game, *Timo's Adventure*, had clinical validity by showing that children with and without ADHD had significant performance differences.

As another example, Fukui et al [88] recruited participants with mild cognitive impairment, participants with Alzheimer disease, and age- and gender-matched healthy control participants and examined whether performance data from their games were able to discriminate between the 3 groups.

Comparison With Theories of Cognition

The results of a game can also be compared with the theories of cognition. For example, if a game is designed to examine attentional blink phenomena, we can refer to the literature on patterns of attentional blink to determine if the results from the game make sense. These comparisons can occur in different ways, for example, comparisons with normative data or a specific theory. Brown et al [49] used a set of gamified tasks. They did not compare those games with a task version directly, but they compared their results with the literature on those tasks, reporting that their games produced *canonical results*. Thirkettle et al [38] compared their results on the basis of demographic effects by grouping participant results according to gender and age and assessed the replication of known effects (eg, increases in age correlated with increases in reaction time). Similarly, Ryokai et al [36] compared their results with the known MOT limits.

Machine Learning

As an additional finding, we found 4 papers that used machine learning in their evaluation. These studies compared the results of a game with the results of a cognitive task or clinical diagnosis and then used machine learning to build a

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classification model for the game results. For example, Jung et al [54] used machine learning to classify game scores by comparing them with MMSE scores, and Mwamba et al [33] classified game data based on children with and without a diagnosis of ADHD.

Evaluation of the Game Aspect

When using digital games for assessment, it is important to evaluate the games themselves. As discussed earlier, many papers in our review discussed using games as assessment tools with the motivation to increase participant engagement with testing. Thus, researchers may want to know if a game is more enjoyable than a traditional task [62,90] or if participants find the game too difficult to play [101].

In our review, only 25 studies evaluated some aspects of gameplay. The majority of studies (n=41) did not evaluate game features. Furthermore, 8 papers did not formally report an evaluation of the game but suggested that some evaluation was done (eg, a sentence in the discussion section that indicates that most participants enjoyed the game [42] and mentioned that participants were asked if they enjoyed the game without reporting the results [57]).

Of the 25 studies that evaluated game play, most used a short questionnaire to assess enjoyment and difficulty, although these measures vary in complexity. For example, Gaggi et al [89] asked children two simple questions about their game experience: "Do you like the game?" and "Is the game difficult to play?" with simple choices for answers: "Yes, a lot; Yes; Not so much; No" and "Easy; Medium; Hard," respectively. On the other end of the spectrum, Szalma et al [37] used a more detailed battery of the NASA (National Aeronautics and Space Administration) Task Load Index (a questionnaire that measures perceived workload) and other questionnaires to measure stress, task engagement, and difficulty.

Game behavior was also used as a metric of enjoyment; for example, Thirkettle et al [38] noted that 1400 participants played their game more than 10 times, and Godwin et al [90] found that their *Monster Mischief* game was three times as popular with children as the MOT task it was based on.

Another way to assess game elements is to directly compare multiple versions of a game or task with different elements included in each version. Miranda and Palmer [64] compared three versions of a visual search game: with points and sound, with only points, and with only sound. Lumsden et al [62] used this approach to compare three versions of a gamified task (ie, a nongame task, a gamified task with points, and a gamified task with a theme).

How Effective Are Assessment Games?

Although our review was mostly concerned with methodology, that is, how assessment games are made and evaluated, we also wanted to explore how effective these games are. How effective are they at an accurate assessment and at participant engagement?

Unfortunately, the general lack of evaluation done by the papers in our review precludes us from answering these questions. In addition, the wide range of methodologies makes it difficult to

compare even the limited studies that do include some evaluation. For example, Miranda and Palmer [64] gamified a visual search task and used it to investigate how participants responded to a task with points and sound effects included. Similarly, Lumsden et al [62] used the same approach with a go/no-go task to examine the effects of points and themes. However, the evidence from these studies is difficult to compare despite their similar methodologies. Miranda and Palmer compared versions of their game with only points, with only sound effects, and with both points and sound effects. They did not compare it with the control version of the task. Lumsden et al compared versions of their game with only points, with only theme, and with a control version of the task but did not have a version that combines points and themes. These differences in evaluation were found across all studies in our review.

Discussion

Principal Findings

We identified and reviewed 74 papers that used a digital game to measure cognitive functions related to attention. We sought to answer the following question: How are digital games used for the cognitive assessment of attention made and measured?

We found three different approaches to making assessment games: gamifying cognitive tasks, creating custom games based on theories of cognition, and exploring potential assessment properties of commercial games.

Games for assessment have two aspects that can be evaluated: the assessment properties (eg, how accurately attention is measured) and game properties (eg, how fun the game is). The papers in our review that evaluated the assessment properties used three approaches: comparison to a traditional cognitive task, comparison to a clinical diagnosis, and comparison to knowledge of cognition; however, most studies did not evaluate the game properties.

From our review, we identified three barriers to the progress in using games for cognitive assessment. We propose recommendations to address these barriers and offer ideas for further research.

Barriers to Progress in the Field

Overview

There are three barriers to making substantial progress in using games for cognitive assessment. The first barrier we identified is that the literature currently perpetuates assumptions about how users interact with assessment games. Second, there is a lack of evaluation of these games. Third, there is no clear standard for integration across the field.

Assumptions

Although the papers in our review did not explicitly state that assumptions about games informed their choices, our results revealed some patterns. In total, 13 papers did not evaluate the assessment aspect of the game. Of these papers, the vast majority were about gamified tasks (9 papers). In addition, of the 33 papers that gamified a traditional task, only 14 evaluated the game by comparing it with the task. This lack of evaluation for

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gamified tasks may be due to the assumption that adding simple elements such as points and graphics will not interfere with performance on the basic task.

In addition, 40 papers chose to use a game for assessment because of a potential increase in participant engagement and enjoyment; however, this choice was rarely followed up with an evaluation of how enjoyable participants found the game. In fact, of these papers, only 18 evaluated game play. This assumption that a game of any type or quality will be engaging and will yield better results than a traditional task is pervasive across the literature, despite evidence to the contrary. For example, Wiley et al [17] analyzed the effects of including points and theme in a gamified task. They found that although points increased participants' experiences of enjoyment, challenge, and meaning, adding a theme actually lowered these experiences. After a theme-based introduction to the task, enjoyment was temporarily higher but dropped after play, likely because the basic game play failed to live up to participants' heightened expectations. Different game experiences influence enjoyment and engagement in ways that cannot always be predicted.

Evaluation

More than half (41/74, 55%) of the papers in our review did not evaluate any aspect of game play, and 17% (13/74) of papers did not evaluate any assessment properties. This lack of evaluation is problematic for the advancement of cognitive assessment games. For the games in our review to be seriously considered as assessment tools in the way that standard cognitive tasks are perceived, they need to be evaluated and validated in the same way.

Only 21 papers from our review evaluated both assessment and game properties. As Levy et al [104] noted, "One of the most significant challenges in designing games for scientific studies is the tension between including enough gamelike elements that produce an engaging game, but also selecting the right elements that will not interfere with the validity and reliability of the game as a scientific method or tool." Each assessment game must be evaluated based on both its assessment value and its game value.

Integration and Standardization

The final barrier to progress is integration across the field. Currently, there is little guidance on how assessment games should be made, evaluated, and used. Although every project will be different (eg, each game will use different tasks, themes, or gamification approaches), for the field to advance, there needs to be integration at the level of the game structure. At the structural level, researchers should develop a clear understanding of how different game mechanics in assessment games (eg, points, theme, rewards, feedback, procedures, rules, game input, and narrative elements) interact with user performance and experience. Some research is being conducted in this regard; for example, multiple studies have shown a classic speed-accuracy trade-off when points are included in an assessment game [17,39]. This type of work should be expanded to other game mechanics, and reviews and meta-analyses should integrate the findings to develop standards within the field. The

majority of the included studies were published in psychology or medical venues, compared with computer science venues, or interdisciplinary venues; therefore, it could be possible that research teams lack formal training in the design and deconstruction of games [105].

Recommendations to Address Barriers

Overview

To help advance the field, we identified the *best practices* from the papers in our review. These include using clearly defined goals to guide the development of a game, ensuring robust evaluation, and working with interdisciplinary teams.

Motivation and Purpose

Describing a clearly stated motivation for using a game over a traditional assessment can justify the use of games in this context. For example, motivation may be to increase engagement with children or reduce dropout rates for long-term monitoring. The game can then be evaluated to determine if it meets the motivation (eg, does it engage children? Does this reduce dropout rates?). This evaluation is important because the field is new enough that the results are often not generalizable.

Clearly articulating a clear long-term goal can set guideposts for the development and evaluation of games for assessment. For example, if the goal is to use a game as a neuropsychology tool, researchers can focus their efforts on making a standardized game that meets robust standards for validity and reliability and has a large normative data set [12]. If the goal is to create a game for widespread dissemination for population-level research, then the focus can be on making the game truly engaging and fun to encourage natural use *in-the-wild*. As an example from our review, McKanna et al [32] identified the need for an unobtrusive way to continuously monitor and detect cognitive decline in older adults. This goal guided their development of a computer game that naturally appealed to older adults and targeted divided attention, a function associated with daily activities that often declines with age.

Evaluation

Evaluating the assessment capacity of assessment games is necessary to establish their validity. Given the new variables that any game element introduces to an assessment, moving forward, a focus on robust evaluation needs to be prioritized for any cognitive assessment game. We can look at cognitive psychology for best practices when evaluating tasks. For example, when developing a new parametric go/no-go task, Langenecker et al [106] measured the sensitivity, construct validity, and test-retest reliability. From our review, Chesham et al [50] measured the validity of their search and match task, a puzzle game designed to assess visual search. To do this, they looked at correlation analyses between performance on the game and performance on traditional tasks.

Measuring the player experience within assessment games is necessary to justify the use of games over traditional assessment tasks. In our review, we identified three approaches to evaluating assessment games: comparison to a task, comparison to a clinical diagnosis, and comparison to theories of cognition. Comparisons to a task and to theories of cognition can help determine

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construct validity. A comparison with a clinical diagnosis may measure the sensitivity. However, there are many other issues that need to be addressed. For example, does the game work for people from different cultures or with different educational backgrounds? Are there practice effects that may interfere with repeated use? Some of the studies in our review addressed questions such as these; for example, Rello et al [94] assessed their game for both English and Spanish speakers; however, every study in our review answered different evaluation questions.

It may be useful to develop best practices around how and what should be evaluated when developing an assessment game. This list should include evaluating the assessment aspects in ways similar to cognitive psychology methods, but it also needs to include evaluating the game aspects. Knowledge on how to evaluate games can come from games user research.

Interdisciplinary Work

Integrating knowledge across the disciplines of psychology, clinical sciences, game design, or user experience will help ensure robust results. Regardless of the goals of the assessment game, the best result will often come from an interdisciplinary team. Levy et al [104] noted that, "...the design of scientifically robust games is often at odds with accepted game design practices." We need to draw from knowledge of both game design and cognitive testing. Interdisciplinary work will be key in developing robust, enjoyable games, and it will also be useful in knowing how to evaluate these games, as discussed earlier. Experts in cognitive psychology, neuropsychology, game design, and games user research can all contribute to this field. As an example from our review, *Smart Aging* by Bottiroli et al [83], a game platform designed to measure various cognitive functions, was developed in collaboration with "neurologists, psychologists, neuropsychologists, bioinformatics, designers, and ICT engineers."

Limitations

There are some limitations to our systematic review. We did not search every database for papers; for example, we ruled out using Springer Link because we could not search by title and abstract. We selected our databases based on the relevance to the field and focused on using a mix of computer science– and psychology-related databases. Similarly, we attempted several combinations of search terms. Some yielded too many results for a feasible review. We aimed to search as comprehensively as we could realistically manage. We struck an appropriate balance with 49,365 records to review after duplicates were removed.

We also used cross-referencing and Google Scholar to check for additional papers that met our criteria; however, it is still possible that we missed some papers.

Our review also only addressed papers that used games to assess cognitive processes related to attention to keep this review to a manageable scope. Many other studies have assessed memory and other cognitive functions using games. We intend to cover memory in another review, and future work should cover games that are used to assess more complicated cognitive functions, such as decision-making.

Another limitation of our selection criteria is our reliance on authors to define their work as a game or task. Our search criteria depended on the inclusion of the word *game* in the title or abstract of the paper. We may have missed papers in our review those that used what authors defined as a *task* but still implemented game elements, such as points. In addition, we may have included papers that used what authors defined as a *game* but could be considered a task.

Finally, our review only covers published work and thus, carries the risk of publication bias. As our review focused on the methodologies used by studies and not the outcomes, this issue is not a significant concern.

Conclusions

We conducted a systematic review to answer the following question: How are digital games used for the cognitive assessment of attention made and measured? We searched a wide range of databases to identify an initial set of 49,365 papers, which we then narrowed to a set of 74 papers that we reviewed in detail. From these studies, we identified three unique approaches for developing a game for assessment. We also identified that, across the field, the focus tends to be on development rather than evaluation. Assumptions about how the application of games to cognitive tasks should improve assessment are widespread but perhaps not widely demonstrated. Our review can act as a resource to help guide the field toward more standardized approaches and rigorous evaluation required for the widespread adoption of assessment games.

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Conflicts of Interest

None declared.

Multimedia Appendix 1 General details of each study. [DOCX File , 25 KB - games v9i3e26449 app1.docx]

Multimedia Appendix 2 Assessment and game details of each study. [DOCX File, 19 KB - games v9i3e26449 app2.docx]

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder MOT: multiple object tracking NASA: National Aeronautics and Space Administration

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Review

Augmented, Mixed, and Virtual Reality-Based Head-Mounted Devices for Medical Education: Systematic Review

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Abstract

Background: Augmented reality (AR), mixed reality (MR), and virtual reality (VR), realized as head-mounted devices (HMDs), may open up new ways of teaching medical content for low-resource settings. The advantages are that HMDs enable repeated practice without adverse effects on the patient in various medical disciplines; may introduce new ways to learn complex medical content; and may alleviate financial, ethical, and supervisory constraints on the use of traditional medical learning materials, like cadavers and other skills lab equipment.

Objective: We examine the effectiveness of AR, MR, and VR HMDs for medical education, whereby we aim to incorporate a global health perspective comprising low- and middle-income countries (LMICs).

Methods: We conducted a systematic review according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) and Cochrane guidelines. Seven medical databases (PubMed, Cochrane Library, Web of Science, Science Direct, PsycINFO, Education Resources Information Centre, and Google Scholar) were searched for peer-reviewed publications from January 1, 2014, to May 31, 2019. An extensive search was carried out to examine relevant literature guided by three concepts of extended reality (XR), which comprises the concepts of AR, MR, and VR, and the concepts of medicine and education. It included health professionals who took part in an HMD intervention that was compared to another teaching or learning method and evaluated with regard to its effectiveness. Quality and risk of bias were assessed with the Medical Education Research Study Quality Instrument, the Newcastle-Ottawa Scale-Education, and A Cochrane Risk of Bias Assessment Tool for Non-Randomized Studies of Interventions. We extracted relevant data and aggregated the data according to the main outcomes of this review (knowledge, skills, and XR HMD).

Results: A total of 27 studies comprising 956 study participants were included. The participants included all types of health care professionals, especially medical students (n=573, 59.9%) and residents (n=289, 30.2%). AR and VR implemented with HMDs were most often used for training in the fields of surgery (n=13, 48%) and anatomy (n=4, 15%). A range of study designs were used, and quantitative methods were clearly dominant (n=21, 78%). Training with AR- and VR-based HMDs was perceived as salient, motivating, and engaging. In the majority of studies (n=17, 63%), HMD-based interventions were found to be effective. A small number of included studies (n=4, 15%) indicated that HMDs were effective for certain aspects of medical skills and knowledge learning and training, while other studies suggested that HMDs were only viable as an additional teaching tool (n=4, 15%). Only 2 (7%) studies found no effectiveness in the use of HMDs.

Conclusions: The majority of included studies suggested that XR-based HMDs have beneficial effects for medical education, whereby only a minority of studies were from LMICs. Nevertheless, as most studies showed at least noninferior results when compared to conventional teaching and training, the results of this review suggest applicability and potential effectiveness in LMICs. Overall, users demonstrated greater enthusiasm and enjoyment in learning with XR-based HMDs. It has to be noted that

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many HMD-based interventions were small-scale and conducted as short-term pilots. To generate relevant evidence in the future, it is key to rigorously evaluate XR-based HMDs with AR and VR implementations, particularly in LMICs, to better understand the strengths and shortcomings of HMDs for medical education.

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KEYWORDS

virtual reality; augmented reality; global health; income-limited countries; medical education

Introduction

Augmented reality (AR), mixed reality (MR), and virtual reality (VR)-based technologies open novel ways of teaching and training for medical education, as they allow for immersive experiences that may foster the teaching and learning of complex medical contents. Especially so-called head-mounted devices (HMDs), most often realized as a headset or glasses, seem to be advantageous and adequate to low- and middle-income countries (LMICs) based on their versatile, low-price, and mobile nature [1,2]. Technologies like HMDs make learning content more accessible and engaging, whereas for educators, it broadens their educational impact beyond the classroom and face-to-face teaching [3,4]. Quality education is key to improve health outcomes for all [5], especially in low-resource settings where there is a dire need to strengthen the health workforce [6], particularly today, as health professionals must acquire a great deal of skills and know-how to become competent practitioners [7]. HMDs can potentially be a catalyst for improving educational efforts by increasing the effectiveness of existing medical training programs, as AR-, MR-, and VR-based HMDs enable repeated practice without adverse effects on the patient in various medical disciplines; may introduce new immersive ways to learn complex medical content; and may alleviate financial, ethical, and supervisory constraints on the use of traditional medical learning materials like cadavers and other skills lab equipment [8-11]. Moreover, disruptive technologies such as HMDs can not only help to learn but also prepare medical learners for a highly technologically advanced workplace [12]. Therefore, HMDs hold the promise to be a potential driver in strengthening health systems and the health workforce, which has been key to increasing global life expectancy in recent years [13]. Particularly, LMICs face health worker shortages, skewed distribution of health professionals toward urban areas, and limitations in skill sets and training that do not aptly address the population's real health needs [13,14]. Regions in Africa and Asia still have alarmingly high health worker shortages [10] despite the Sustainable Development Goals (SDGs) calling for a substantial increase in the recruitment, development, training, and retention of the health workforce in income-limited countries (SDG goal 3C) [15]. To successfully achieve the SDGs for 2030, digital technologies may be a key element, as they bear the potential to enhance health professional performance and training in a rapid and cost-effective way [1,2]. In addition, digital technologies are versatile and are well able today to reflect the varied training needs of health professionals covering a broad field of teaching and training needs, clinical competencies, and skills such as therapeutic and diagnostic skills and communication skills. Nowadays, technologies provide an experience close to reality,

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without putting the patient at risk during training. Technologies provide a quality standard of technical medical skills, as they are scalable and repeatable until skills are fit for practice. In particular, HMDs are versatile in their use compared to specialized individual simulators already used for medical training and available at low prices, and for providing increased learning space mobility—features particularly valuable in low-resource contexts [1,2,8,9].

Currently, there is a lack of insights on HMDs particularly in LMICs, as most reviews on HMDs have focused on high-income countries, on AR for medical education, or on AR and VR but not in the context of health [16-20]. This systematic review took a global perspective. Technologies are constantly evolving and there is a need for obtaining an overview of current trends in a global context. No other review was found that had considered HMDs for global health professional training considering a recent time frame.

The main objective of this systematic review is to screen the current literature evaluating HMDs using AR, MR, and VR for medical education, and to elucidate the effectiveness of HMDs for medical education in a global context, particularly with regards to LMICs. Two main research questions guided the systematic review: (1) what is the effectiveness of using HMDs for medical education, specifically for knowledge and skills, and (2) what are the strengths and weaknesses of HMDs in medical education?

Methods

This systematic review was conducted according to the Cochrane Collaboration Handbook for systematic reviews [21] and reported according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses; see Multimedia Appendix 1) [22]. There was no review protocol published and the review was not registered.

Data Source, Search Strategy, and Inclusion and Exclusion Criteria

Seven medical and educational databases for peer-reviewed literature were searched comprising PubMed, Cochrane Library, Web of Science, Science Direct, PsycINFO, Education Resources Information Centre, and Google Scholar (200 first results were extracted, according to Haddaway et al [23]). Gray literature databases that were searched comprised WorldCat (45 results were used from each of the three search concepts *XR*, *medicine*, and *education*) and Global Index Medicus.

In addition, reference lists of selected articles have been hand-searched and included if inclusion and exclusion criteria were met. As relevant HMD technology was first commercially

introduced in 2014 [24], publications were only included if published after January 1, 2014, until the end of the study period, which was May 31, 2019, and were restricted to the English language. Surveys, editorials, and conference papers were excluded, as well as literature that had no abstract or full-text available.

The PICOS (population, intervention, comparison, outcome, study design) framework guided the inclusion and exclusion criteria of this study [25] (see Table 1). To ensure coverage of

all relevant literature to this rather novel topic, search terms were compiled comprehensively and were grouped into the three search concepts of *extended reality* (XR; which subsumes the concepts of VR, AR, and MR), *medicine*, and *education*. The following search terms or keywords were used alone or in combination: *virtual reality, augmented reality, mixed reality, medical, health, clinical, education, teaching, training,* and *learning* (see Multimedia Appendix 2 for a detailed overview of the search strategy). The PRISMA flowchart is shown in Figure 1 depicting the screening process.

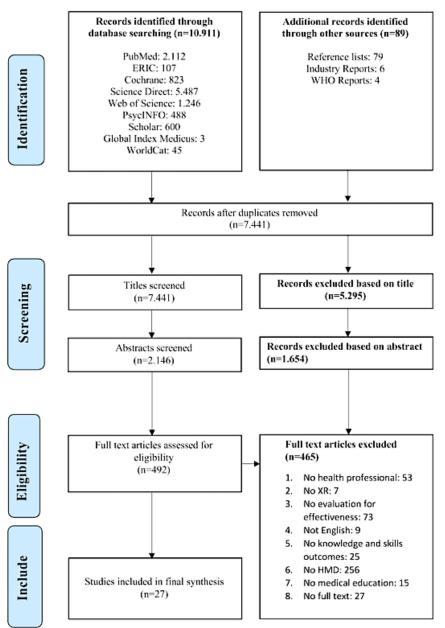
Table 1. PICOS (population, intervention, comparison, outcome, study design) framework (adapted from Methley et al [25]).

Framework	Description	Inclusion	Exclusion
Population	Health professionals who received medical education	Health professionals, nursing and midwifery professionals, modern health associate profes- sionals, nursing and midwifery associate pro- fessionals	Health management and support workers who are not in health service provisioning
Intervention	Head-mounted displays based on virtual reality, augmented reality, or mixed reality	Head-mounted displays of all kinds that include glasses or goggles	Devices that are not head-mounted displays
Comparison	Modern vs traditional methods for medical education to evaluate effectiveness of XR ^a tools	Books, pen and paper, chalkboard, face-to-face teaching, traditional lectures	No evaluation of the effectiveness of XR devices
Outcome	Improved or not improved learning outcome	Concrete learning outcome/evaluation of effec- tiveness in learning	No concrete outcome
Study	Literature in English, published between Jan 1 to May 31, 2019	Literature as identified via the search strategy	Literature reviews, meta-analyses, opinion papers; non-English literature; literature published before Jan 1, 2014, and after May 31, 2019

^aXR: extended reality.



Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart for systematic reviews. ERIC: Education Resources Information Centre; HMD: head-mounted display; WHO: World Health Organization; XR: extended reality.



Data Extraction and Study Quality Assessment

Articles were independently screened by two researchers using the eligibility criteria of the PICOS framework. Data were extracted as recommended by the Cochrane Handbook [21] (for detailed data extraction table see Multimedia Appendix 3). Any disagreements were resolved by discussion between the two screening authors. Population characteristics were derived from the studies, including author, year, place, journal, country of study, study design, evaluation methods, number of evaluation methods, type of data analysis, effectiveness, type of study population, medical discipline of study, type of XR, type of HMD, type of learning, study duration, and references.

Quality and risk of bias was assessed with the Medical Education Research Study Quality Instrument (MERSQI), the Newcastle-Ottawa Scale-Education (NOS-E), and "A Cochrane

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Risk of Bias Assessment Tool for Non-Randomized Studies" (ACROBAT-NRSI) [26-28].

Synthesis Method

Data synthesis is reported according to the SWiM (Synthesis Without Meta-analysis) reporting guideline [29]. The research question guided the synthesis groupings, and we focused on the effect of XR HMDs on knowledge and skills gained in relation to the HMD devices used. Furthermore, we reflected each synthesis group according to their medical specialties, as we thought that each medical specialty is different in its focus on knowledge or skills training. No standardization metric was applied. The synthesis method was to extract relevant sections of the studies with regard to knowledge and skills gained, as well as the specific XR HMD. Overall, the risk of bias assessment of nonrandomized study designs showed no critical results (see Multimedia Appendix 4 for details). Accordingly,

the 27 included studies were synthesized with equal weight. We did not restrict the study design. Hence, we did not conduct a meta-analysis, as studies were quite heterogenous, and the included studies reported different quantities and qualities about knowledge and skills. Effectiveness was synthesized according to the respective study reports. The tables aggregate information about the study characteristics and focal areas of this review (knowledge, skills, XR HMD).

Results

Study Characteristics

A total of 27 studies was included in the review: 17 (63%) VR studies, 7 (26%) AR studies, 2 (7%) MR-focused studies, and 1 (4%) VR and AR study (see Table 2 for study details). Although 24 (89%) studies used only a single HMD, 3 (11%) studies compared two HMDs. All studies were in an academic or hospital setting and mostly compared HMDs to conventional face-to-face training methods [2,30-41]. The included studies used an HMD worn on the head.

Included studies were categorized according to three levels of knowledge (adapted and modified from Górski et al [42], see Multimedia Appendix 5): (1) theoretical knowledge (eg, anatomical atlases and preoperative planning), (2) practical skills (eg, operation trainings and surgical simulators), and (3) attitudes (eg, self-confidence, communication skills, and patient-centeredness).

Overall, the included studies (N=27) comprised a study population of 956 study participants. Sample sizes ranged from 1 participant to 178 participants, with a mean of 35 participants (see Multimedia Appendix 6 for details of the number and type of study participants).

The medical procedures described across studies varied widely. Studies in surgery included training in neurosurgery [43], gastrectomy [2], total hip arthroplasty [35,37], laparoscopy [44], dental surgery [32,45], surgical ophthalmoscopy [33], peg transfer practice [46], or surgical knot training [47] and central line and catheter insertion [48,49]. Anatomy teaching was covered in 4 (15%) studies, 3 of which involved 3D learning structures in neuroanatomy [39,50,51], such as training on the brain cerebrum. Luursema et al [34] focused on the effect of visual ability on anatomical understanding. Ferrandini Price et al [38] trained emergency medicine with a "triage for a mass casualty incident," Rai et al [31] focused on ophthalmoscopy with "binocular indirect ophthalmoscopy," Siff and Mehta [52] evaluated "an interactive holographic curriculum" for gynecology training, and Bing et al [53] looked into cervical cancer surgery in Zambia. In the field of urology, Butt et al [40] conducted catheterization. Digital slides were analyzed in the field of pathology [54]; dental implants in dentistry; [45] and, in the field of geriatrics, Dyer et al [55] concentrated on neurodegenerative diseases.



 Table 2. Characteristics of included studies.

Study characteristics	Studies (N=27), n (%)
Year of publication	
2014-2015	4 (15)
2016-2017	9 (33)
2018-2019	14 (52)
Country classification by income-level	
Low-income country	0 (0)
Middle-income country	2 (7)
High-income country	25 (93)
Country of study	
US	10 (37)
Canada	3 (11)
UK	3 (11)
Australia	2 (7)
Germany	2 (7)
France	1 (4)
Ireland	1 (4)
Spain	1 (4)
Netherlands	1 (4)
China	1 (4)
Taiwan	1 (4)
Zambia	1 (4)
Reported study design	
Quantitative	21 (78)
Qualitative	5 (19)
Mixed methods	1 (4)
Evaluation methods	
Skills tests	18 (67)
Questionnaires	16 (59)
Recordings	6 (22)
Knowledge tests	5 (19)
Surveys	4 (15)
Observation	4 (15)
Self-assessment	3 (11)
Others	5 (19)
Number of evaluation methods used	
One method	16 (59)
Two methods	9 (33)
Three methods	2 (7)
More than three methods	0 (0)
Data analysis conducted in publication	
Inferential statistics	15 (56)
Descriptive statistics	10 (37)

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Study characteristics	Studies (N=27), n (%)
Qualitative analysis	1 (4)
No analysis identified	1 (4)
Self-concluded effectiveness	
Effective	17 (63)
Partly effective	4 (15)
Useful only as additional tool	4 (15)
No proven effectiveness	2 (7)
Study population ^a	
Students	10 (37)
Residents	8 (30)
Physicians/nurses	3 (11)
Mixed training levels	6 (22)
Medical discipline	
Surgery	13 (48)
Anatomy	4 (15)
Gynecology	2 (7)
Emergency medicine	2 (7)
Ophthalmology	2 (7)
Urology	1 (4)
Pathology	1 (4)
Geriatrics	1 (4)
Dentistry	1 (4)
Mode of XR ^b used	
VR ^c	17 (63)
AR^d	7 (26)
MR ^e	2 (7)
Combined information	1 (4)
	1 (4)
Type of head-mounted display ^f (model and type of XR)	0.400
Oculus Rift (Consumer V1/DK2; VR)	8 (30)
HTC Vive (2016; VR)	4 (15)
Samsung Gear VR (not specified; VR)	4 (15)
MS HoloLens (Development Ed; MR)	3 (11)
Eyesi Indirect System Simulator (Version 1.1.3; AR)	2 (7)
Google Glass (Trial Version; AR) No information on brand	2 (7)
	2 (7)
Brother AirScouter (WD-200B)	1 (4)
Daydream View Headset (Not specified; VR)	1 (4)
Epson Moverio (BT-200; AR) Sony HMZ (T1 3D Viewer; VR)	1 (4)
	1 (4)
Type of learning and medical discipline Practical skills	18 (67)

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Study characteristics	Studies (N=27), n (%)
Surgery	11 (41)
Emergency medicine	2 (7)
Ophthalmology	2 (7)
Dentistry	1 (4)
Urology	1 (4)
Gynecology	1 (4)
Theoretical knowledge	7 (26)
Anatomy	4 (15)
Surgery	1 (4)
Pathology	1 (4)
Gynecology	1 (4)
Attitudes	2 (7)
Geriatrics	1 (4)
Surgery	1 (4)
Duration of Intervention	
<1 month	21 (78)
1 month to 6 months	3 (11)
7-12 months	1 (4)
1 year to 2 years	1 (4)
>2 years	1 (4)

^aResidents were medical doctors in specialized training after completing medical school, under supervision of an experienced doctor. Physicians or nurses were professionals with several years of accredited experience in their field. Mixed training levels indicate that participants of two or more distinct educational levels were part of the study, such as residents and students combined.

^bXR: extended reality.

^cVR: virtual reality.

^dAR: augmented reality.

^eMR: mixed reality.

¹Multiple types of head-mounted displays may have been used within a study.

Effectiveness of Knowledge, Skills, and Attitudes

In most of the 27 studies, skills were taught with HMDs in the field of surgery (n=18, 67%). Some studies (n=7, 26%) focused on knowledge transfer, mainly in the field of anatomy, and a few studies (n=2, 7%) trained on perceptions and self-confidence. HMDs varied across studies by brand, model, functionality, and type of XR (see Multimedia Appendix 7 for details on reported effectiveness).

Skills

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Out of the 27 studies, 18 (67%) were identified that focused on skills outcomes [2,30,31,33,35-38,40,41,44-49,53,56].

Surgery (11 Studies)

Barré et al [2] explored a VR-based scenario to train medical professionals on sleeve gastrectomy, which study participants described as "realistic and useful to learn surgery" (device: HTC Vive). Sensors for the VR-based scenario were attached to real-life surgical instruments for navigation in a virtually created operating room. The authors found a reduction in cognitive effort and a decrease in stress during prolonged periods of

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standing during surgical practice [2]. Huang et al [48] focused on "AR simulation of venous catheters" (device: Brother AirScouter), in which AR glasses were used to display instructions on procedural steps of catheter insertion in the form of a digital overlay of information to participants during the medical process. Using AR HMDs was perceived as useful for skills transfer in the operating room [48]. Yoganathan et al [47] found that 360° videos of surgical knot training produced major advantages, as they improved the ability to tie knots during surgery even as stand-alone learning (device: unspecified). Hooper et al [37] taught hip arthroplasty, but the results were unclear as to the impact on medical knowledge (device: Oculus Rift CV1). The authors reported that if the VR training was conducted right before the actual surgery, it may have a positive impact on technical abilities and acknowledged that the impact of VR for surgery would significantly increase in the years to come. Logishetty et al [35] found that the quality of hip surgery performed through AR did not differ from that experienced by in-person training with a physician (device: MS HoloLens). Nonetheless, the authors still perceived AR as a valuable tool for other surgical procedures related to arthroplasty. Peden et

al [33] tested HMDs for the learning of suture skills by medical students, whereby standard face-to-face instruction compared to HMDs showed similar skills outcomes (device: Google Glass). Qin et al [46] compared simulators and a variety of XR devices for peg transfer training (devices: HTC Vive, Samsung Gear). Overall, medical simulation systems contributed to a more immersive and successful training environment for peg transfer [46]. Rochlen et al [49] evaluated the usability and feasibility of AR technology for needle insertion for central venous catheter placement for medical students (device: Google Glass). The authors found that AR technology may constitute an important addition to medical skills training.

Harrington et al [56] discovered that surgeons were more attentive when training in 360° instead of in 2D environments for learning laparoscopic cholecystectomy (device: Samsung Gear VR). The study participants, which were preclinical undergraduate students, found the 360° learning beneficial and entertaining, whereby no significant difference in information retention was found between 360° learning and 2D videos [56]. Huber et al [44] investigated experiences of learning laparoscopic skills (peg transfer, cholecystectomy) with a VR-based HMD (device: HTC Vive) compared to a simulator and found that the use of training with HMD was feasible and that participants were excited about the immersion provided by the HMD. Accuracy scores between the two comparison groups were equal, so the outcome of laparoscopic performance was noninferior [44]. Wu et al [30] tested the feasibility of ultrasound procedures (ultrasound-guided central line procedure) with two groups: one group with the AR-based HMD (device: Google Glass) and the other group using traditional ultrasound [30]. The AR-based HMD projected a digital layer at the corner of the glasses to see whether physicians could increase their focus on the procedure. Overall, the authors found that the Google Glass could be effective in ultrasound training, with the only caveat that study participants needed more time being familiarized with the technology, as well as "more needle redirections, but less head movements" [30].

Emergency Medicine (2 Studies)

Azimi et al [41] evaluated whether nursing students and novice learners could improve the learning of the emergency medical procedure of needle chest decompression virtually using an HMD (device: MS HoloLens) [41]. There were no adverse effects of nurses' emergency training using HMDs, and participants improved in terms of frequency of training and enthusiasm, and recalled and demonstrated proficiency in their training days later [41]. In an emergency scenario with VR HMDs, Ferrandini Price et al [38] tested the stress of study participants of "basic triage in a mass accident event" and found that VR cannot yet replace a clinical simulation. Therefore, they recommended VR as a complementing training method (device: Samsung Gear VR).

Ophthalmology (2 Studies)

Leitritz et al [36] found that inexperienced students practice ophthalmoscopic examination better after HMD training (device: ARO). Rai et al [31] compared AR to face-to-face teaching in the field of ophthalmoscopy and found that AR simulation may be superior for skills learning, especially for novice

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ophthalmology students (device: EyeSI BIO simulator with headpiece).

Dentistry (1 Study)

Lin et al [45] tested an AR-based dental implant placement system (device: Sony HMS-T1) and evaluated the precision of the virtually planned versus the actual prepared implant position. The integration of the AR technology considerably reduced the deviation of placing the implant from planned position, and the accuracy of computer-aided implant surgery increased [45].

Urology (1 Study)

Butt et al [40] reviewed VR systems for "urinary catheterization" and found that undergraduate nursing students were enthusiastic about applying it to practical scenarios (device: Samsung Gear).

Gynecology (1 Study)

Bing et al [53] replicated hysterectomy training (removal of uterus) in a virtual 3D environment for Zambian surgery trainees (device: Oculus Rift). The authors concluded that "affordable VR might have the potential to enhance access to cancer treatment globally" [53].

Knowledge

Out of the 27 studies, 7 (26%) studies evaluated the outcome of knowledge with regard to XR interventions [34,39,43,50-52,54].

Anatomy (4 Studies)

Moro et al [50] evaluated the acquisition of anatomical knowledge (spine anatomy) and compared two different learning modes: desktop-based (device: Oculus Rift) and mobile-based (device: Gear VR). Both groups performed similarly on the knowledge test, although a number of study participants experienced fuzzy vision and malaise using VR. Stepan et al [51] identified neuroanatomical test scores of participants using HMDs (device: Oculus Rift) compared to participants who practiced with conventional anatomy books. The VR-based training led to more engagement, learner motivation, and enjoyment, although there was no difference in exam performance between the two groups. Ekstrand et al [39], evaluated in a randomized controlled study the benefits of VR-based HMD neuroanatomy training and compared it to learning with a paper-based 15-page booklet focusing on anatomy training for medical students. Ekstrand et al [39] mentioned that the HTC Vive in neuroanatomy training can be used as an additional tool to increase knowledge gain but that the VR group did not surpass the control group with respect to learning outcomes. They found similar knowledge test results for VR and learning from books [39]. Luursema et al [34] examined the usability of VR-based HMDs for anatomy learning (cognitive load and problem-solving strategies) for users with respect to stereoptic depth. They concluded that it was not evident whether depth perception advanced or impeded the uptake of anatomical knowledge. The Luursema et al [34] study stated that digital interventions neither enhanced nor impeded knowledge outcomes in anatomy.

Surgery (1 Study)

Bairamian et al [43] compared a 3D-printed model to VR-based HMD angiogram models (device: Google Daydream HMD in connection with a smartphone). The HMD offered better resolution and zoom capabilities for study participants (neurosurgical trainees, neurosurgeons), but the 3D-printed model offered better depth perception and manipulation opportunities. The authors concluded that VR-based HMD angiogram may be a viable alternative to 3D-printed models, with untapped educational potential [43].

Pathology (1 Study)

Farahani et al [54] evaluated the feasibility of using VR-based HMDs for reading digital pathology slides of lymph nodes (device: Oculus Rift). Study participants (pathologists) reported that VR pathology slides were limited in their resolution and that they faced difficulties navigating the VR device. Overall, study participants were able to produce accurate diagnoses, and high diagnoses concordance was reached compared between the VR-based HMD and traditional slide system [54].

Gynecology (1 Study)

Siff and Mehta [52] introduced an interactive holographic training module for teaching urogynecologic surgical anatomy (device: MS HoloLens), which involved holograms of female organs, livestreaming of surgical videos, and 3D-projected organs to enhance structural understanding (ligament suspension, sacrospinous ligament fixation). Siff and Mehta [52] observed that the interactive holographic mode of learning was effective in the acquisition of knowledge for surgical anatomy. Study participants ranked the AR-based training as much better when compared to conventional training [52].

Attitudes

Out of the total 27 studies, 2 (7%) studies [32,55] evaluated the effects of HMD training on specific attitudes of health professionals. Dyer et al [55] investigated whether the understanding of neurodegenerative diseases and their impact on patients could be made more transparent to medical students by training with a VR-based HMD (device: Oculus Rift). The results revealed that the impact of simulation on the attitudes of participants was significant [55]. Pulijala et al [32] focused on the impact of "VR surgery on the self-confidence of surgical residents." They found that the "self-esteem of participants could be increased" [32] when training with the HMD (device: Oculus Rift). This was especially true for participants with little clinical experience. Both interventions were evaluated as effective, since understanding of diseases and self-confidence in surgery increased. The effect on self-confidence was "especially high for inexperienced physicians" [32].

Evaluation Methods

Of the 27 studies, the most common evaluation methods were practical skills tests (n=18, 67%), followed by questionnaires (n=16, 59%), video recordings of procedures (n=6, 22%), knowledge tests (n=5, 19%), surveys (n=4, 15%), observations (n=4, 15%), self-assessments (n=3, 11%), and others (n=5, 19%).

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Practical skills tests comprised in some cases of observing study participants when repeating learned procedures or repeating practical skills. Questionnaires included general questionnaires, questionnaires combined with follow-up assessments, and Likert scales. Generally, authors used multiple questionnaires throughout the interventions. Videos were generally recorded during practice sessions of medical trainings and were later evaluated. Bing et al [53] measured how participants moved during the simulation and how much time was spent to fulfill the task. The surgeons could verify their performance scores that were recorded by the simulator. Knowledge and skills were usually assessed prior to and post intervention. Surveys followed the Validation of Instructional Materials Motivation Survey [57] or the System Usability Survey for the measurement of participant perceptions on usefulness [40]. Participant self-assessment was also evaluated, in which authors asked students to assess their own performance, as self-written evaluation text or self-assessment questionnaire [2,52,53]. Other evaluation methods included using students' drawings of the nerve head to assess diagnostic capabilities [36], saliva samples to elucidate stress levels during training [38], the use of dental computer tomography images to measure the differences between implant locations [45], and examination of the precision of acetabular placement [35].

Discussion

General Aspects

The results showed that HMDs are at least comparable to traditional methods of medical education and beneficial in terms of increasing students' motivation for learning (see Multimedia Appendix 8 for an overview of benefits, shortcomings, and recommendations described within included studies). HMDs allow for repeated use of difficult training scenarios in an immersive and realistic environment, such as emergency procedures or rare complications during surgery. The studies found benefits and shortcomings of HMDs. Studies based their findings on improving and enhancing HMDs.

XR-based HMDs are currently dominantly used in high-income countries; only 2 [46,53] studies were conducted in LMICs. Nevertheless, HMDs may be particularly beneficial in a low-resource context to provide training for direly needed health care workers based on their versatile, mobile, and immersive nature. Bing et al [53] implemented and evaluated HMDs for surgical training in Zambia, which was found to be effective. The adoption of XR-based HMDs in other medical settings may most likely increase in the next years and may foster medical teaching and training especially in settings where there is a need for time-effective and cost-effective education [58]. Particularly, recent developments like the HMD Oculus Quest seem to be particularly promising for LMIC contexts. The potential for XR-based HMDs in other countries and settings, particularly in LMICs, need to be studied further. In addition, long-term effects of using HMDs on learners' knowledge and skills in various medical education settings and the integration into medical curricula needs to be further researched. Further technical advancements are needed, and traditional methods of education are not to be ignored.



In the following sections, the Discussion is structured according to the research questions of this review: What is the effectiveness of using HMDs for medical education, specifically for knowledge and skills, and what are the strengths and weaknesses of HMDs in medical education?

Effectiveness

The studies in this review generally categorized an intervention as effective if the majority of the study population achieved higher scores in tests (pre-posttest, exercises) or participant observations as compared to traditional instructional approaches, such as books and analogue surgery or ultrasound procedures.

Not all studies reported effective outcomes for the use of HMDs in medical education. Some studies described the disadvantages of HMDs, such as motion sickness and nausea, technical problems, and stress. A systematic review underlined that these disadvantages may impede learning and training [9]. It is unclear if symptoms of motion sickness and nausea are related to beginners' attempts to become familiar with the technology or if these persist long-term and may potentially impede learning or education. A study has found that women more often are faced with motion sickness using VR devices and that stabilization of the users' body may alleviate symptoms [59]. In addition, effects may differ as AR devices combine real and virtual environments, which should reduce the experienced adverse health effects in VR applications, such as blurred vision, disorientation, and cybersickness. These adverse effects of individuals using HMDs may vary depending on the device. As, for example, AR devices combine real and virtual environments, they seem to mitigate negative health effects such as blurred vision, disorientation, and cybersickness [7].

It has to be taken into account that technology acceptance for XR-based HMDs may differ between individual learners, as inexperienced users may require more time and effort using HMDs for educational purposes.

In addition, realistic feedback was at times not implemented. For instance, "surgical errors that occurred in virtual training were not followed by complications such as simulated patient bleeding or variations in anatomy" [53]. Contextual factors such as sizes, sounds, and functionalities of instruments of virtual operating rooms need to be extremely precise and realistic. Otherwise, there is the potential of erroneous learning and training [8]. Nevertheless, with the continuous development of technologically sophisticated learning tools, more advancements become available that may supplement XR-based HMDs with audio and visual information [7].

Skills

The progression from knowledge to skills follows four levels of competences as per Miller's Pyramid of Professional Competence [60]. Particularly, the *see one, do one, teach one, and simulate one* concept in line with Miller's Pyramid underlines the potential of XR-based HMDs, which can implement this concept for medical teaching and skills training. Particularly, as students have limited time to learn with cadavers, if at all, they are required to supplement their anatomical knowledge through self-directed study. This material is frequently presented in the form of 2D supplementary resources

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such as lecture slides, textbooks, and flashcards [7]. HMDs, like other disruptive technologies, encourage students to be active and self-directed learners who set their own learning pace through hands-on experiences. Active learning has shown to lead to improved educational outcomes such as increased learning retention [61]. Through the use of XR-based HMDs, learners may gain a more realistic understanding of medical concepts [19]. Learners training with HMDs were shown to improve practical skills, reduce stress, and gain self-confidence for the actual surgery [32,52]. Furthermore, the high level of experience needed in the operating room can be easily and repeatedly gained with XR-based HMDs [8,16]. Our review highlighted possibilities of repeatedly practicing surgical operations such as hysterectomy, laparoscopy, or total hip arthroscopy via HMDs. In this review, HMDs were mostly used in the fields of surgery and anatomy with positive skill outcomes. The main benefits of studies have shown decreased surgical error rates, cost-effectiveness, and improved knowledge. The predominance of surgery and anatomy may be that both have a long-standing history of simulation training beginning in the late 1980s with simple simulation [62]. In ophthalmology, examining the virtual retina and gaze of a virtual patient increases practice time, as normally, practice is with the real pupils of a patient's eye [31,36]. Resultantly, less patients need to participate in training sessions in ophthalmology [36]. A potential application that seems adequate for low-resource contexts could be HMD-based training for cataract surgery, as cataracts are still quite common in these settings [63].

During emergencies, physicians work under increased intensity while simultaneously working at reduced capacity due to increased stress. XR-based training scenarios can be effective in helping clinicians better understand the situations they need to be prepared for [8,64].

Knowledge

Some studies in this review pointed out that 3D models of human bodies significantly improved learning outcomes, with HMDs providing 360° views, as new structures and concepts are processed to enhance overall comprehension [65]. "Threshold concepts" are crucial to understand practical applications, such as with anatomy [65]. Without knowledge of anatomical structures, students will not be able to excel in surgery. The findings in this review suggest that XR-based HMDs set the hurdle lower for "threshold concepts" because students immerse themselves in physical structures, which increases understanding and later information retrieval during actual operations. In addition, using HMDs to view 3D brain structures appears to be more motivating and engaging than traditional methods such as books [8,39,51,66]. The lack of spatial understanding and imagination when reading traditional books might increase this phenomenon [39]. HMDs enable the understanding of complex organ structures [66]. There has been a significant increase in volume of medical information expected of students in modern times, and they are moving into technology-enhanced resources to increase learner engagement and authenticity [11].

Despite higher motivation and enjoyment for learning anatomy with HMDs, there was no significant difference in knowledge

acquisition when compared to learning from textbooks [39,51]. This is similar to other reports [11], and similar to other XR applications, such as for patient treatment where studies that did examine efficacy demonstrated preliminary evidence of similar effectiveness or more effectiveness of XR interventions than their selected conventional therapy [67]. Ultimately, increased motivation to study and understand 3D structural complexities is an important aspect [51].

The duration of the various XR HMD study sessions has yet to be examined in detail in the numerous studies that have been done. Some may find it more pleasant to spend longer or shorter periods training with XR HMDs to gain the greatest possible knowledge [7]. The fact that there is no difference in learning outcomes when using XR-based HMDs is encouraging and validates the possibilities for incorporating these innovative technologies into medical education [11]. Likely, the most effective method to teach anatomy, for example, may be to combine multiple resources in addition to XR-based HMDs like plastic models, dissections, and learning software [7]. Particularly in LMICs, XR-based HMDs may be able to strengthen and scale interactive learning and training in anatomy and other surgical skills.

Attitudes

Attitudes are often neglected in medical education to the detriment of patients [68]. Communication and problem-solving skills as well as empathy are vital for patient care. Studies of this review showed that not only diagnostic and therapeutic skills can be trained, but also attitudes. For example, in the field of geriatrics, XR-based HMD training was shown to foster empathy for older adult patients [55]. The simulation was a scenario in which the user was an older person with an age-related disease such as Alzheimer disease. Being immersed in this surrounding provided a realistic point-of-view into older patients' perceptions. In addition, physicians were successfully trained on communication skills while interacting with patients via VR-based avatars [69]. Through XR-based virtual patients, difficult conversations can be simulated [70]. In this way, communication and other soft skills may be trained more effectively and detailed for handling challenging patient situations. HMDs can be used for both diagnostic and therapeutic training as well as for communication skills and attitudes.

Evaluation Methods

Most included studies evaluated the effectiveness of HMDs (ie, through pre- and postknowledge tests, practical exercises, or self-assessments). The term effectiveness is used in many different contexts with varying definitions [71], consisting of several components: feasibility, cost, safety, and applicability to specific contexts [72]. A successful technological implementation and evaluation considers multiple levels: the individual learner, the learning environment, the context of the learning implementation, the technological environment, and the pedagogics involved in the learning implementation [73]. In studies, the criteria determining the effectiveness or ineffectiveness of an intervention was not based on a unified definition. Whereas some studies provided more information on HMD costs, others focused more on ways that XR-based

HMDs can be used across various medical disciplines. Adhering to a standardized framework for implementation and evaluation of XR-based HMDs is key to generating good and comparable evidence that can guide digital health implementations. To this end, first endeavors seem to be on their way to improve methodological quality. The Virtual Reality Clinical Outcomes Research Experts (VR-CORE) international working group compiled a three-part framework for best practices in developing and testing VR treatments to improve patient outcomes. This framework targets the development of high quality, effective, and safe VR treatments [74]. Similarly, a framework would be needed to guide XR-based interventions for medical education. For the evaluation of XR-based interventions, the World Health Organization guide on monitoring and evaluating digital health interventions may already be used as a guide [58].

Strengths and Limitations

Study quality and bias were evaluated using three assessment tools (MERSQI, NOS-E, ACROBAT-NRSI). Most studies in this systematic review had relatively high quality scores for study design, sampling response rates, and types of data. This might be due to a large number of randomized controlled trials included in this review. This paper followed well-established methods of conducting and reporting systematic reviews [21,22].

The methodology of this review had limitations. Participants were restricted to medical professionals. In addition, solely English publications were included, which could have led to the exclusion of relevant articles in other languages. Only HMDs were included, even though other devices that use XR in medical education exist (eg, magic mirrors, large simulators, or serious games). Hence, the focus of this review was on mobile solutions in the field. Not all gray literature was screened, which could have also led to the exclusion of suitable papers. One further limitation is that we did not consider the costs of developing XR content, which is of particular relevance for XR-based applications in LMICs. Future studies should take into consideration effort and costs of developing XR-based content to provide a better basis for decision-making.

Although various studies have focused on specific countries or continents, this systematic review provided a global perspective. Types of health professionals were not limited to a specific medical discipline. The synthesis of findings has been reported narratively, as we included different study types.

Conclusions and Recommendations

The majority of studies included in this systematic review considered the XR-based intervention as at least noninferior to the traditional teaching methods. Most XR-based HMDs have been reported as an engaging and enjoyable tool for learners to improve their knowledge and skills. We approached this systematic review from a global perspective; however, we only found 1 study from a low-resource context using XR-based HMDs. Probably, this is an indicator that HMDs are not yet widely used in low-resource contexts, although this review shows that HMDs could provide a high quality element for medical education in LMICs. One positive aspect is that decreased access to cadavers cause high costs, which may be reduced by using XR-based HMDs for medical education [51].

Furthermore, HMDs offer the possibility of scalability and repeated practice, such as for anatomy, without adverse effects on the patient in various medical disciplines, especially in the field of surgery. The use of this technology may support the understanding of complex 3D structures, and the technology is a general training tool to prepare for the increase of technologies in the medical workspace. In addition, other disciplines such as pathology, ophthalmology, emergency medicine, gynecology, and dentistry reported effective outcomes with XR-based HMDs. XR-based HMDs can be seen as a valuable resource that has potential to strengthen medical education.

However, the deployment of HMDs in the medical setting requires further evaluation and technical advancement, for example, for HMD-based training tools. XR-based technology is still a rather novel technology, slowly unfolding its usefulness for medical education. Surgery and anatomy are quite prominent in HMD use, but it is unclear whether and how other medical disciplines may benefit, such as pediatrics. Currently, a framework or guideline for XR-based HMD interventions is lacking to guide implementations and evaluations, although initiatives like the VR-CORE international working group are working to close this gap. Further research is also needed for other requirements like financial aspects, implementation and training, technical feasibility, and reliability. Overall, based on the results of this review, XR-based HMDs seem to be a valuable component for medical education and can be recommended as an additional tool for teaching and learning particularly complex spatial structures. Based on our experience in low-income contexts, we also identified potential for the application of XR-based HMDs for medical education in LMICs, although more use cases and more research is needed.

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Authors' Contributions

SB contributed toward the systematic review screening, conceptualization, and writing of the original draft and draft revision. LL contributed toward the systematic review screening and data synthesizing. TB and FN contributed toward the writing of the draft revision. CB contributed toward the writing of the original draft and visualization.

Conflicts of Interest

None declared.

Multimedia Appendix 1

PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 Checklist. [DOCX File, 32 KB - games_v9i3e29080_app1.docx]

Multimedia Appendix 2 Search strings. [XLSX File (Microsoft Excel File), 12 KB - games_v9i3e29080_app2.xlsx]

Multimedia Appendix 3 Data extraction. [DOCX File , 65 KB - games v9i3e29080 app3.docx]

Multimedia Appendix 4 Quality assessment. [DOCX File , 80 KB - games v9i3e29080 app4.docx]

Multimedia Appendix 5 Three levels of knowledge. [DOCX File , 60 KB - games v9i3e29080 app5.docx]

Multimedia Appendix 6 Details of number and type of study participants. [DOCX File , 16 KB - games v9i3e29080 app6.docx]

Multimedia Appendix 7 Reported effectiveness. [DOCX File , 19 KB - games v9i3e29080 app7.docx]

Multimedia Appendix 8

Benefits, shortcomings, and recommendations described within included studies. [DOCX File , 14 KB - games_v9i3e29080_app8.docx]

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Abbreviations

ACROBAT-NRSI: A Cochrane Risk of Bias Assessment Tool for Non-Randomized Studies AR: augmented reality HMD: head-mounted device LMIC: low- and middle-income country MERSQI: Medical Education Research Study Quality Instrument MR: mixed reality NOS-E: Newcastle-Ottawa Scale-Education PICOS: population, intervention, comparison, outcome, study design PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analysis SDG: Sustainable Development Goal SWIM: Synthesis Without Meta-analysis VR: virtual reality VR-CORE: Virtual Reality Clinical Outcomes Research Experts XR: extended reality

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Original Paper

Use of a Virtual Reality Simulator for Tendon Repair Training: Randomized Controlled Trial

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Abstract

Background: Virtual reality (VR) simulators have become widespread tools for training medical students and residents in medical schools. Students using VR simulators are provided with a 3D human model to observe the details by using multiple senses and they can participate in an environment that is similar to reality.

Objective: The aim of this study was to promote a new approach consisting of a shared and independent study platform for medical orthopedic students, to compare traditional tendon repair training with VR simulation of tendon repair, and to evaluate future applications of VR simulation in the academic medical field.

Methods: In this study, 121 participants were randomly allocated to VR or control groups. The participants in the VR group studied the tendon repair technique via the VR simulator, while the control group followed traditional tendon repair teaching methods. The final assessment for the medical students involved performing tendon repair with the "Kessler tendon repair with 2 interrupted tendon repair knots" (KS) method and the "Bunnell tendon repair with figure 8 tendon repair" (BS) method on a synthetic model. The operative performance was evaluated using the global rating scale.

Results: Of the 121 participants, 117 participants finished the assessment and 4 participants were lost to follow-up. The overall performance (a total score of 35) of the VR group using the KS method and the BS method was significantly higher (P<.001) than that of the control group. Thus, participants who received VR simulator training had a significantly higher score on the global rating scale than those who received traditional tendon repair training (P<.001).

Conclusions: Our study shows that compared with the traditional tendon repair method, the VR simulator for learning tendon suturing resulted in a significant improvement of the medical students in the time in motion, flow of operation, and knowledge of the procedure. Therefore, VR simulator development in the future would most likely be beneficial for medical education and clinical practice.

Trial Registration: Chinese Clinical Trial Registry ChiCTR2100046648; http://www.chictr.org.cn/hvshowproject.aspx?id=90180

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KEYWORDS

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virtual reality simulators; tendon suture; medical education

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Introduction

The incidence of tendon rupture has been increasing owing to the increasing number of people participating in recreational and competitive sports [1]. Various factors such as the intensity of exercise, overuse, genetic predisposition, and aging can cause tendon rupture [2-4]. Ruptured tendons can have delayed recovery and a high frequency of recurrence [5,6]. Tendon repair is one of the most commonly used techniques in the orthopedics field [7]. Accuracy and proficiency in the suture technique is a fundamental surgical skill that will directly influence the result of the performed operation [8]. Medical students should master both basic and practical suturing concepts to perform an outstanding operation [9]. The standardized goal for flexor tendon repair is to obtain sufficient tensile strength and to facilitate a better recovery [10]. In addition, the repair will allow early mobilization, prevent adhesion formation [11], stimulate tendon healing [12], and improve clinical outcomes. Therefore, tendon repair is an essential skill in the orthopedics field [13,14]. Tendon repair and suture techniques are part of the orthopedic course during clinical training. In traditional training, students only have limited time to practice owing to cost limitations [15,16]. During clinical practice, a real patient is involved at every step in the process. Because of the lack of practical training, medical students need to be guided through a long learning curve to become independent in clinical practice [17].

In recent years, the use of virtual reality (VR) simulators has become widespread in medical school, and VR simulators are promoted for both medical students and resident training [18]. VR simulators for orthopedics provide a holistic learning application, which produces a close-up surgical training experience. Students are provided with a 3D human model to directly observe human details from the point of view of multiple senses, including vision and hearing, and they can participate in an environment relatively close to reality. The use of virtual practical teaching content expands and enriches teaching quality and content [19]. In addition, the use of a VR simulator is a skill that requires time and practice to master. Skills involved in using a simulator include adjusting the master controls, endo wrists, camera navigation, and the requirement for students to picture the VR simulator environment in reality [20]. Recent studies have applied VR simulators in surgical training [21-23], but the aim of this study was to promote a new approach consisting of a shared and independent study platform for medical student education. This study compared traditional tendon repair training with VR simulation of tendon repair and evaluated future applications of VR simulation in the academic medical field.

Methods

Study Design

This study is a parallel-design randomized controlled trial comparing VR and control groups. This study was approved by

the ethics committee of the First Affiliated Hospital of Jinan University and registered in the Chinese Clinical Trial Registry (Registry: ChiCTR2100046648). Information was collected from all participants after obtaining written informed consent in accordance with the Declaration of Helsinki. All participants were required to complete the final assessment, which was performing tendon repair on synthetic models with 2 different knots, that is, the "Kessler tendon repair with 2 interrupted tendon repair knots" and the "Bunnell tendon repair with figure 8 tendon repair" (KS and BS methods, respectively). The CONSORT checklist was used for this trial.

Participants

Senior medical students were the eligible participants in this study. They were required to complete the following fundamental courses before entering the randomized control trial: (1) human anatomy, (2) physiology, (3) biochemistry, (4) pathology, (5) pathophysiology, (6) diagnostics, (7) internal medicine, (8) orthopedics, (9) surgical probation, and (10) other professional basic clinical courses. This study excluded any participant who did not meet the above requirements. Written informed consent with a clearly stated study plan was given to all participants. The purpose of this trial was explained to the participants. After informed consent had been signed, we asked the medical students to perform tendon repair on synthetic simulations. A baseline score was given by an orthopedic specialist. Other baseline information, including gender, age, and grade point average, was collected from the medical school database.

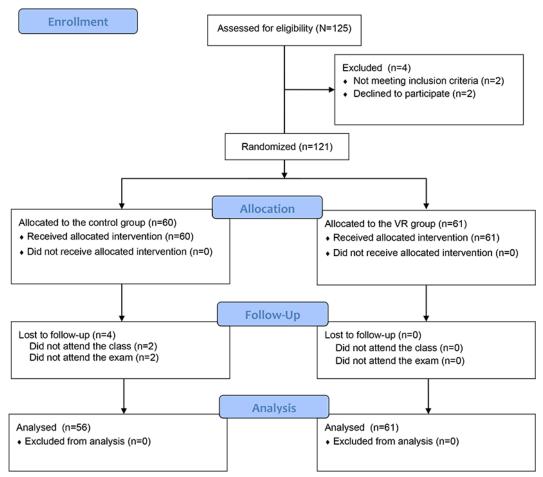
Allocation

All participants provided written, informed, and oral independently witnessed consent to participate in the research study. A random allocation sequence was generated using a random number table. A sequence was used to allocate the groups of participants to the VR and control groups. For the examination, the students performed tendon repair on a synthetic model. All participants were randomly assigned to one of the two groups. Participants in the VR group (n=61) learned the technique of tendon repair through the VR simulator method, whereas the control group (n=60) used the traditional tendon repair teaching method. The examiners were well-trained surgeons and unaffiliated with the medical school; they evaluated and assigned a score to each final product immediately without knowing the allocation list in a nonbiased manner during preintervention and postintervention assessments. In order to ensure the rigor of the examination, we included a short training session for the examiners. Training helps to clarify the examiner's role, required behavior, review the marking guidance, marking assignment to standardize the exam, and encourage the consistency of the examiner's marking behavior. At the end of the training, examiners also did a marking exercise to scrutinize examiners' marking behavior. During the examination, medical students were asked not to tell the examiner which group they were assigned to (Figure 1).



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Figure 1. CONSORT 2010 flow diagram showing the study process. VR: virtual reality.



Interventions

The control group participants were required to participate in complete 8 hours of lectures and a 6-hour practical class in medical school for 2 weeks. The participants learned about traumatic orthopedic theory and the fundamentals of tendon repair during the lectures. They practiced tendon repair on synthetic models under the professor's guidance. In the practice class, students were given a PowerPoint presentation, which illustrations, photographs, and provided step-by-step instructions. They were instructed to review the training material for 1 hour. The VR group participants were required to take the same course as the control group, except for the guided PowerPoint review part. Instead, they practiced with VR simulators (including the VR version and the personal computer [PC] version) for 1 hour in class. The medical students practiced

under guidance with detailed instructions. The VR simulator focusses on every participant's performance while performing tendon repair. The operation in the VR simulator is divided into practice and examination modes. Corresponding notes for each step during the practice mode were provided; however, no notes were provided for the examination mode (Multimedia Appendix 1). The students were required to finish all the required learning in the practice mode before entering the examination mode for assessment. For the VR training section, while half of the students were practicing on the VR simulator, the rest of the students were practicing on the PC version in the training center. These students shifted the training modes after 30 minutes of VR training (see Table 1). All trainings were performed within the classes, and both groups had exactly the same opportunity for practice time.

Table 1. Illustration of the trainings undertaken by each group.

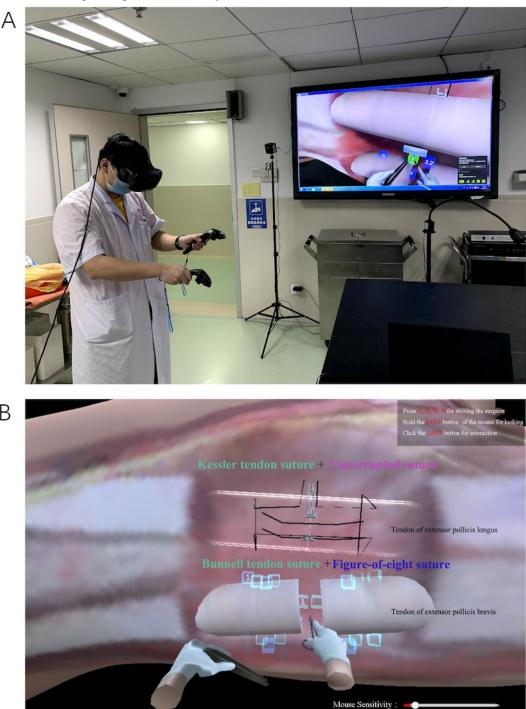
Trainings	Virtual reality group	Control group
Lectures (total 8 h)	✓	✓
Practical class (total 6 h)	\checkmark	\checkmark
Guided PowerPoint Review (within the practical class)		\checkmark
Virtual reality + personal computer practice (within the practical class)	✓	
Virtual reality + personal computer assessment (within the practical class)	1	

The VR Platform

The VR simulator used in this study was created by Jinan University and the Department of Orthopedic Surgery and Sports Medicine Center [24]. All VR simulators were classified as HTC Vive VR [25], and the software was SteamVR (JinKe Lu) [26]. The VR simulator method used in this study included an independent study section in which each participant was required to study all the theories on the VR simulator website. This website is open to the public after registration on the website. Two versions are available (ie, PC and VR simulator versions). Students were able to learn the method of tendon repair by controlling the keyboard and mouse in the PC version. Although the PC version is on a computer, a 360° scenario to enhance the study environment is still included. The VR simulator version requires the student to have the HTC Vive VR controller to practice repairing a tendon. Both versions were open to students for practice according to their needs. In addition, the practical study section of tendon repair is performed using the VR simulator with individual steps for each procedure (comprising 7 steps in total). The website provides a section in which students and teachers can communicate and share ideas with each other. This program allows the students to learn in-depth while enhancing their learning through the communication section of the VR simulator. This web-based discussion can overcome the barriers of time and distance. In addition, we measured the effectiveness of this platform, including the PC and VR versions. Because the whole training package was considered, the VR group students were divided into VR and PC groups (Figure 2).



Figure 2. (A) A medical student practicing with a virtual reality simulator; (B) the examination mode for the Kessler and Bunnell tendon suture modes.



Performance and Assessment

В

Both the control and VR groups participated in the research study for 14 days. The results were calculated using the global rating scale. Seven dimensions were incorporated into the tool. The global rating scale shows different aspects of the operative performance. This technology was compared with the traditional teaching method by using the global rating scale for several aspects: (1) repair with respect to tissue, (2) time in motion, (3) instrument handling, (4) tendon repair skill, (5) flow of operation, (6) knowledge of procedure and final suture, and (7) qualitative and objective assessment of all tendon repair performances [27,28]. Each column was scored on a 5-point

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XSL•F RenderX scale. Explicit descriptors were designed to guide the examiner when evaluating the students' performance. Each item was scored from 1 (poor performance) to 5 (good performance). Higher scores on the 35-point global rating scale in the final assessment indicated that the participants using the specific method had better performance with respect to the tendon suturing technique [27]. The global rating scale is widely used in the evaluation of surgical behavior, including objective and subjective criteria [29]. It has been used for various types of surgical evaluations such as arthroscopic surgery [30], endoscopic surgery [31], pediatric surgery [32], and orthopedic surgery [33]. Additionally, it has been validated for use with

VR systems because it measures nontechnical cognitive skills such as decision making and judgment [34].

Statistical Analysis

Data were analyzed using the SPSS 23.0 (IBM Corp) software package [35]. The baseline information, including age and grade point average, was analyzed using the independent two-tailed *t* test for parametric data [36]. Differences in the objective and semiobjective measurements between the 2 groups were analyzed using the Mann-Whitney *U* test for nonparametric data [37]. The level of agreement between the semiobjective assessments made by the 2 experts was estimated by the Cohen *k* coefficient. *P* values less than .05 were considered significant [38].

Results

Between August 1, 2019, and August 12, 2020, 121 potential participants were assessed for study participation in the Medical School of Jinan University. Four participants from the control group dropped out of the program for personal reasons. All participants were required to undergo a final assessment on synthetic models, and the overall score sheet was used to calculate the results. This study analyzed all participants by using the global rating scale described above. The global rating scale baseline is shown for assessing tendon repair differences in the control and VR groups (Table 2). A comparison of the participants in both groups according to age, gender, grade point average, and pretest evaluation revealed no educationally

 Table 2. Baseline characteristics.

relevant or significant differences. The follow-up ended on September 30, 2020.

Posttraining scores on the global rating scale were used to assess tendon repair by the two groups. Table 3 shows a comparison of the global rating scale scores between the KS and BS methods.

With respect to tissue, no significant difference was found between the VR and control groups using the KS method (P=.22) and the BS method (P=.21). Participants in the VR group showed higher scores than the control group for time in motion (P < .001) for the KS method and the BS method, thereby indicating that the VR group produced better results for time in motion. Regarding instrument handling, no significant difference was found between the VR and control groups for either the KS or the BS method (KS and BS methods P=.31 and .16, respectively). With respect to suture skill, the VR group performed better than the control group by using the BS method than the KS method (P<.001). In the flow of operation, the VR group performed better than the control group with the KS and BS methods (P<.001). With respect to procedure knowledge, the VR group performed better than the control group when performing the KS method (P<.001) and the BS method (P < .001). The KS method (P = .048) and the BS method (P < .001)yielded significant results in the final product. Thus, the overall performance of the VR group was significantly better (P<.001) than that of the control group with both KS and BS methods (*P*<.001).

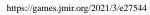
Characteristics	Control group (n=56)	Virtual reality group (n=61)	P value
Age (years), mean (SD)	23.07 (0.97)	22.93 (1.01)	.46
Gender (male), n (%)	24 (43)	31 (51)	.39
Grade point average, mean (SD)	3.02 (0.54)	3.19 (0.49)	.66
Kessler tendon repair with 2 interrupted tendon repair knots, median (IQR)	8.00 (7-9)	8.00 (7-9)	.13
Bunnell tendon repair with figure 8 tendon repair, median (IQR)	8.00 (7-9)	8.00 (7-9)	.25



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Table 3. Posttraining scores on the global rating scale to assess tendon repair.^a

epair method, aspects considered, global rating scale score (1: poor, 5: pod)	Control group (n=56)	Virtual reality group (n=61)	P value
essler tendon repair with 2 interrupted tendon repair knots		_	
With respect to tissue, n (%)			.22
1	0 (0)	8 (13)	
2	3 (5)	41 (67)	
3	52 (93)	10 (16)	
4	1 (2)	2 (3)	
5	0 (0)	0 (0)	
Time in motion, n (%)			<.001
1	2 (4)	0 (0)	
2	14 (25)	0 (0)	
3	23 (41)	20 (33)	
4	17 (30)	40 (66)	
5	0 (0)	1 (2)	
Instrument handling, n (%)			.31
1	0 (0)	0 (0)	
2	8 (14)	13 (21)	
3	42 (75)	43 (71)	
4	6 (11)	5 (8)	
5	0 (0)	0 (0)	
Suture skill, n (%)			.05
1	0 (0)	0 (0)	
2	11 (20)	6 (10)	
3	36 (64)	38 (62)	
4	9 (16)	14 (23)	
5	0 (0)	3 (5)	
Flow of operation, n (%)			<.001
1	0 (0)	0 (0)	
2	19 (34)	0 (0)	
3	33 (59)	11 (18)	
4	4 (7)	49 (80)	
5	0 (0)	1 (2)	
Knowledge of procedure, n (%)			<.001
1	0 (0)	0 (0)	
2	15 (27)	1 (2)	
3	41 (73)	1 (2)	
4	0 (0)	42 (69)	
5	0 (0)	17 (28)	
Final product, n (%)			.048
1	0 (0)	0 (0)	
2	3 (5)	12 (20)	
3	49 (88)	24 (39)	



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tepair method, aspects considered, global rating scale score (1: poor, 5: ood)	Control group (n=56)	Virtual reality group (n=61)	P value
4	3 (5)	22 (36)	
5	1 (2)	3 (5)	
Overall performance, median (range)	20 (18-22)	24 (21-29)	<.001
unnell tendon repair with figure 8 tendon repair			
With respect to tissue, n (%)			.21
1	0 (0)	0 (0)	
2	15 (27)	23 (38)	
3	41 (73)	38 (62)	
4	0 (0)	0 (0)	
5	0 (0)	0 (0)	
Time in motion, n (%)			<.001
1	0 (0)	0 (0)	
2	15 (27)	5 (8)	
3	41 (73)	32 (53)	
4	0 (0)	23 (74)	
5	0 (0)	1 (2)	
Instrument handling, n (%)			.16
1	0 (0)	0 (0)	
2	8 (14)	15 (25)	
3	32 (57)	33 (54)	
4	16 (29)	13(21)	
5	0 (0)	0 (0)	
Suture skill, n (%)			<.001
1	0 (0)	0 (0)	
2	17 (30)	10 (16)	
3	39 (70)	30 (49)	
4	0 (0)	21 (34)	
5	0 (0)	0 (0)	
Flow of operation, n (%)			<.001
1	0 (0)	0 (0)	
2	27 (48)	1 (2)	
3	25 (45)	26 (43)	
4	0 (0)	28 (46)	
5	4 (7)	6 (10)	
Knowledge of procedure, n (%)			<.001
1	0 (0)	0 (0)	
2	21 (38)	2 (3)	
3	21 (38)	11 (18)	
4	14 (25)	47 (77)	
5	0 (0)	1 (2)	
Final product, n (%)			<.001
1	0 (0)	0 (0)	

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Repair method, aspects considered, global rating scale score (1: poor, 5: good)	Control group (n=56)	Virtual reality group (n=61)	P value
2	8 (14)	11 (18)	
3	41 (73)	31 (51)	
4	1 (2)	9 (15)	
5	6 (11)	10 (16)	
Overall performance, median (range)	20.00 (16-23)	23.00 (20-26)	<.001

^aData in italics indicate significant differences. Both the methods were assessed using the 35-point global rating scale.

Discussion

Principal Results

Several surgical trainings involve composite models, VR simulation, cognitive task analysis, and cadaver specimens. VR-simulated studies for surgical practice, such as laparoscopic, cardiovascular, and arthroscopic surgeries, can be found in the literature [39-41]. In the field of orthopedics, researchers mainly focus on sophisticated surgical procedures, for example, (thoracic) pedicle screw placement and insertion (lateral mass screw placement) [42-44], (percutaneous) vertebroplasty [45], knee arthroscopy [38], and hip arthroplasty [46]. These procedures are performed by surgeons who are specialized in orthopedics. In medical schools, for every general practice physician, standard tendon repair is of prime importance in fundamental surgical skills. Thus, it is necessary to develop tendon repair training [47]. To our knowledge, this is the first study to adopt VR simulation for tendon repair training. Adopting VR simulation in regular curricula is challenging owing to the limited efficacy of VR as a learning tool [48]. To clarify the effectiveness, we demonstrated that the VR simulator was an effective tool in the acquisition of tendon repair in our blinded randomized trial. Modern VR simulations have a common disadvantage, that is, high cost. Clarke [48] reported that individual simulators cost up to 6-figure sums. Our platform removed the cost for the students and was open to the public to maximize cost-effectiveness. To consider whether the VR simulator is an educational tool, the results have to be statistically significant with positive feedback. If the surgical performance of the VR group participants did not improve, the VR simulator was not considered as part of the regular training.

A VR simulator plays a major role in the medical field. The lack of medical practice and uneven distribution of medical resources in various regions has resulted in a decrease in clinical practice opportunities for medical students. In addition to tendon repair studies, the VR simulator can perform simulated surgery. Future surgeons can practice with a VR simulator until they are comfortable performing the operation. In addition, experienced surgeons can also study the simulation aspect of the VR simulator to learn and explore new surgical techniques or to discover other surgical options. The application of virtual technology in medicine, medical education, and clinical treatment will have a major impact on the medical system.

During the COVID-19 pandemic, the use of technology has become a popular topic in the medical education field. Tendon repair is a procedure that requires senior professional surgeons;

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therefore, medical students and junior doctors may not have sufficient practice to be able to perform suturing independently. A possible solution to this problem is that junior doctors practice using the VR simulator, thereby becoming more familiar with the procedure and more confident when performing it. The VR simulator can maximize a medical student's efficiency with respect to mastering this technique. It has been proven that the VR simulator in a simulation laboratory rather than in an operating room is a better practice method than the traditional classroom study in terms of the flexibility of location [20]. Medical students or residents can perform tendon repair via the VR simulator before performing a formal operation. Using the VR simulator serves the purpose of shortening the operating time, reducing operation errors, and alleviating patients' postprocedural pain [49]. However, the expense of textbooks or teaching assistance when using the traditional method has no significant comparison with the investment in equipment for VR simulators.

The VR simulator can provide a realistic surgical scenario, thus allowing students to train for a particular skill continuously or to master any unfamiliar procedure. The findings of our study show that students learning via the VR simulator had significantly better scores than those learning via the traditional method with respect to the tendon repair technique (P < .001). This finding may indicate that students using a VR simulator will be able to follow the whole operation more carefully and master the knowledge of the procedure in the future. While we were developing the VR simulator, we tried to mimic reality based on mathematical models by simulating a surgical setting, instruments, training objects, and interactions. We aimed to create an ideal simulator that is realistic in multiple dimensions such as simulation physics, optical properties, and haptic feedback [50]. The system allows students to apply their knowledge and practical skills in a realistic and tactile environment. Another advantage of the VR simulator method is that students can independently perform the surgery, hence increasing the student's ability to master the technique fully. A VR simulator allows a student to practice at his/her convenience with multiple repetitions, regardless of the availability of cadavers or human trials [51]. Using the VR simulator, the student can maximize his/her surgical efficiency at his/her own learning time even after the scheduled class, which will serve to increase the study's performance and study result.

A VR simulator can reduce the high costs of conducting animal or human trials [52]. More realistic training usually involves training on animals, but this method is expensive and not available in many medical schools. A VR simulator would

provide many benefits in this situation. VR simulators allow students to repeat the exercise several times-an action that can ensure that students are totally familiar with all important concepts before surgery. In addition, students are able to familiarize themselves with the technique before surgery, which also guarantees safety for the patient. Studies show that surgeons using VR and other simulation methods for practicing surgical techniques can reduce operative time or possible errors, thereby increasing their confidence and decreasing uncertainty in the procedure outcomes [53]. In addition, most surveyed residents and directors believe that a surgical simulation is a useful tool for complementing traditional forms of training on animals, cadavers, or synthetic models [51]. Although the texture of operation cannot be simulated exactly on a VR simulator, using animals, cadavers, or synthetic models with a VR simulator could also allow students to practice their techniques with more understanding, hence reducing the cost and availability issue of animals, cadavers, and synthetic models.

Surgical training is different from other courses in medical school because students need to be exposed to nonstandard or beyond standard levels of teaching to help them understand how much they need to learn or improve. Studying with different methods can help students have a clear understanding of this curriculum. Surgical education departments have already purchased some effective training equipment that can help medical students achieve consistent and measurably high level of performance. Therefore, combining traditional and alternative teaching methods such as composite models and cognitive task analysis is necessary for the future [54]. Al-Nammari et al [55] found that the average duration of orthopedic education in medical schools in the United Kingdom was approximately 2.65 weeks; however, medical schools may not provide their students with enough scheduled course time to master musculoskeletal medicine. One of the solutions to this problem is that students combine VR simulation with traditional methods, which will save time and maximize students' efforts in musculoskeletal medicine if the student is interested in this field. This study also shows that students with interest in orthopedics had a statistically better understanding of musculoskeletal medicine than their counterparts. In a broader view, more elite students entering the field of musculoskeletal medicine will increase the possibility of new discoveries in musculoskeletal medicine.

VR simulators have good reusability. Once a VR simulator is established, the study will not be limited to that particular location or the number of students. The VR software can be freely downloaded by students from the internet. Therefore, medical students can study in any location and are not limited to the classroom or training room. Rather than taking turns practicing on subjects, students are able to practice together using the VR simulator. The 3 important advantages of students using VR simulators concurrently are as follows: (1) VR simulators allow students to perform the experiment together, (2) VR simulators allow the exchange of ideas or knowledge of a topic at the same level, and (3) VR simulators ensure that everyone is on schedule for the course.

VR simulators will be part of the future technology in the medical field, and medical students should be exposed to this technology as soon as possible to familiarize themselves with

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this method. In addition, feedback from students using a VR simulator can help improve the simulator, and further developments may be performed. The application of virtual technology in the field of medicine, medical education, and clinical treatment will have a major impact on health care and the development of the medical field and on the training of young doctors. Both software and hardware in the VR simulator can be flexibly configured according to the needs of teaching. In addition to tendon repair, VR simulators provide a set of virtual instruments that can be developed into different functions. The scope of virtual orthopedics is very wide and includes the fields of endoscopic protection, radiosurgery, microsurgery, and remote surgery. Moreover, a VR simulator is currently used in neurosurgery, eye, heart, plastic, and abdominal surgeries, and many other areas. Therefore, the widespread use of a VR simulator indicates that studying or performing surgery via a VR simulator is an effective method for completing this training task.

This study is the first to show that a VR simulator can also be applicable in medical schools and that it is a very effective method for medical students to enhance their learning through multiple repetitions by participating in a 360° VR environment. In addition, a VR simulator should be used in sections not only for complex surgeries but also in important presurgical sections, for example, tendon suturing. Studies have shown that medical students enjoy early exposure to clinical practice and perceive that it is valuable for future studies [56,57]. As mentioned earlier, multiple medical professions have attempted to utilize VR simulators for their medical training. However, most professions cannot overcome a critical issue-the high cost. This high cost also results in only using the compatible device of the VR simulator to minimize costs. The VR simulator program was uploaded on the internet, and all medical students could choose the versions according to their own needs and the available equipment. The PC version can be downloaded on the internet at no cost. This inexpensive, remote, detailed, sustainable, and effective platform should be used in medical schools for all medical students. A successful education system should be accessible to all students [58]. This VR simulator with high accessibility allows different students to have multiple practice opportunities and to participate in in-depth discussions in the specific communication section. Designing this program was costly; however, with more students using this program, the cost-effectiveness of this system can maximized.

Despite the benefits of using VR simulators to train medical students, there are some challenges for medical schools to adopt this new approach in the future. For designing the program, the development corporation or the program writers who are not medical professionals have limited concepts or knowledge of the orthopedic procedure. This may lead to simulation results of nondetailed procedures, and medical students may miss the surgical details when practicing surgery in VR simulators. To overcome this obstacle, we had extensive discussions and we shared opinions back and forth between the medical school and the development team during the early period of establishing the VR simulator. It took at least a year to achieve an acceptable VR simulator for medical students. The other problem of VR simulators is the lack of validated score measures. Therefore,

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the final assessment was evaluated on synthetic models by using the global rating scale. Surgical training is a comprehensive process; therefore, medical students and surgeons may take years to master a surgical technique. The VR simulator is part of the comprehensive training but not the only training technique. Our findings show that the VR simulator is an effective method among the traditional teaching methods. We hope that future studies can focus on an effective VR simulator measurement scale or comparative evaluations between simulators.

Limitations

The follow-up period in this study can only reflect the short-term effect of the VR simulator, which was a limitation of this study. The long-term effects on orthopedic specialists who practice on VR simulators could take years to evaluate.

Conclusion

Compared to the traditional tendon repair method, the VR simulator for learning tendon repair significantly improves medical students' time in motion, suture skill, the flow of operation, and knowledge of the surgical procedure. Our paper sets an example for future VR simulator development for medical curricula.

Authors' Contributions

TNM, JP, and WKM designed the study and wrote the manuscript. WKM and QH reviewed the risk of bias of the studies and the manuscript. JC and JL extracted the data from the studies. THS and JD interpreted the results. JL and ZZ supervised the entire study. The authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1 Virtual reality simulator showing every step of the suturing process. [DOCX File , 16 KB - games v9i3e27544 app1.docx]

Multimedia Appendix 2 CONSORT-eHEALTH checklist (V 1.6.1). [PDF File (Adobe PDF File), 1295 KB - games_v9i3e27544_app2.pdf]

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Abbreviations

BS: Bunnell tendon repair with figure 8 tendon repairKS: Kessler tendon repair with 2 interrupted tendon repair knotsPC: personal computerVR: virtual reality

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Original Paper

Medical Students' Perceptions of Play and Learning: Qualitative Study With Focus Groups and Thematic Analysis

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Abstract

Background: In times where distance learning is becoming the norm, game-based learning (GBL) is increasingly applied to health profession education. Yet, decisions for if, when, how, and for whom GBL should be designed cannot be made on a solid empirical basis. Though the act of play seems to be intertwined with GBL, it is generally ignored in the current scientific literature.

Objective: The objective of our study was to explore students' perceptions of play in leisure time and of GBL as part of a mechanistic, bottom-up approach towards evidence-informed design and implementation of GBL in health profession education.

Methods: We conducted 6 focus group discussions with medical and dentistry students, which were analyzed using thematic analysis.

Results: A total of 58 students participated. We identified 4 major themes based on the students' perception of play in leisure time and on the combination of play and learning. Our results indicate that, while play preferences were highly various in our health profession student cohort, pleasure was the common ground reported for playing. Crucially, play and the serious act of learning seemed paradoxical, indicating that the value and meaning of play are strongly context-dependent for students.

Conclusions: Four key points can be constructed from our study. First, students play for pleasure. Perceptions of pleasure vary considerably among students. Second, students consider play as inefficient. Inefficiency will only be justified when it increases learning. Third, play should be balanced with the serious and only be used for difficult or tedious courses. Fourth, GBL activities should not be made compulsory for students. We provide practical implications and directions for future research.

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KEYWORDS

gamification; serious games; game-based learning; medical education; computers; new technology; focus group; play; qualitative

Introduction

In times where distance learning is becoming the norm, game-based learning (GBL) is increasingly applied to health profession education [1,2]. Yet, recent reviews in this field indicate that GBL research is still in its infancy and that robust study designs based on sound theoretical foundations or supporting scientific evidence are scarce [3-5]. Although certain

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trends in GBL use can be observed, there seems to be little theoretical support to clarify the effects of GBL on academic learning [4]. Most studies report on the use of GBL applications that are tailored to specific local settings [4]. Therefore, decisions about implementing game-like interventions — if, when, how, and for whom — cannot be made on a solid empirical basis. This increases the likelihood of suboptimal and even counterproductive educational design. In this study, we took a user-driven approach in an attempt to unravel key

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processes that could explain why and how GBL does or does not work in health profession education, therewith advancing the science and practice in this field.

GBL has been applied based on the idea that play and learning are closely intertwined [6,7]. Intriguingly, studies investigating GBL in academic settings do not seem to explicitly scrutinize, measure, or mention play [3-5,8,9]. GBL studies mainly focus on outcome measures such as learning outcome, motivation, and likability of GBL [4] but seem to dismiss play itself. This situation seems to persist despite significant scientific interest in the fundamentals of play-learning interaction [10-13]. Generally, empirical evidence supports claims that play positively influences the learning of problem solving [14-16], creativity [17,18], and self-regulatory skills [19]. Most knowledge on this play-learning interaction stems from early experimental animal research [20,21] or research on developmental psychology in children (eg, [14,22]). By comparison, play in the realm of adult learning has received very little attention, especially with regard to GBL.

The studies that came closest to research on play-learning interactions in educational contexts for adult learning were quantitative in nature and primarily used questionnaires aimed at examining experiences with already existing games or to inform the design of a specific game [23-27]. However, these studies did not investigate how play can be elicited in students or, more specifically, which type of play can benefit or support student learning, in which situations, or under which conditions. Furthermore, because of the specific study set-up or study intent, participants in such studies may have directed their answers to a specific game or game design, which does not allow for generalization of the results to other contexts or game designs. Next to quantitative studies, qualitative approaches have been employed in order to describe adult playfulness [28] or inform game design [29-33]. Findings of these studies gave insight into self-perceived reasons for adult engagement in play such as stress relief, challenge, and friendship. However, whether these needs for play in adults can also be met in combination with learning was not explored in these studies. Thus, the links between play, academic learning, and GBL remain a blind spot in the literature.

Provided that there are meaningful play-learning interactions in GBL, even when the nature of that interaction is unknown, we need to understand how to elicit play in students. But what exactly is play, how do we define play, and how do we relate play to GBL? There is no univocal answer to any of these questions, since there is considerable disagreement in the scientific literature as to what constitutes play and games [13,34]. Interestingly, and perhaps as a logical consequence of this disagreement, there is strong consensus that playfulness is an individual predisposition [35] and that the liking of play is dependent on personal opinions, characteristics [36-38], and context [34]. Some propositions have been made by play scholars to classify different expressions of play and distinguish play from other behaviors such as exploration [13,39]. Probably most interesting in this regard is the distinction between paidia (free, spontaneous, expressive, creative forms of play) and ludus (rule-bound play) [40]. These heuristics can be very valuable for the theoretical conceptualization of GBL, because GBL

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design seems to relate much more to rule-bound "ludic" play [4,26,40] than to free, creative "paidic" play. Furthermore, the strong individual character of play that has been established in the literature seems to require qualitative research approaches to understand students' perceptions of play and academic learning, especially in relation to GBL.

In the present study, we took inspiration from play research as a first step towards a mechanistic analysis of GBL effects. We employed the qualitative method of open focus group discussions to help us gain deeper insight into medical and dentistry students' perceptions of play and learning by exploring their ideas, interpretations, feelings, and actions [41] as well as favorable circumstances or limitations for engaging in GBL activities. Although, at this point, we do not have scientific reasons to assume that the range of opinions on play would vary significantly across students as a function of the academic level or discipline they are enrolled in, we chose to focus on medical and dental students for 2 main reasons. First, our main teaching experience as well as our research interest in GBL lie within the context of health profession education. Second, if play preferences are indeed highly individual and contextual, this would also apply to students enrolled in a particular program or discipline. In summary, in this focus group study, we explored health professions students' perceptions of what constitutes play, play-learning interaction, and if, how, and when GBL material should be designed and implemented in health professions education to foster their learning.

Methods

Context

We conducted this study at the University of Groningen, University Medical Center Groningen, the Netherlands, between March 2019 and April 2019. The 6-year undergraduate medical curriculum of the University of Groningen is comprised of a 3-year Bachelor's phase and a 3-year Master's phase. The Bachelor's program includes 2 Dutch-taught and 2 English-taught tracks, called learning communities. The program is problem-based and patient- and student-centred, with a focus on tutor groups, practicals, and e-learning rather than lectures. The students are expected to be proactive, and they are encouraged to develop self-regulated and self-directed learning skills to pursue lifelong learning. The 3-year Master's program includes 2.5 years of clinical rotations (1 year of junior clerkships, 1 year of senior clerkships, 0.5 year of elective clerkship), and 0.5 year master thesis.

The 6-year undergraduate dentistry curriculum of the University of Groningen, likewise, is comprised of a 3-year Bachelor's phase and 3-year Master's phase and has a patient-centred approach. Compared to medicine, the dentistry Bachelor's phase has a stronger focus on lectures and practicals and is taught in Dutch only. The Master's phase consists of 1 year of mainly skills labs and practicals, while the final 2 years mainly consist of clinical rotations and a master thesis. Both medicine and dentistry students use e-learning, and teachers sometimes apply GBL, but there is no considerable nor structural implementation of GBL in either curriculum.

Participants and Ethical Considerations

We used convenience sampling and invited all medical and dental students to participate in our study via an online announcement on the virtual learning environment of the University of Groningen, which is also used as a communication platform and is visible to all students (N=1600). We explained that the purpose of the focus group study was to gain more insight into students' perceptions of play due to increasing interest in GBL. It was communicated that students not interested in games would also be able to participate in this study. We did not set specific exclusion criteria.

Ethical approval was obtained via the Netherlands Association for Medical Education (January 11, 2019). Prior to the start of each focus group session, the participants signed an informed consent form and completed a brief demographic questionnaire. They were informed that participation was on a voluntary basis and that they had the right to withdraw at any time if they were not comfortable with the study. After each session, participants received a gift certificate of €10 (US \$11.88) for their time and effort.

Focus Group Sessions

The focus group sessions followed the guidelines as described by Krueger et al [42] as well as the Association for Medical Education in Europe (AMEE) guideline on using focus groups [41]. Initially, 6 focus groups sessions (4 Dutch and 2 English sessions, with a maximum capacity of 13 students per session) were planned, each lasting 1.5-2 hours.

With the consent of the students, all meetings were audiotaped for later transcription and analysis. It was explained that there were no correct nor incorrect answers and that we were interested in all ideas and perceptions. The discussions were structured around a short break. Before the break, discussions aimed at exploring playful behavior in leisure time. After the break, discussions continued and focused on participants' ideas and perceptions of the play-learning interaction and how GBL could be implemented in the curricula to foster their learning. We used a topic list with open-ended questions (Textbox 1) and encouraged further discussion. The first 4 sessions were moderated by 1 of the authors (AJ). An observer (Ob1) was seated outside the group and took detailed field notes of group dynamics, atmosphere, and nonverbal communications. The last 2 sessions were moderated by the observer of the first 4 sessions and, consequently, a different observer (Ob2) was used. To create an open and social atmosphere, pizza and soft drinks were served.

After 4 sessions, our sample provided sufficient information power to address the aims of this study [43]. The information we had gathered from these focus groups was used to fine-tune and add some questions to the topic list for the final 2 focus group sessions (Textbox 2). Since no new information was obtained in these 2 sessions, we decided not to schedule any further sessions [42].

Textbox 1. General question route for focus group discussions.

reaction in Octor for focus group discussions.		
1.	Opening question	
	• What is your favorite game?	
2.	Discussion on games and gameplay	
	• Why do you like your favorite game?	
	• Which type of games do you dislike? And why?	
	• How does your favorite game night look like?	
	• What do you think about when thinking of playing games?	
	• Do you play less now than when you were young? Why so? Do you wish it were different?	
3.	Break	
4.	Discussion on game-based learning and implementation	
	• Try to think about how you would like to use a game or game elements within the current education. What would that look like? Try to invent something in groups of 2 / 3 that you would actually like to use yourself.	

- Let's talk about your ideas. Why did you choose this course and these game elements?
- Is your intrinsic motivation (not) enough obvious? Is using game-elements really necessary?
- Suppose you are the director of your education; how would you organize your education with GBL?
- 5. Summary
 - "summary of discussion" Did I summarize it correctly? Anyone want to add something?

Textbox 2. Additional questions

- What does a game make 'addictive'?
- Does anyone not like to play games?
- When do you prefer to play?
- Do you ever play drinking games? Why do you think that is attractive?
- Which type of play elements do you believe would work in education?

Data Analysis

All audiotapes were transcribed verbatim and anonymized before analysis. Atlas.ti (version: 8.4) was used as software to help us manage and analyze the data [44]. The method of thematic analysis was used to evaluate the data [42]. We used the most widely adopted approach for thematic analysis [45] outlined by Braun and Clark [46] and consisting of 6 steps: (1) familiarization with the data, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, (6) producing the manuscript. Notably, this method of analysis is recursive, meaning that each subsequent step in the analysis might have prompted us to circle back to earlier steps in light of newly emerged themes or data [45]. The detailed observers' field notes facilitated additional exploration of themes when needed throughout the entire process.

First, coders (AvG and Ob1) familiarized themselves with the data by examining and re-examining the transcripts and audiotapes. Second, initial codes were generated (Avg and Ob1)

 Table 1. Initial coding framework.

to organize the data on potential items of interest [45]. One
focus group discussion was coded (AvG and Ob1); thereafter,
the coders discussed and defined a coding framework for the
remaining dataset while denoting possible patterns or
discrepancies between the codes (Table 1) [46]. All
disagreements between coders were resolved via discussion
between the coders. Open coding was used to ensure flexibility
to incorporate themes outside our questioning route or initial
coding table (Table 1) [47]. Third, the identified codes from all
focus groups were discussed with the entire team in order to
construct themes. We inductively [41] and iteratively
constructed themes by comparing, analyzing, combining, and
mapping codes [45]. Fourth, the team (iteratively) reviewed the
identified themes to examine whether they were sufficiently
common and coherent, but also whether they were sufficiently
distinct from each other to justify separation [45,46,48]. Fifth,
we ensured that the denominators of our themes were adequately
clear and descriptive. Finally, we wrote the manuscript, which
proved to be a continuation of the iterative interpretation and
analytic process of thematic analysis [49].

Preliminary codes	Examples	
Meaning	Luck and unpredictability, ownership, meaning	
Escapism	Fantasy, immersion, escapism, relaxation	
Social	Being together, helping each other	
Strategy	Strategy	
Mechanics	Duration, variation	
Achievement	Challenge, wining, losing, competition, revenge, provocation	
Devotion	Dark play, eagerness	
Exploration	Storytelling, learning new things, curiosity	
Applicability for learning	Difficulty subject, boring, paradox with leisure	

Reflections

Our research team consisted of researchers with various backgrounds, supporting a critical examination and interpretation of the data from multiple perspectives. During the team discussions, we deliberately addressed all these perspectives, while allowing each team member to make an equal contribution.

AvG has a medical degree, is appointed as a lecturer (ie, anatomist), has a research interest in the motivational pull of play and games, and develops GBL strategies. JG is an associate professor of anatomy with a research interest in affective neuroscience and motivational forces in education. AJ is a full

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professor of Health Professions Education and Research with ample experience in qualitative research. Ob1 is a master student in Dentistry, assists multiple (clinical) educators in developing e-learning, and helped perform this study as part of her graduation assignment.

AvG and JG did not join the focus group sessions because they might know the participating students; AJ did not know any of them. Ob1 knew some participants in 2 out of 4 focus group sessions she observed; however, these participants did not consider this to be a problem, and they felt free to speak their minds. When Ob1 acted as a moderator, she did not know any of the participants.

Results

A total of 58 participants volunteered to participate (41 women and 17 men; mean age 22.8 years, range 18-31 years). This sample was comprised of 30 Bachelor students in Medicine, 8 Master students in Medicine, 2 Bachelor students in Dentistry, and 18 Master students in Dentistry. Of the participants, 51 reported to be of Dutch nationality and 7 of a nationality other than Dutch (Brazilian, French, Israeli, Italian, Saudi Arabian, Romanian, South African). The number of participants joining each focus group ranged between 7 and 13 students. One focus group session only included dentistry students (n=13), 1 session was predominantly attended by dentistry students (6 of 7 were dentistry students), 1 session was predominantly attended by medicine students (11 of 12 were medical students), and 3 sessions (including the 2 English sessions) were only attended by medical students. We found no distinct differences between the opinion on play or GBL between dentistry and medical students. The detailed field notes yielded no additional results for analysis.

We chose to present our findings based on the structure of the focus group discussions: first, students' perceptions of play in leisure time, then their perceptions of GBL, and finally, the interaction between play and learning. In the following sections, quotations are used to illustrate the findings. Identified themes are in *bold and italic*, and identified sub-themes are **bold**.

Perceptions of Play in Leisure Time

At the start of each focus group session, students discussed their favorite games in leisure time. A great diversity of favorite game genres was mentioned by the students, for example, puzzle/jigsaw games, shooting games, strategy games, sport games, and adventure games. As one student stated: "I think there's no game that everyone likes to play..."

All students liked to play, but the amount of play in leisure time ranged considerably from only once a year to daily. *Pleasure* seemed to be the common ground as to why students engaged in games, in all their diversity.

Pleasure

Whether the games were solitary (eg, patience, jigsaw, or shooter games) or multiplayer or collaborative (eg, Monopoly, settlers of Catan, or FIFA), students felt that games should be fun. However, ways to achieve a pleasurable experience from play varied considerably across students.

For instance, fun could come from the **joy of winning** ("I really like winning."), from the **feeling of supremacy and achieving something** ("You are special. You have something that others don't have."), or from **the delight of getting a good story out of a game** ("I've always seen video games as 'my book kind of thing.' I don't read a lot of books, so I get my stories from games.")

A striking aspect that was highlighted in the discussions was that not only the pleasure experience itself (eg, the experience of a victory) but also the **sense of pleasurable anticipation** motivated students to continue playing: "I continue playing until I win the final match."

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Students indicated that pleasure should **not be easily obtainable:** "it has to be a challenge to win."

Reward uncertainty seemed to modulate the impact of the pleasure experience, such that uncertain wins were associated with greater pleasure than certain wins. Upon analyzing the students' statements, it became clear that they experienced greater joy after a difficult win, compared to easy wins:

... father always wins [at Scrabble], that's not the worst. ... it also gives more satisfaction if you beat him.

What I like, is when you really make a brilliant move, so someone else just doesn't win, but you do.

However, the degree of reward uncertainty seemed to have an optimum. Students said that if the reward seemed out of reach and their chances of winning were little to none, or even close to a certain loss, all anticipatory tension was gone. When students no longer had fun or prospect of pleasure, they felt less motivated to continue playing:

When you keep losing, you're done with it [the game] It [Monopoly] takes too long. You're like "let's just stop, do we really have to finish [the game]?"

The final major part of the pleasure experienced in play that was brought up in the discussions was social pleasure. Students tended to play games in groups of close friends or family or with new people (met in pubs, societies, or a digital world), which helped them gain or strengthen the sense of collectiveness and sociability:

It [playing a game with each other] makes you feel like you are in your own world.

You can talk about the game and about everyday life, which offers opportunities for discussion.

... then you just want it [the game] to last a long time, because you have such a good time with each other.

Students mentioned that play more easily **creates a bond**, a sense of social togetherness, which in turn can also be enriched through play: "... it makes you feel connected."

However, the sociability of play could also backfire when players with competitive spirits who could not win (sore losers) ruined the game:

I'm very fanatic. If I lose, I'll also be grumpy for an hour. A lot of people also don't like to play a game with me.

The sociability of play could also backfire when players who disliked strong competition were disappointed because play was merely reduced to competitiveness and the desire to win:

If they are all very fanatic, it (the game) doesn't matter that much to me anymore.

Perceptions of Game-Based Learning

In order to keep the balance between play and the serious act of learning, participants brought up and discussed their *perceived requirements* and the *relevance* for implementing GBL.

Perceived Requirements

Despite a possible unpleasant confrontation with the serious world (see the Paradox section), competition was believed to enhance learning:

The more you compete, the more you will learn by yourself, because you want to improve.

However, in order to keep competition playful and in balance with the more serious part of learning, students felt that players' identities should remain confidential in GBL using competition (for example by choosing a nickname) or that players should be grouped into (collaborative) teams:

They [the other students] are allowed to see the [game] results, but then anonymously.

When you're losing [a teamplay game], you're not losing alone. So that's also nice.

Students' perceptions of meaningful GBL design generally stayed **close to their learning task** at hand (ie, the learning task itself could be easily recognized). Students particularly referred to disciplines they found difficult or tedious, such as anatomy, physiology, cell biology, immunology, or statistics:

... if courses are really tedious and dry, it [GBL] shows you that it's [the course content is] useful, and if you play it right, the [new] knowledge sticks.

... if you can find a game to make people understand physiology, you're a genius!

Furthermore, students often mentioned **game versions of their future workplace** (based on The Sims game), which gave them opportunities to learn playfully by building their own practice:

I used to play The Sims a lot and really liked to build. ... Wouldn't it be great to build your own dentistry practice in a Sims kind of way!? Designing your practice, doing treatment, making money to go to courses in which you can learn new treatments, through which you can make even more money so you can improve your practice, can get more staff etc. ...

Relevance

Students' opinions on the need for GBL were divided:

I don't necessarily want to play a game every time I go to class.

... yes, I think we need it [GBL].

Although there was some debate about how frequently GBL should be used, the consensus seemed to be that GBL could support learning. At times, the medical education continuum was experience as long-lasting, hectic, and stressful:

It [dentistry] is really a study for the long haul.

We are all really stressed, and everyone's stressing each other out, like: "Have you passed the exam/the test?" or "Did you hear? He hasn't passed it [the exam/the test]!"

Subsequently, students mentioned that adding playful fun to learning might help **relieve stress** in stressful times:

Why not make it a little more light-hearted? Just to relieve the tension every now and then.

Nevertheless, students felt that there has to be a **balance** between the playful and the serious, which has to be respected:

If we turn aspects of the 6-year learning process into play, it feels as if the/all seriousness has been lost.

The extent to which the serious and the playful should be balanced depended very much on personal preferences. Therefore, an approach **tailored** to students' needs would be the best fit according to the students:

Make it an extra activity, because playing a game just doesn't work for some people...

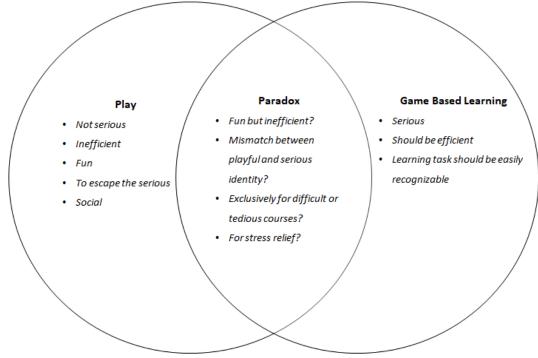
I think it's also important to keep in mind that everybody is different ...

Perceptions of the Interaction Between Play and Learning

The combination of play and the serious act of learning seemed *paradoxical* to students (Figure 1).



Figure 1. A paradoxical interaction between play and game-based learning based on identified subthemes.



Paradox

Students overwhelmingly indicated that GBL should **not** be made **compulsory**. Compulsory play sounded for them like a "contradictio in terminis": Play would become serious, which cannot be play:

If you are forced to play games, it would be like school.

If it [a GBL activity] becomes compulsory, then I don't like it anymore.

Students considered play to be a leisure-time activity to temporarily **escape** the serious demands of daily life:

It's really relaxation, just something completely different [play], which has nothing to do with anything else.

Integrating play and the serious act of learning into education, therefore, seemed to be a paradox:

I think it's strange that you can be enjoying gameplay in your private life for fun and relaxation, but apparently, if you frame it as "education," it suddenly becomes too much.

Indeed, although students were apt to think of play as pleasure during leisure time, it was difficult for them to link play and pleasure to academic learning:

I find it difficult to see it [learning/GBL] as a game because it's all so serious. Something is depending on it. And when I think of playing games, I think "Ah, cozy, fun!"

If I have to get together with everyone for a joint activity [GBL], then I think "No, I just have my own way of studying. And if I deviate from that, then I get really upset."

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Students believed that adding play [to education] would **reduce their learning efficiency**:

You probably have to "camouflage" the learning [part], which will probably require more study time. I think (educational) games just have to be short and efficient...

If something [GBL] really takes a lot of time, then people are inclined to think, as always: "I just quickly read this [book] instead of wasting my time on a game."

In addition to reduced learning efficiency, the paradox of play and learning was attributed to a **mismatch in identity** in play as compared to reality:

That's the funny thing with games; you can pretend to be different than you normally are.

Losing a game in the imaginary play environment was never seen as fun but considered trivial nonetheless; from a gameplay point of view, the game was over, and the ending was (most of time) appreciated: "It's just a game."

However, students felt that their playful imaginary identity would be lost in learning. Losing a game in a learning activity or environment was considered to possibly lead to unpleasant and stressful confrontations with the real world:

... because it's a game, just a one-time thing. And here, even if it's just a Kahoot, and in general, sometimes you just have a group of questions you really don't know anything about. But you can take it personally, even though you don't have to. And think "I'm not a good student, but I want to become a good doctor" and "they're all going to be better doctors than me" and "my resume is not good enough."

In such cases, students particularly mentioned that competition had influenced this **unfavorable confrontation with the serious**:

I think you don't want to show [your peers] that you're not able to do something [well], and if you do it [GBL] in the form of a competition, that there's always someone better than you. You have the feeling that you're less good at it.

Or, students were concerned that competitive behavior in games would become prominent in their education as well:

I'm already chasing all the credits [in the curriculum] and I feel like it [competitive GBL] would make me too competitive, too reward focused.

Discussion

In our study, we took inspiration from play research as a first step towards a mechanistic analysis of GBL effects. On the basis of open focus group discussions, we explored how medical and dental students perceived play in leisure time as well as in the context of academic learning, GBL in particular. The student samples were representative of the student population in terms of age, intellectual level (university students), and academic interest (medicine and dentistry). All students reported that they liked to play in leisure time. However, analysis of the transcripts showed that they had very different ideas about how pleasure could be achieved through play. Although we intentionally did not refer to a specific definition or conceptualization of play during the focus group discussions, students naturally discussed play in the context of digital, card, and board games. At the evaluative level, we observed a strong tendency towards rule-bound "ludic" play and only a weak tendency towards free, creative "paidic" forms of play [34,40,50-52]. An important observation from our analysis pertains to the context-dependency of the reported playfulness. Students openly and enthusiastically discussed play in leisure time, but when they were asked to discuss play in the context of GBL and academic learning, they began to carefully formulate their perceptions of play. They became cautious and began to change their perceptions of play, and many even became sceptical or disapproving. It seems that the outcomes of our focus group study not only allowed us to confirm some of the key principles of adult play (eg, challenge and sociability) [34,50,51,53] but also enabled us to generalize these to the context of health profession education. Moreover, we were able to identify key elements to consider in deciding if, how, and when to adopt GBL in health profession education to, possibly, foster learning.

Pleasure was a central theme in the open focus group discussions. This is not surprising because play, in its most fundamental expression, is seen as one of the primary positive emotions common to all mammals. Interestingly, students' perceptions of what made play pleasurable varied considerably and involved not only positive affect (eg, fun, sociability) but also affective states that can be taken in a more negative way (eg, the urge to win). This variation persisted across participants and focus group sessions, even though the focus group composition was similar regarding demographic characteristics. This finding is consistent with previous literature stating that

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play preference, inclination to play, and the meaning of play are associated with many variables such as culture [54-56], personality [57-59], gender [60-62], and play frequency [63,64]. Attesting to the variable nature of play liking is that even negative affect, such as feelings of guilt or antisocial behaviors like sadism and violence [65-67], can be pursued in play and games and might be considered pleasurable in certain contexts [68-71]. It thus seems clear that in humans, any analysis of the interaction between pleasure and play must also exceed the level of primary emotion.

In our analysis of the transcripts, we adopted a multilevel conceptualization of pleasure [72], where we consider pleasure as more than just the joy of playing, which resonates findings from other fields such as developmental psychology, psychoanalysis, and neuroscience [18,72-74]. Pleasure research showed that various positive and negative behaviors and incentives can activate the same pleasure system in the brain and that pleasure is contextual and mainly dependent on individual experiences [75,76]. Pleasure can also refer to mood states (eg, happiness [77], a feeling of content), which can be maintained by perseverance [78,79], even at the cost of momentary negative affect [80,81]. Human play has also been associated with interest [82-84], surprise [85-87], and arousal [88-90]. In our focus group discussions, some students mentioned that the anticipatory joy of possibly winning as a main reason why playing was fun for them. Students also discussed the pleasure of uncertainty in this respect. On one hand, they perceived the pleasure of uncertainty (imagining winning the game) as more motivating than the pure pleasure of certainly winning ("difficult wins over easy wins"). On the other hand, they perceived a high probability of not being able to achieve the desired outcome (certain loss) as demotivating and in fact, as a reason to end the game, which is in line with the literature [91]. Indeed, is it well established that reward probability has a powerful effect on the anticipatory state of pleasure; the greater the reward uncertainty, the greater the motivating effect will be, but only if there is (at least) some probability in receiving that reward [91,92].

Another frequently discussed element of play pleasure was sociality. Many students believed that playing together was way more fun than playing alone. This is in line with findings of research in animals other than humans, in which social play is characterized as a high-level reward [93,94], more pleasurable than other forms of social interaction [95-97], and, intriguingly, at times even more pleasurable than food [98,99]. Also in human studies, it has empirically been shown that a prominent characteristic of social play is its high reward value [98,100]. However, some students appeared to be hesitant of social play; they perceived that pleasure gained from social play was sensitive to any dominance hierarchy within the player group.

A main observation from the focus group sessions was that students' enthusiasm about play dampened when the context of the discussion shifted from leisure time to academic learning and GBL. Students mentioned many instances where play could be beneficial for their learning or even for their personal well-being. However, students also mentioned that GBL felt, at times, like a paradox and that play cannot be implemented in every course. Perhaps, this might be attributed to a shift from

intrinsic motivation (free play in leisure time) and extrinsic motivation (when play becomes task-based and therefore, possibly, less fun). Another important aspect of this particular discussion was that students perceived the implementation of play as the opposite of efficient learning. This criticism had to do with the underlying belief that academic learning is serious and that the opposite of seriousness is play. Students indicated that the act of academic learning should be efficient but saw play as inefficient. Nevertheless, they seemed to justify the inefficiency of play when it could increase the efficiency of learning. They saw the greatest benefits for somewhat tedious, difficult subject matter. As a corollary, this may also imply that if students judge a particular learning activity as too playful, they will criticize it as inefficient and rather prefer to avoid participating. This is in line with the moderate enjoyment hypothesis theorizing that the general relationship between entertainment and learning is an inverse u-shape [101]. According to this hypothesis, entertainment (and the resulting pleasure) only facilitates learning up to a certain point, the peak of the inverted u-shape. After that point, learning will decrease, possibly due to distraction (leading to inefficiency) of entertainment [88]. Interestingly, but paradoxically enough, pleasure associated with playing may be perceived as hindering the achievement of higher (academic) goals, which, in turn, is also part of the pursuit of happiness and well-being by providing long-term pleasures [75].

Considering play as inefficient corresponds with the literature on this subject. For instance, Suits [51] stated that all play involves sacrifice of efficiency; there are always easier ways to obtain goals than through play. In golf, for example, there are far more efficient ways to get a small round object into the ground than with the swing of a golf club, but the voluntary acceptance of game rules permits the player to do so [51]. He and many others argued that, without the voluntary acceptance of these rules (with an inherent loss of efficiency), play will be lost [34,50-52]. Voluntarily accepting rules in favor of less efficient means also resonates with our finding. Students stated that play implemented as a learning tool (ie, GBL) should not become a compulsory activity for students. This is in line with work from developmental psychologists [102,103], research on motivational theories applied to play [104], and views from play scholars [34,50,51].

Students' opinions about competition in play varied considerably, depending on the context. When students considered competition in the context of leisure time play, their focus was on the (prospective) joy of winning, and they could also interpret winning and losing as trivial outcomes of play. However, students saw it as a serious matter in the context of academic learning. They felt that competitive elements in a learning environment could possibly lead to unwanted and stressful confrontations with the serious world or make them too reward focused. Nevertheless, competition was believed to enhance learning but especially when played in teams or when played anonymously.

Finally, our findings can be explained by various theories on motivation and game design. For instance, the findings that students play for sociability and challenge, but need to feel free in doing so, closely ties in with the self-determination theory

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[105]. This theory has been linked to videogames [106], serious games [107], and gamification [108,109] in prior studies and states that individuals are intrinsically motivated when the basic psychological needs of feelings of competence (challenges), relatedness (sociability), and autonomy are met. Many of our findings reflect these psychological needs, yet students did not seem to prefer all 3 psychological needs simultaneously. For instance, some students implicitly mentioned that competence was an important indicator to continue play: the possibility to improve oneself. Others, however, did not play for competence, but rather for the sake of sociability (pertaining to the "relatedness" need). Also differing from the relatedness need was the finding of students who were interested in a single player game that draws them into the storyline. Autonomy on the other hand was very much agreed upon; play should not be compulsory. Building on the self-determination theory, Nicholson's RECIPE for meaningful gamification is a design theory that describes 6 elements (Reflection, Engagement, Information, Choice, Exposition, and Play) in order to attain intrinsically motivated usage [109]. This theory is in line with many of our findings. For instance, GBL/play should be free (Play element), should be a choice (Choice element), should not deviate too much from the real-world setting (otherwise it might be deemed inefficient; Information and Exposition element), should be challenging and socially engaging (Engagement element), and should have a narrative (Exposition element).

Practical and Research Implications

In research on GBL, design choices have rarely been made explicit, and most studies use the same type of design [4]. However, perceptions of play are highly individual, contextual, and variable, so one-design-fits-all approaches do not seem to work well for GBL research, according to our results. A thorough understanding of specific students' perceptions within a culture or university might therefore play a pivotal role in utilizing the full potential of GBL. In the future, researchers and educators should map students' play preferences before implementing GBL. Such information is essential for both the design of effective GBL activities and transfer of existing research into educational practice. As a first step in designing GBL and engaging in evidence-based decision making, teachers need to compare the play preferences of research participants in the study design with the play preferences of their own target group. This information also helps researchers understand and clarify what type of design works, for whom, and in what situation or circumstances. Thanks to the manageable and flexible possibilities of digital media, such an approach will bring tailor-made education a step closer.

Educators who want to implement GBL should aim at balancing the interaction between play and learning, harmonizing the right amount of play with the serious to increase efficiency of learning. What educators first should determine when they engage in teaching difficult subjects is whether there is a real need for play by identifying problems in students' learning attitudes or learning behaviors [4]. Currently, determining the *right* amount of play and *how* learning efficiency can be improved seem to depend on intuition and personal perceptions

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rather than evidence-based decision and is therefore an area for future research.

One of our main findings was that participants strongly expected, or found, pleasure in play. The pleasure in games is strongly related to playing time [90]. Longer periods of time spent at GBL might indicate increased repetition of the learning material which, in turn, will lead to improved learning outcomes and retention [4,110-113]. Educators who want to design GBL could, therefore, adopt different positive motivational forces of pleasure as a method to guide their design. Using pleasure as a motivational force also opens up exciting new ways for research. Negative motivational forces (eg, violence) are also often observed in games [65,66], but their roles have rarely been investigated in the context of GBL [3,4,9,114].

We identified sociability as a major incentive for medical and dental students to play. Consequently, social play might be an interesting design option for GBL material. Strikingly, social play is underrepresented in GBL research, since most studies adopt a single player approach [4,9,26,114,115]. Although students felt that competition could enhance their learning, educators should be careful with implementing competitive elements in GBL, because these may also cause undesired effects such as increased stress. Playing in teams or in anonymity may be more appropriate options for such scenarios.

Strengths and Limitations

A strength of our focus group study may be that it generated a rich understanding of students' perceptions, experiences, and beliefs with respect to play and the interaction between play and learning. An experienced moderator guided the focus group sessions and stimulated in-depth discussions; we thoroughly explored students' perceptions; 2 independent researchers identified codes; and the whole team, including the moderator, discussed and reflected on themes.

As in any focus group study, the identified themes unavoidably bear some relation to the original impetus for asking the questions and designing the interview guide. We tried to counteract this by actively encouraging input from all students during the sessions, even if it deviated from the original topic list.

In focus group studies, researchers sometimes meet with their participants to verify the generated themes. Although we did end every focus group discussion with a summary, to check whether our summary was appropriate to how the participants experienced it, we did not opt to meet with our participants, which potentially could have altered our outcome.

The gender ratio in our sample was imbalanced in favor of female students (70% were women). Although this ratio

represents the Dutch medical student population [116], some countries might have gender ratios more balanced towards men (eg, medical schools in the United States have around 50% of their students as men [117]). Literature argues that the liking of play differs between genders [118,119]. Therefore, there is a possibility that our findings are more pertinent to female students. Yet, our aim was not to provide a generalization, or find a consensus, during the focus group. Even in our coding, we aimed to include varied opinions on play and GBL. However, although we tried to counteract an imbalance towards female students, results might be localized to the students of Dutch medical schools.

The meaning of play is associated with many variables such as culture [54-56]. Since we used convenience sampling, the participants in this study predominantly had a similar ethnic background (European/Caucasian) and possibly also a similar socioeconomic background [120]. Therefore, cultural and regional differences might have affected the results of our study. In a different setting, the same methodology might yield different results.

Finally, our findings on the play-learning interaction reflect students' perceptions. Perceptions, however, do not always reflect actual behavior, meaning that students do not always do what they say they do. For example, in a study on using leader boards to increase the use of laparoscopic simulators, the majority of the surgical residents mentioned that they were not motivated by leader boards. However, the results showed that the time students in the competition group had spent on the simulation was higher than in the control group [121]. Additionally, because students in our sample had little experience with GBL, they might not have fully understood all the possibilities of GBL and, therefore, might have provided limited answers. Nonetheless, we believe that our findings offer important insights for future research to examine which design and GBL situation hold the highest promise for learning.

Conclusion

With this focus group study, we aimed to explore students' perceptions of play and the play-learning interaction. We explored what they considered to be play and how they believed it could interact with their learning. Four key points emerge from our study. First, students play for pleasure. Perceptions of pleasure vary considerably among students. Second, students consider play as inefficient. Inefficiency will only be justified when it increases learning. Third, play should be balanced with the serious and only used for difficult or tedious courses. Fourth, GBL activities should not be made compulsory for students, since there is a discrepancy between the serious of compulsory activities and the free nature of play.

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Conflicts of Interest

None declared.

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Abbreviations

AMEE: Association for Medical Education in Europe **GBL:** game-based learning

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Original Paper

Involvement of End Users in the Development of Serious Games for Health Care Professions Education: Systematic Descriptive Review

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Abstract

Background: On the basis of ethical and methodological arguments, numerous calls have been made to increase the involvement of end users in the development of serious games (SGs). Involving end users in the development process is considered a way to give them power and control over educational software that is designed for them. It can also help identify areas for improvement in the design of SGs and improve their efficacy in targeted learning outcomes. However, no recognized guidelines or frameworks exist to guide end users' involvement in SG development.

Objective: The aim of this study is to describe how end users are involved in the development of SGs for health care professions education.

Methods: We examined the literature presenting the development of 45 SGs that had reached the stage of efficacy evaluation in randomized trials. One author performed data extraction using an ad hoc form based on a design and development framework for SGs. Data were then coded and synthesized on the basis of similarities. The coding scheme was refined iteratively with the involvement of a second author. Results are presented using frequencies and percentages.

Results: End users' involvement was mentioned in the development of 21 of 45 SGs. The number of end users involved ranged from 12 to 36. End users were often involved in answering specific concerns that arose during the SG design (n=6) or in testing a prototype (n=12). In many cases, researchers solicited input from end users regarding the goals to reach (n=10) or the functional esthetics of the SGs (n=7). Most researchers used self-reported questionnaires (n=7).

Conclusions: Researchers mentioned end users' involvement in the development of less than half of the identified SGs, and this involvement was also poorly described. These findings represent significant limitations to evaluating the impact of the involvement of end users on the efficacy of SGs and in making recommendations regarding their involvement.

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KEYWORDS

game-based learning; health professions education; participatory design; systematic review; user-centered design; serious games; game development; end users; education

Introduction

Serious games (SGs) are video games designed with a primary educational purpose [1]. SGs are based on the premise that learners who experience high levels of engagement and motivation during an educational experience can achieve better learning outcomes [2]. Thus, SGs combine design elements such as goals, rewards, and narrative events, that are likely to evoke positive emotions in learners (eg, joy, surprise), capture and sustain their attention, and fuel their desire to play to offer an engaging and motivating learning experience [2]. In health care professions education, developing an SG can be a long, complex, and expensive undertaking, as the input of a team of several actors including content experts and game designers is required [3,4]. Olszewski and Wolbrink [3] proposed a three-stage development framework to promote the efficiency of this process and efficacy of an SG. In the first design stage, the team must establish the learning objectives and map learners' experience in the SG. This entails defining the goals, feedback, and rewards as well as the narrative and esthetics that will bring the virtual world to life and allow interactions [2]. During the second programing stage, SG design elements are gradually combined into one or several prototypes. In the third testing stage, the team tests these prototypes and suggests modifications to the design of the SG. Throughout the development process, the team must pay close attention to various design principles to ensure that learners remain motivated and engaged and that the SG is effective for learning [2,4]. For example, the knowledge and skills needed to meet the goals presented in the SG should match the learners' knowledge and skill level. If learners perceive the goals as being too easy or difficult, they may become bored or stressed [5].

The involvement of end users (in this case, the health care professionals and students for whom the SG is intended) in the SG development process may help ensure that these design principles are followed and that the SG offers an engaging and motivating learning experience [6]. Researchers [7,8] have described different roles or levels of involvement for end users in the development of SGs: they can be consulted about their learning needs and design preferences in the first design stage, or they can provide feedback and answers to specific concerns that arise later during the second programing stage. Some end users may be involved at the third stage of prototype testing, while others may be co-designers if they lead or contribute substantially to the development process.

However, involving end users could increase the complexity of the SG development process and, by extension, the cost and time needed. Assessing end users' learning needs and design preferences before establishing learning objectives and mapping their experience, or having end users test prototypes, are additional steps that require further resources and planning [7,9-11] with no guarantee of cost-effectiveness according to current evidence. For example, in their systematic review, DeSmet et al [8] found that health games developed with

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patients as co-designers were not more effective than those in which patients were not involved in development. Along with authors of previous reviews and studies, they underlined a paucity of data on how end users are selected to participate in SG development, the methods used to elicit their input, the elements on which their input is solicited, and the extent to which their input is integrated into the SG [8,11,12]. These data could allow researchers and developers to consider the involvement of end users based on others' experience in this field.

Thus, in the absence of evidence, guidelines, or a design framework to specifically guide end users' involvement, this systematic review aimed to describe end users' involvement in the development of SGs for health care professions education. Specifically, we sought to answer the following questions:

- 1. What criteria are used to select end users in the development of SGs?
- 2. How are end users involved in the development of SGs?
- 3. What SG design elements are assessed and modified following end users' involvement?

Methods

Review Design

This study was a descriptive review of end users' involvement (concept) in the development of SGs (context) for health care professionals and students (population). Descriptive reviews allow the identification of trends in a representative sample of published literature regarding prespecified methodological or theoretical elements [13]. This descriptive review builds on the methods used and results found in a previous systematic review aimed at evaluating the efficacy of SGs in health care professions education [14,15].

For this review, "end users' involvement" was considered an umbrella term for inviting health care professionals and students to contribute to the design or refinement of an SG in any of the three stages of the development process prior to efficacy evaluation [3]. Health care professionals and students with any level of education (from undergraduate to postgraduate education, continuing education) or from any clinical setting were considered. However, SGs for patients were not considered. All SGs that were included aimed to improve learning outcomes (eg, knowledge, skills, attitudes, behaviors) related to various clinical situations or topics.

Reference Identification and Selection

For a previous systematic review [14], we developed a search strategy to identify randomized controlled trials (RCTs), evaluating the efficacy of SGs among health care professionals and students. The search strategy combined keywords and index terms related to health care professions (eg, *nurses, medical* students), SGs (eg, *game-based learning, educational game*), and learning outcomes (eg, *knowledge acquisition, skill*

development). On May 26, 2020, we searched six bibliographical databases: Cumulative Index of Nursing and Allied Health (EBSCO), EMBASE (OVID), ERIC (ProQuest), PsycINFO (APA PsycNET), PubMed (NCBI), and Web of Science—SCI and SSCI (ISI – Thomson Scientific). Two review authors performed the reference selection independently, identifying 45 SGs whose efficacy had been evaluated in 46 published RCTs. Further details regarding the search strategy and selection process for this previous review are published elsewhere [14-16]. The complete search strategy for all bibliographical databases is also presented in Multimedia Appendix 1.

For the current review, we focused on all development work prior to these 46 RCTs. As evaluating the efficacy of an intervention represents one of the last stages in its development [17-19], we considered that SGs that had been the object of RCTs had gone beyond the prototype programing and testing phases [3]. Thus, including only SGs that had been the object of RCTs allowed us to be confident that their development was complete as well as the end users' involvement in it. One review author performed a backward reference search in the reference lists of the 46 RCTs to identify prior work that described the development of the SGs. When the name of an SG was provided, this review author also performed hand searches in Google to identify additional work describing its development. We included all types of work regarding the development of the SGs (eg, qualitative or quantitative empirical research, discussion on the development process) and all types of reporting (eg, conference abstract, poster, journal article, web page). A second review author also independently identified work related to the development of 8 SGs chosen randomly (18% of the 45 included SGs). This was to ensure that all relevant work was included. In medical record reviews, an independent audit of at least 10% of the sample is frequently recommended [20]; however, as no additional references could be identified for these 8 SGs, it was deemed satisfactory.

Data Extraction and Synthesis

The unit of analysis was the included SGs. All documents related to a single SG were considered concurrently to describe the characteristics of end users' involvement during the development of a particular SG. Thus, all frequency counts are based on the number of SGs rather than the number of papers included in this review.

Using an ad hoc data extraction grid based on the review aims and questions, one reviewer extracted all excerpts regarding end users' involvement in SG development and categorized them according to the research questions:

- What criteria were used to select end users: end users' involvement (ie, reported or not), number of end users involved, and eligibility criteria
- How were end users involved: what role was assigned to end users in the development of SGs? The roles were as follows: (1) as consultants at the onset of design, to share their learning needs or design preferences; (2) as consultants during design, to provide feedback and answers to specific concerns; (3) as prototype testers, toward the end of development; and (4) as co-designers throughout development, as a regular member of the team [3,7,8]. We also extracted the methods used to elicit end users' input (eg, individual interviews, think-aloud methods).
- What SG design elements were assessed and modified following end users' involvement: elements for which end-user input was elicited (see Table 1) and its influence on SG development
- Researchers' views and recommendations on end users' involvement

We coded data of the elements for which end users' input was elicited and how their input was integrated into the SG (ie, how the SG was modified following end-user input) based on the SG design framework by Alexiou and Schippers [2]. We further synthesized them using an inductive approach based on data similarities. A second review author independently performed data extraction and coding. We refined the coding scheme until no difference from the results of the first reviewer was noted. This occurred after data extraction and coding were performed in a random sample of 8/45 SGs (18%). The results are presented narratively and by using descriptive statistics (frequencies and percentages) when appropriate.

Table 1. Elements in the serious game design framework by Alexiou and Schippers [2].

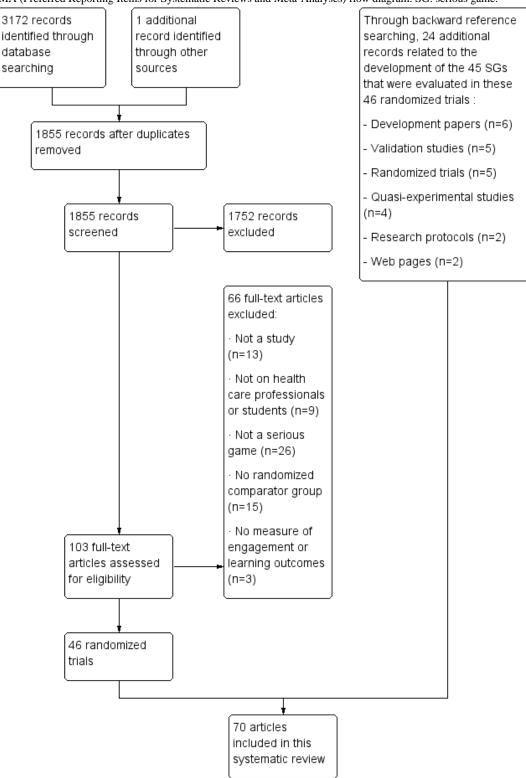
Element	Definition
Esthetics	Audio and visual elements that allow learners to perceive a harmonious and coherent virtual world (hedonic esthetics, eg, beauty or realism of the audiovisual rendering, background music) and to interact with the serious game (functional esthetics, eg, the user interface)
Narrative	The perspective through which learners explore the virtual world (protagonist), the figures that inhabit this world with whom learners can interact (secondary characters), and the situations that arise from learners' actions and mark the evolution of this world (narrative events, eg, new game levels)
Game mechanics	What learners are expected to achieve in the serious game (goals), what they receive for doing so (rewards, eg, points, badges), and the help provided to facilitate their progression (feedback)

Results

Development of the 45 SGs was described in 70 papers. Figure 1 presents the PRISMA (Preferred Reporting Items for

Systematic Reviews and Meta-Analyses) flow diagram for paper selection. End users' involvement in the development process was explicitly mentioned for 21/45 SGs (47%; see Multimedia Appendix 2). The following sections present results regarding end user involvement in the development of these 21 SGs.





What Selection Criteria Were Used to Select End Users in the Development of SGs?

The number of end users involved was reported for 9 of the 21 SGs (43%) and ranged from 12 to 36, with a median of 27 (IQR: 16) [21-29]. For 3/21 SGs (14%), the number of end users was defined by convenience: all readily accessible individuals were approached, and those who agreed to participate were enrolled [21,23,26]. No justification was found for the number of end

users involved in the remaining 6/21 SGs (29%) [22,24,25,27-29].

Eligibility criteria for end-user selection were reported for the development of 1 of the 21 SGs (5%). Researchers selected an equal number of men and women with varying degrees of experience in gaming, but they did not provide a rationale for that decision [24].

How Were End Users Involved During the Development of SGs?

We identified the role given to end users in the development

Table 2. End users' roles in the development of serious games (N=21).

process of 17/21 SGs (81%) [21-37]. Table 2 reports the end users' roles in SG development and the methods used to elicit their input.

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Role and methods used to elicit input ^a	Value, n (%)	References
Consultant at the onset of the design stage	2 (10)	[35,37]
Undescribed questionnaire	1 (5)	[35]
Not reported	1 (5)	[37]
Consultant later in the design stage	6 (29)	[25,28,29,32,36,37]
Multiple-choice questionnaire	2 (10)	[25,29]
Focus group	1 (5)	[32]
Not reported	3 (14)	[28,36,37]
Prototype tester	12 (57)	[21-24,26-28,30,33-35,37]
Ad hoc Likert scales with written comments	3 (14)	[22,23,34]
Adaptation of the System Usability Scale	1 (5)	[24]
Undescribed questionnaire	1 (5)	[35]
Think-aloud method	1 (5)	[24]
Recording of in-game interactions	1 (5)	[24]
Co-designers	1 (5)	[31]
Unclear	4 (19)	[38-41]

^aEnd users had more than one role in the development of 3 serious games [28,35,37].

As Table 2 shows, end users were more often prototype testers (12/21, 57%), and their input was frequently elicited through questionnaires (7/21, 33%). Details regarding the content of these questionnaires and their development process were rarely provided (4/21, 19%). For one SG, authors used the System Usability Scale [42] with additional items regarding its ease of use and alignment with end users' design preferences [24,43]. The System Usability Scale consists of 10 statements regarding the ease and speed of use of software, and end users are asked to express their level of agreement with each statement on a 5-point scale. Besides questionnaires, researchers also recorded end users' interactions with a prototype of the SG and asked them to think aloud during their gaming experience. Based on the effect on end users' experience with the SG, each interaction was then classified as either positive, neutral, or negative [24].

Only 1 of the 21 SGs (5%) was developed with end users as co-designers who oversaw the development of the clinical content [31]. This SG aimed to improve nurses' confidence and

skills in teaching the correct inhaler technique to patients. With these learning objectives in mind, a group of nurses developed the clinical content, which consisted of a description of seven steps to be followed during the self-administration of inhaled medication. The rest of the development team then developed the narrative of the SG around these seven steps.

What SG Design Elements Were Assessed and Modified Following End Users' Involvement?

Elements for which end-user input was elicited were reported for 15/21 SGs (71%) [21-26,28-31,34-37,39]. Researchers also stated that they modified 10 of the 21 SGs (48%) according to end-user input [23-25,27,30,33-35,37,39]; however, they detailed the modifications for only 5 SGs (24%) [24,25,27,35,39]. Table 3 reports the results regarding end users' input in SG design. End users' input was most frequently elicited regarding the goals of the SGs (10/21, 48%); their input regarding hedonic esthetics (2/21, 10%) and narratives (1/21, 5%) rarely received focus.



Table 3. End users' input on serious game design.

Serious game design ele- ment	Value, n (%)	References	Aspects for which input was elicited	Modifications made to the serious game
Functional esthetics	7 (33)	[21-24,28,37]	Instructions for interacting with the serious game, interface clarity, and ease of use	More emphasis on visual cues in the virtu- al environment, reduction of the written material on the screen, addition of high- lights and shadows to facilitate visualiza- tion of the cursor, and correction of tech- nical glitches
Hedonic esthetics	2 (10)	[24,35]	Volume of the background music	Addition of options to switch off or decrease the volume of the background music
Protagonist and sec- ondary characters	1 (5)	[22]	Length of the dialogues between the pro- tagonist and secondary characters	Modifications not detailed
Narrative events	0 (0)	N/A ^a	N/A	N/A
Goals	10 (48)	[22-25,29,31,35-37,39]	Level of challenge and validity of the learning content	Tailoring of the level of challenge
Feedback	3 (14)	[24,26,34]	Feedback complexity and how it helped end users situate their progression	Addition of a progression bar to provide further feedback on end users' progression
Rewards	0 (0)	N/A	N/A	N/A

^aN/A: not applicable.

Discussion

Principal Results

Our review of 70 references indicated that end users were involved in the development of less than half the 45 SGs in health care professions education. They most often took the role of prototype testers during the later stages of SG development, and they were rarely involved as co-designers or consultants at the onset of development. In addition, researchers often used questionnaires to elicit end-user input. Other methods such as focus groups and individual interviews were rarely used. The level of challenge and functional esthetics were the aspects of SGs for which end users' input was most frequently elicited.

Comparison With Prior Work

Several criteria could be used to select end users in the development of SGs. In this review, criteria were mentioned for only one SG and focused on gender and gaming experience [24]. Garber et al [44] underlined that current evidence does not clearly support gender differences in learning preferences. Indeed, suggested gender differences in SGs relate to gameplay preferences (ie, competition for men and collaboration for women) and their perceived educational value (ie, higher in men than in women) [44,45]. However, in health care professions education, once the SGs reached the stage of efficacy evaluation, gender-based analyses have yet to reveal significant differences in learning outcomes [46-48]. Thus, the extent to which SG design should be informed by end users' gender to improve its efficacy remains unknown. Diehl et al [24] mentioned gaming experience as another criterion for the selection of end users, noting that users with a small or large amount of gaming experience provided the richest input. Similarly, Boeker et al [22] reported that end users with the least amount of gaming experience had the most issues in their interactions with the SG. Given the limited evidence regarding

https://games.jmir.org/2021/3/e28650

criteria for end user selection, we suggest that researchers should include all end users without considering predetermined characteristics. We encourage them to report on differences in the input of end users based on gender, gaming experience, or other characteristics that could have played a role in the input obtained and in the result of their involvement.

The number of end users involved in SG development ranged from 12 to 36, and these numbers seemed to be mostly based on convenience, as the available end users were approached. Current sample size estimation approaches that are not focused on statistical power only seem suited to testing SG prototypes, as the numbers they suggest can still be considerable [49,50]. However, as the development and refinement of an SG is highly iterative, and many versions of the design of the game are proposed during the first development stages [3], including several end users at the onset of development can represent a challenge. In the broader fields of intervention development and participatory research, authors have suggested that establishing a dialogue with a small number of end users during the initial development stages-aiming for depth rather than breadth—is more important than obtaining a large sample size [17,51]. This suggestion is consistent with qualitative methods such as individual interviews or focus group discussions. However, the use of qualitative methods was described only twice, and only once before the testing of an SG prototype [24,32]. Thus, we suggest that researchers explore methods to elicit end users' input that are suited for smaller samples, such as qualitative methods. This approach may help researchers acquire a rich understanding of end users' perspectives on the design of an SG.

The results also elucidate the gap between eliciting and integrating end-user input into the SG design. Few researchers described the changes made to SGs following end-user involvement, and none discussed their decision-making process.



Kelly [52] argued that considering end users' input can be uncomfortable for researchers and, therefore, Kelly recommends that the researchers attempt to find a compromise between making all the decisions themselves and relinquishing all forms of decisions to end users. It has been suggested that not all end users' input should be directly integrated into an SG and that experts in the field should review what could potentially improve the efficacy of an SG [9,53]. Further research is needed to identify what elements of end users' input are the most valuable, and at what stage of the development process; thus, researchers should describe their rationale for eliciting end users' input and their decision-making process for integrating this input.

In this review, we did not identify literature (published or accessible on the web) on the development of most SGs that were the object of an RCT. However, in papers detailing the results of RCTs, we found many instances of authors referring to previous unpublished studies related to the development of their SGs [28,31,39]. This could point to the existence of literature on development that researchers or editors of scientific journals did not consider suitable for publication [54,55]. We argue that sharing this type of experience may prove valuable for planning future SG developments. Further, as current publications of work related to the development of SGs often focus on end users as prototype testers, researchers should consider publishing their experience with end users as consultants, especially in the first stages of SG development or as co-designers. In this review, we found that end users often served the needs of researchers and developers either to answer their concerns or to test a prototype through a fixed protocol. This limits end users' contribution to designing SGs as well as researchers' ability to potentially substantially change the design of an SG once it has reached the testing phase.

Limitations

The strengths of this descriptive review are that it entailed a comprehensive literature search to ensure that all SGs that had been the object of an RCT were found. The selection process was conducted independently and in pairs to ensure that all relevant papers were included; however, SGs that had not been the object of an RCT were not considered in this review. If the development of these SGs were still in progress, only a partial portrait of their development would have been provided. Other limitations include the data extraction process, which was conducted by a single review author for most SGs. This was judged adequate, as the aim of this work was descriptive and no efficacy data were extracted. Finally, as underlined in the discussion, this review was limited to work available on the internet.

Conclusions

Considering that end users' involvement was poorly described in the SGs under review, we suggest that researchers publish information on the nature of end-user involvement, including the characteristics of the end users selected, content of the instruments used to elicit their input, modifications made to the SGs based on end-user input, and lessons learned throughout the development process. As few researchers reported end users' involvement in the initial development, those opting for this type of involvement should consider sharing their views on the process. Moreover, researchers should consider involving end users with varying levels of gaming experience and combining different methods to elicit their input to gain further insights into issues that may undermine the efficacy of SGs.

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Conflicts of Interest

None declared.

Multimedia Appendix 1 All search strategies. [DOCX File, 29 KB - games v9i3e28650 app1.docx]

Multimedia Appendix 2

Key elements of end users' involvement in the development of serious games in health care professions education. [DOCX File, 20 KB - games v9i3e28650 app2.docx]

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Abbreviations

RCT: randomized controlled trial **SG:** serious game

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Original Paper

A Didactic Escape Game for Emergency Medicine Aimed at Learning to Work as a Team and Making Diagnoses: Methodology for Game Development

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Abstract

Background: In the health care environment, teamwork is paramount, especially when referring to patient safety. We are interested in recent and innovative solutions such as escape games, which is a type of adventure game that may be highly useful as an educational tool, potentially combining good communication skills with successful gamification. They involve teams of 5 to 10 individuals who are "locked" in the same room and must collaborate to solve puzzles while under pressure from a timer.

Objective: The purpose of this paper was to describe the steps involved in creating and implementing an educational escape game. This tool can then be put into service or further developed by trainers who wish to use it for learning interprofessional collaboration. Therefore, we started with an experience of creating an educational escape game for emergency medicine teams.

Methods: We chose to develop an educational escape game by using 6 successive steps. First, we built a team. Second, we chose the pedagogical objectives. Third, we gamified (switched from objectives to scenario). Next, we found the human and material resources needed. Thereafter, we designed briefing and debriefing. Lastly, we tested the game.

Results: By following these 6 steps, we created the first ambulant educational escape game that teaches people, or nurses, doctors, and paramedics, working in emergency medicine to work as a team.

Conclusions: From a pedagogic point of view, this game may be a good tool for helping people in multidisciplinary fields (medical and paramedical teams) to learn how to work collaboratively and to communicate as a group. Above all, it seems to be an innovative tool that complements medical simulation–based learning and thus consolidates traditional education.

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KEYWORDS

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training techniques; educational technique; game theories; emergency medicine; games; education; escape game; simulation-based training; pedagogical; serious games; emergency medicine training

Introduction

In France, emergency medicine, especially as it pertains to prehospital settings, involves a team of complementary practitioners, including doctors, nurses, ambulance drivers, and nurses' assistants, who must all work as a team. For this team, 2 aspects are essential: communication and time management. Above all, communication in teamwork is the foundation of effective medical care and is associated with a significant reduction in adverse events [1,2]. Communication within the team is essential, but it is poorly taught, including during continuing medical education [3]. Sharara-Chamia et al [3] reported that emergency physicians lack knowledge about communicating in teams. Currently, there is no consensus on how to effectively teach these skills in health education [4]. To improve teamwork communication training, several educational tools, including medical simulation-based tools, have been developed [3,5].

Gamification is a technique rooted in active learning approaches and is currently being developed, especially in health education [6], and it could satisfy this need. This technique involves applying game design elements to traditionally nongame contexts, such as conventional learning activities [7] and is an innovative tool [8]. According to Rutledge et al [7], gamification differs from serious games, in that it is applied to an existing learning activity or curriculum. Its aim is to help students to meet the objectives of the activity or curriculum. This technique increases participant motivation and engagement [8], which are major determinants of learning [9]. Gamification has a major impact on motivation [7,10,11]. It complements both resident subspecialty and undergraduate student education and can be integrated into simulation-based training [12].

We were interested in recent and innovative solutions such as escape games, which is a type of adventure game that may be highly useful as an educational tool and could combine learning good communication skills with successful gamification. It involves teams of 5 to 10 individuals who are "locked" in the same room and must collaborate to solve puzzles while being subject to a time limit. The main goals of escape games are to develop teamwork and promote concepts used for crew resource management [13-15]. Currently, most escape rooms are supported by private start-ups and are exclusively aimed at the leisure market. The game takes place in the presence of a facilitator, who may be with the players or outside the room (usually with video surveillance and possible ongoing communication with the players). These games are often used to promote team-building in companies. These games are already used in a relevant way in school education [16] and for specific knowledge-learning objectives for pharmacists, for example [17]. Therefore, it may be of interest to use this new tool for training medical teams in interprofessional cooperation [18]. We believe that this tool can effectively teach interprofessional cooperation, especially communication, which is needed to efficiently delegate tasks and use the available time [18,19] to meet the demands of serious, real-life clinical situations. Additionally, the resolution of 1 scenario suggests a collegial decision, which could be placed in the context of medical uncertainty [20].

While the scientific literature on educational escape games and how to evaluate their educational impact is growing [18], point-by-point methods on how to create such games in health education have been poorly described. The purpose of this paper is to describe the steps involved in creating and implementing an educational escape game. This tool can then be put into service and further developed by trainers who wish to use it for learning interprofessional collaboration. Therefore, we started with an experience of creating an educational escape game for emergency medicine teams.

Methods

Methods Overview

An educational pilot game was conducted to apply 6 steps of developing escape games to the emergency medicine field. Therefore, a multidisciplinary team was set up, which comprised 5 experts in gaming and gamification. The escape game was created between November 2018 and May 2019 through monthly meetings. Our escape game scenario and all its game components have been submitted to the French National Institute of Intellectual Property for commercial protection. An evaluation is underway and will be the subject of another paper.

To develop an educational escape game, we proposed the implementation of 6 successive steps, which are summarized in Table 1.



Table 1. The 6 steps of developing an escape game

#	Step	Objectives
1	Build a team	• To create 2 or more subgroups: 1 that worked on the design of the game and 1 that worked on the educational/scientific content
2	Choose educational objectives	 To create a synopsis of the escape game To choose 2 levels of educational objectives: those that are common to all team members and those that are specific to team members' professions.
3	Gamify: switching from objectives to scenario	• To combine the educational objectives of gameplay with its interactive elements and thus develop the educational content of the game
4	Find human and material resources	 To provide a facilitator role To list the necessary material To assemble and create the game
5	Create the briefing and debriefing phases	 To write a rule book To write an introduction/briefing of the game To write the key steps to guide debriefing
6	Test the game	 To test the game and material with real teams and to ensure that the diagnostic process can be followed in the allotted time. To identify key points in the game where players might need help. To write a guide for the facilitator To evaluate the educational impact using conventional scales

Step 1: Build a Team

In our experience and opinion, the team needed to be composed of 2 to 5 people. In our opinion, all team members must always have had considerable experience as players or in designing game scenarios, including escape, role play, live-action role play, or board games. We believe it is important to have an experience as a player to create this type of tool to better advice development through real-life knowledge. The second point, to which we draw attention, was that it was essential that the professional's skills of team members be adapted to the target audience. The creation of subgroups makes it possible to work more efficiently by harnessing the specific skills of each group member.

Step 2: Choose Educational Objectives

To develop the game, it was possible to start from a synopsis (global idea of a scenario in which a clinical case will be inserted) or to start from a clinical case and imagine a synopsis. In fact, the synopsis can be derived from the objectives, or the construction of the synopsis involves defining learning objectives.

It was important to choose 2 levels of educational objectives: those that are common to all team members and those that are specific to each team member's profession. The common objectives toward learning communication skills in teamwork were (1) expressing ideas, knowledge, and opinions clearly, concisely, and kindly; (2) acquiring knowledge about the professional skills of the other team members; and (3) sharing responsibility for the result in a collegial fashion.

The medical and paramedical objectives represented clinical situations presented in the game. Its level of complexity and content must be adapted in accordance with the skills of the participants. This content must comply with current

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recommendations and consensus. This scenario allowed participants to generate the most probable diagnostic hypotheses regarding the symptoms and then to restrict the scope of the hypotheses by collecting and interpreting additional data to best fit the expert's reasoning [21].

Step 3: Gamify—Switching From Objectives to Scenario

This step combined the educational objectives of gameplay with its interactional elements, thus forming the educational content of the game. For such a game to be successful, the players needed to have a gaming attitude [22]. This playful attitude was defined by Henriot [22], who stated that to play, one must enter the game and play a role in it. In simulation-based training, where participants assume their own or a given role, the escape game requires that the players must adopt a player's attitude to learn lessons from the game. We can thus observe the group being created and see a natural distribution of tasks (reading, searching, and puzzles being solved in accordance with individuals' skills), often with the emergence of a leader.

In the same spirit of play, the scenario did not necessarily have to reflect an actual situation but it should have been realistic enough so that learning can be readily transferable to actual clinical situations, consistent with the "exposition" element of Nicholson's RECIPE for meaningful gamification [23]. However, the scenario was fictitious. The choice of the setting (contemporary, futuristic, or uchronic era) and history was left to the creators. The setting was important because it created the dimension of "play" and placed the learners in a gambling situation.

As in simulation-based training, the escape game was based on reality. Although the setting may be modified, the clinical scenario chosen must be authentic. To create the scenario, the

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group must think about all of the probable decision-making paths the players could take, allowing the players freedom in the game. This scenario was the decisional algorithm of the game, providing the different paths that could be followed by the learners.

It was important to think about the creation of the game beforehand so that the players can see it to completion. The success of the game lay in allowing it to fully unfold so that the players could have all the elements to make their collegial decision (relevant or not). The important factor was not the outcome but rather the way in which it was achieved.

Gameplay interactions could be chosen in accordance with player strengths, experiences with escape games, or specific support research (eg, the "now escape" website [24]). To ensure that the diagnostic process could be completed in the allotted time and that the players experience adequate time pressure, the game should include 3 to 4 gameplay interactions—or play elements—that require handling (eg, codes, locks, or puzzles) over 10 minutes of gameplay.

As the game progresses, the in-game content makes it possible to suggest all the probable etiologies of the fixed diagnostic setting and to eliminate the various hypotheses. The elements that lead to the right diagnosis are only provided after all components have been presented. The game's progress was thus essentially controlled by the timepoint configuration of the game elements. Upon conclusion, players must have had all cards in hand. They could then make their final and collective decision and be able to explain their reasoning.

Step 4: Find Human and Material Resources

Integration and Roles of a Facilitator

The facilitator had several roles: (1) to introduce the game: the details of the game can be presented by various supportive elements such as a video or cards; (2) to guide the game and bring in new elements if necessary (eg, changes in the clinical situation or data that would be sought by participants as part of their diagnostic process, but are not available) with strict time control; and (3) to control the game duration by assisting if necessary. The facilitator must be familiar with the entire course of the game and all possible paths or outcomes.

The facilitator could be located with the players or outside the room with voice access and video surveillance. To make the game more immersive, we proposed to position the facilitator directly with the players and thus give him/her a key role with the players. This made it easier to guide the players during the game. In addition, this approach allows for fewer technical and financial constraints. However, to ensure full player immersion in the game, the facilitator must be completely committed to the game and may require actor training. He/she must fit perfectly into the scenario and have a valid role in the story.

Listing the Material

The set of material required for the game should be listed at the same time during scenario creation. It should include (1) the clinical case and background elements; (2) padlocks of different types (code, key, etc) that can be fixed to boxes, books, etc; and (3) more elaborate puzzles (labyrinths, sets of magnets, etc).

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To represent the etiological elements of the clinical case, each diagnostic etiological component could be represented as an object or symbol in the game (eg, a letter). Set elements were important because they place the learners in the game situation and make it more immersive, but this also allows hiding of clues.

Assembling the Material

To promote a hypothetical deductive diagnostic approach (as we mentioned earlier), the material must be presented in a precise way and the order of opening the padlocks must also be specified. Hence, for example, to open box B, a clue needed to be present in box A. In addition to the role of the facilitator, these elements allowed the order of discovery of the diagnostic guidance elements to be controlled. The order of these elements must remain within a clinical logic, as in the simulation.

Step 5: Create the Briefing and Debriefing Phases

As in simulation-based training, 2 essential phases of the escape game, namely briefing and debriefing, must be carried out.

Briefing

Briefing was intended to allow the players to know the questions they have to answer. It should also make the game immersive. This was best achieved by the facilitator and his/her acting skills during the introduction of the game. However, before entering the playground, details of the mission could be presented by various supportive elements (eg, video or cards), but must be adapted to the context of the synopsis.

Debriefing

Debriefing was a key step because it reinforces the learning process [25]. As in aeronautical debriefings, the investment of the facilitator in the game is inversely proportional to the level of investment of the group being trained [26].

It is essential that the facilitator adapts his/her debriefing to the level of the group. Each debriefing was unique in its content but has been structured on the basis of written guidelines before the game starts.

While the structure of the debriefing was standardized, the content was not. The standardized structure covers all the main components of scientific content and links them with the game's progress. By contrast, communication of the team was specific to each group.

Step 6: Testing of the Game

Initial Testing for Adjustments and Creation of the Animation

This type of test allowed us to see if the puzzle sequence was the right one. It was designed not to evaluate the game but rather to highlight any possible inconsistencies in the game's sequence.

After purchasing the materials for the game (chosen in accordance with the elements described above) and setting up all the play mechanisms, we recommended that the game be tested with "naïve" players; that is, players who were not part of the game development process.

This test was very important because it allowed for refinement of both the game and the game documents and helped correct elements that do not unfold as planned. This test also makes it possible to observe the timing of the game in real life and how facilitating certain elements of the game can improve it. In addition, the test reveals the key timing points of the game, which must occur to allow the game to progress and end in the allotted time. These key points must be completed at predetermined points in the game. The test can also highlight facilitating elements that the facilitator could use to ensure that the game is completed on time. For example, depending on how the scenario develops, the facilitator could communicate with the group providing planned elements and sample sentences that contain clues.

The final step was to document the entire game algorithm along with all of its facilitating and game elements. It was also necessary to create debriefing sheets to help the facilitator complete his/her role. The game must be standardized and follow a specific protocol in terms of how it was presented and when its elements are brought into play. This protocol was written for and presented to the facilitator. The facilitator must be trained specifically on how the game should progress, his/her attitude to the game, and the nature of the facilitating elements.

Assessment of Educational Impact

This evaluation phase was important because it allowed the game to evolve further. There are several ways to evaluate an educational model. Of these, the most widely used was Kirkpatrick model [27] with 1 to 3 levels. It was possible to carry out an evaluation in the following way: obtaining participants' satisfaction with a focus group (level 1), partially

Textbox 1. Synopsis.

"An attack occurred on an airliner. The terrorist is gravely ill and about twenty passengers are showing suspicious symptoms. You are a team of specialists commissioned by the local authorities as part of an emergency plan to solve this problem. You have 30 minutes to report before the information is released to the general public. Final diagnosis:

The suspected terrorist has severe pulmonary embolism, and his clinical condition is aggravated by poisoning with nitric oxide"

Our pedagogical objectives were to develop communication within the team and to accompany the learners in a diagnostic reasoning within a complex situation.

Our group objectives were as follows: (1) analyzing the diagnostic process at the medical and paramedical level; (2) analyzing the elements reported by third parties in a clinical situation (eg, firefighters or family members); (3) building a sense of observation; and (4) developing curiosity.

Our specific objectives (including medical and paramedical ones) were as follows: to examine the etiology of nontraumatic coma, to examine the etiology of pulmonary embolism and other causes of acute respiratory failure and make a diagnostic process of pulmonary embolism, observe clinical presentations of nitric oxide poisoning, and participate in a disaster medicine environment with multiple victims.

Our players had to solve a complex clinical case within a multi-victim situation. In our game, the learners played the role

of an emergency medicine team: specific roles were not assigned to retain the gaming spirit. The roles would have to be quickly assigned, either spontaneously or allocated by a leader. Then, by reading the information contained in the "victim files" and by searching the suspected terrorist's belongings, the team members can understand their current state of health. Furthermore, external events may disrupt the game.

Step 3: Gamify—Switching From Objectives to Scenario

From our synopsis and objectives, we then developed a more detailed scenario. The team of disaster medicine specialists is dispatched on an emergency plan in the context of a highly probable bioterrorist exposure with approximately 20 victims. An introductory video is shown in which the local authorities explains the situation. A suspected terrorist is currently in a very serious condition and has exposed 20 passengers to an unknown substance. The team has 30 minutes to solve the problem because the local authorities must report to the president

because it was acquired from participants in a declarative manner with a remote questionnaire (level 2), and determining perceptible changes in practice in a declarative way using a remote questionnaire (level 3) [27]. We believe that an educational escape game allows reaching the first 2 levels of this scale. This evaluation of educational impact should be carried out systematically for each new health training course and would allow for improvements in gameplay as the game progresses.

Results

Step 1: Build a Team

We created a team of 4 people who all had in common a wealth of experience as players and creators of gaming content. The group was coordinated by 1 of the 2 emergency physicians who also had experience in medical education. The game design group consisted of a game designer/nurse anesthetist and a player (non-health professional). The educational/scientific group consisted of 2 emergency medicine physicians. These subgroups worked both separately and collaboratively.

Step 2: Choose Educational Objectives

Our game was aimed at medical residents, junior physicians, nurses and assistant nurses, and paramedics who work in the emergency department and who require initial and continuing education.

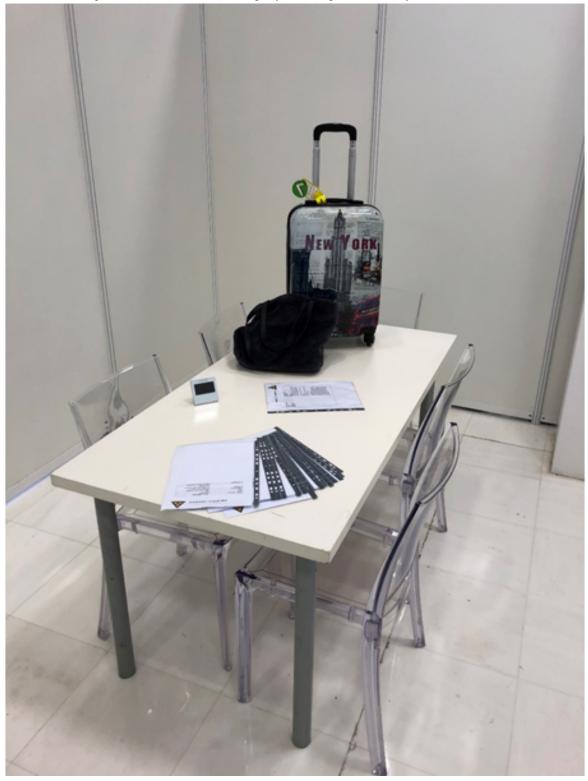
We chose to start from the synopsis and then worked toward the educational objectives. A synopsis is the overall concept of the game. The synopsis emerged after brainstorming (Textbox 1) and allowed us to develop all the objectives.

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of the French Republic within this time limit. For our game, the initial clinical case was presented in hard copy at the end of the video. This hard copy fit into the scenario as a medical document

that was created and was not a representation of the patient (Figure 1).

Figure 1. Contents of the escape room that was used for the emergency medicine game in this study.



In reality, the young, female terrorist has a real medical problem. She presents with a serious pulmonary embolism, and this is aggravated by group poisoning with nitric oxide. The players have the following at their disposal: the passengers' medical files and the medical file of the terrorist, as well as her personal belongings, to solve the problem. The players have to solve a

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XSL•FO RenderX complex medical problem: that of the terrorist and of the other victims. In addition, they have to conclude through logic deduction (or not) on the risk to the local population, with respect to this attack.

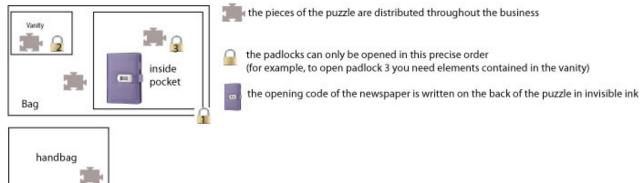
Our 30-minute game included 8 gameplay interactions in the form of a puzzle or handled objects. We chose the gameplay interactions on the basis of our preferences as players, our experiences with escape games, and our research on the "now escape" website [24], which contains valuable ideas for gameplay interactions. For example, the final element of the

game was a young woman's diary, which explained her background and allowed for an understanding of the entire clinical case and to deduce the clinical diagnosis. This puzzle is detailed in Textbox 2; we need to see this nesting like a Russian doll (Figure 2).

Textbox 2. Diary puzzle.

The final element of the game was the young woman's diary, which explained her entire background and allowed for an understanding of the entire clinical case and also to deduce the medical diagnosis. This diary was locked with a 4-digit code. The code was hidden in invisible ink on the back of a puzzle that the players had to reconstruct. (1) the blue light lamp was hidden in the young woman's handbag and (2) the pieces of the puzzle were distributed throughout the young woman's belongings. Once the puzzle was reconstructed and turned over, the code could be found. However, in order to obtain all the pieces of the puzzle, it was necessary to succeed in opening all the locks (suitcase, vanity, second part of suitcase, etc).

Figure 2. Diary enigma.



The facilitator served as a link between the doctor taking care of the patient and the victims (physically separated from the group so as to not "contaminate the team") and the expert team. In addition, the facilitator could intervene to guide the players and provide them with additional medical evidence but also the progress of the terrorist's and passengers' symptoms, to guide the players or to provide them with additional medical documents (a laboratory result, an electrocardiograph, or an X-ray). To make the game mobile, we chose to give players access to the patient's personal suitcase and bags in a closed room. The players were in this room with the facilitator.

Step 4: Find Human and Material Resources

The facilitator was trained in how to conduct the game and the role he/she was expected to play.

Other clues pointed to other diagnoses that needed to be excluded as the game progressed Similarly, we applied this approach to the group diagnosis, which could be elicited through careful clinical analysis. All the materials were listed by the group (an example of the material for the diagnosis of pulmonary embolism is provided in Textbox 3).

Textbox 3. Game elements and material for the diagnosis of a pulmonary embolism: an example.

Pulmonary embolism was the probable diagnosis because of the following reasons [28]:

- Elements of the story: long-haul plane flight
- The young woman's belongings included, a cigarette packet, birth control pills, compression stockings, and a photo of her in a cast
- Clinical presentation: acute respiratory failure, an electrocardiogram and a typical blood gas picture. (communicated by the facilitator at H+25mn)
- A positive pregnancy test and positive d-dimer (communicated by the facilitator at H+15mn)
- At the end of the game, the diary (the enigma mentioned earlier) recounted that she was wearing little support, despite her history of phlebitis and her recent fracture.

We made the game mobile by giving players access to the patient's personal suitcase and belongings in a closed room (Figure 1). Our escape game is thus portable and can be easily transported on public transport by 1 or 2 people and with minimal equipment (trunk or suitcase) required. These items are then transported to a closed 12-m² space (Figure 3).

Figure 3. Exterior of the 12-m² escape room that was used for the emergency-medicine game in this study.



Step 5: Create the Briefing and Debriefing Phases

Briefing

After listing the rules of the game (Multimedia Appendix 1), the facilitator introduces himself as an intern on the military base and hands over the video message from the local authorities, who then explains the mission to the team before the beginning of the game. The facilitator then leads the players into the room and the game begins.

Debriefing

Debriefing takes place immediately after the end of the game. After reviewing the diagnostic process, the facilitator first asks for the group's opinion on their communication and then seeks to highlight with the group the strengths and weaknesses of their communication (self-assessment and heteroassessment as in the simulation [25]). To authenticate this, the facilitator also encourages players to talk about similar real-life experiences they may have had. The general setting of our debriefing is provided in Multimedia Appendix 2.

Step 6: Testing the Game

Initial Testing

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To be able to adjust gameplay, we tested the game completely with 2 teams of 5 players who work in health care. We advise testing with 2 different teams. We observed the interlocking nature of the different stages of our gaming and did not find any major issues. After the first run-through, we adjusted an enigma that was problematic with regard to readability (codes

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were hidden in jars containing elements of a recipe to be put back in order but the numbers were too difficult to read). This test allowed us to understand what the pivotal points of the game were; that is, code A must be solved before H+12 minutes, otherwise the game might not be completed in time. This allowed us to predict the times at which the facilitator should intervene. Thus, after adjustments, the second run-through was a success. In both cases, the evaluation from participants was positive.

Educational Evaluation

Educational evaluation using focus groups on the day and through questionnaires 3 month later will be the subject of a subsequent study.

Discussion

Overview

Our objectives were to define the creative stages needed to produce an educational escape game to help trainers who wish to develop a tool for learning team communication and the diagnostic approach. We believe that, to our knowledge, we have created the first ambulant, educational escape game that teaches staff (nurses, doctors, and paramedics), working in emergency medicine, to work as a team, and we have defined 6 steps for its creation.

The methodological setting that we have established can be used to create other games and is more detailed than that described in the literature [16-18] and was specifically created

for the purpose of learning team communication and the diagnostic process in medical science.

Indeed, escape games could target a wide range of professions and can be used with most clinical cases. Our setting allows the creation of a multidisciplinary, mobile, and accessible game that promotes teamwork. Of note, our model also gives freedom to choose specific educational objectives. Educational escapes games are particularly adapted to the following objectives: the need for collegial decision-making and complex clinical situations involving several professions, and teamwork situations. All of these situations require excellent communication skills. Furthermore, in our opinion, any medical theme could be considered, even complex ethical ones.

While we were creating our game, we realized that student immersion is the key to educational success. It is also important that the game can take place at any time (present, past, or future) and at any location (hospital, outdoors, a house, or a public place). It could also be possible to invite our players to experience life aboard a spaceship.

The games we encountered in the literature [16-18,29,30] are not mobile like ours is; the mobility of our game is a real asset because it is easily transportable and can be played at any venue.

Nevertheless, in our opinion, a limitation of our proposed educational game is that it is not designed to develop technical medical skills but rather nontechnical skills such as communication. We could, however, well imagine puzzles that may involve technical skills (such as successful intubation to unlock a key).

The main objective of the escape game is to teach the players how to communicate with each other as a team and promote team cohesion [14,15]. Improved team cohesion is one of the most important benefits of collaborative learning methods (including games) that involve small training groups [31].

As with all educational games [4,15,18,19,29,30,32], we believe that our escape game could improve learning and the motivation to learn. Our game seems complementary to other games because it favors team cohesion, which is particularly important in emergency medicine. While there are other escape games in the literature, they only targeted medical students [18,30,32] or resident nurses/nursing students [19,29]; they did not aim to improve team dynamics.

Finally, since no roles are formally assigned, we work mainly on the evolution of the group and how it functions (eg, leadership is not assigned to an individual; rather, a leader often emerges in the group to help lead the group to a successful conclusion).

The escape game is similar to simulation-based training since it promotes team dynamics. Furthermore, they both involve a debriefing, which consolidates their educational impact. It should be noted that this debriefing exists in the escape game as part of the game and allows players to understand the puzzles they have experienced. The debriefing and its link with real-life situations provide authenticity to the situation and help consolidate the learning; this, in turn, results in successful gameplay.

However, differences can be observed in terms of educational emphasis that this game lays. The escape game emphasizes learning about the diagnostic process and communication skills without necessarily requiring undertaking technical and medical tasks. By contrast, simulation focuses on "real-life" technical and medical settings and is not an immersive game. Our game does not involve technical, medical, or paramedical activities; the situation is fictitious and aims at learning the diagnostic process and team communication. As we have seen, the learner is in a gaming situation rather than in a professional setting.

Limitations

The main limitation of our paper is the setting and development of the educational escape game. It is indeed not possible to draw concrete conclusions on the effects of the game on students and the outcome or learning improvement, and we can only make assumptions.

Conclusions

In our opinion, an escape game complements standard health training. It is particularly suitable for the field of emergency medicine, but our setting allows us to adapt it to any type of health profession or medical specialty. From an educational point of view, it may be a good tool for helping people in multidisciplinary fields (medical and paramedical teams) to learn how to work collaboratively and to communicate as a group. Above all, it is an innovative tool that complements medical simulation–based learning and thus consolidates traditional medical education. At present, a methodology for creating this type of educational game has not been proposed. Our team is currently evaluating the long-term educational benefits of our methodology and our game.

Acknowledgments

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Conflicts of Interest

The authors have completed the International Committee of Medical Journal Editors' uniform disclosure form. They declare that (1) the submitted work has not been supported by any organization other than the funding agency listed above (eg, the French Society of Emergency Medicine), (2) they have no financial relationships with any organizations that might have an interest in

the submitted work in the previous 3 years, and (3) they have no other relationships or activities that could appear to have influenced the submitted work.

Multimedia Appendix 1 Addendum I: rules of the game. [DOCX File, 12 KB - games_v9i3e27291_app1.docx]

Multimedia Appendix 2 Addendum II: debriefing plan. [DOCX File, 12 KB - games v9i3e27291 app2.docx]

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Review

Association of Extensive Video Gaming and Cognitive Function Changes in Brain-Imaging Studies of Pro Gamers and Individuals With Gaming Disorder: Systematic Literature Review

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Abstract

Background: The World Health Organization announced the inclusion of gaming disorder (GD) in the International Classification of Diseases, 11th Revision, despite some concerns. However, video gaming has been associated with the enhancement of cognitive function. Moreover, despite comparable extensive video gaming, pro gamers have not shown any of the negative symptoms that individuals with GD have reported. It is important to understand the association between extensive video gaming and alterations in brain regions more objectively.

Objective: This study aimed to systematically explore the association between extensive video gaming and changes in cognitive function by focusing on pro gamers and individuals with GD.

Methods: Studies about pro gamers and individuals with GD were searched for in the PubMed and Web of Science databases using relevant search terms, for example, "pro-gamers" and "(Internet) gaming disorder." While studies for pro gamers were searched for without date restrictions, only studies published since 2013 about individuals with GD were included in search results. Article selection was conducted by following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines.

Results: By following the PRISMA guidelines, 1903 records with unique titles were identified. Through the screening process of titles and abstracts, 86 full-text articles were accessed to determine their eligibility. A total of 18 studies were included in this systematic review. Among the included 18 studies, six studies included pro gamers as participants, one study included both pro gamers and individuals with GD, and 11 studies included individuals with GD. Pro gamers showed structural and functional alterations in brain regions (eg, the left cingulate cortex, the insula subregions, and the prefrontal regions). Cognitive function (eg, attention and sensorimotor function) and cognitive control improved in pro gamers. Individuals with GD showed structural and functional alterations in brain regions (eg, the striatum, the orbitofrontal cortex, and the amygdala) that were associated with impaired cognitive control and higher levels of craving video game playing. They also showed increased cortical thickness in the middle temporal cortex, which indicated the acquisition of better skills. Moreover, it was suggested that various factors (eg, gaming expertise, duration or severity of GD, and level of self-control) seemed to modulate the association of extensive video game playing with changes in cognitive function.

Conclusions: Although a limited number of studies were identified that included pro gamers and/or individuals who reported showing symptoms of GD for more than 1 year, this review contributed to the objective understanding of the association between extensive video game playing and changes in cognitive function. Conducting studies with a longitudinal design or with various comparison groups in the future would be helpful in deepening the understanding of this association.

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KEYWORDS

brain imaging; cognitive function; gaming disorder; pro gamers; video games; cognition; brain; games; gaming

Introduction

Background

Video game playing has become one of the most popular leisure activities [1]. With the growing popularity of video game playing, a minority of individuals have been reported to play video games in problematic ways, resulting in negative consequences (eg, withdrawal from socializing and death) [2-4]. By focusing on problematic video gaming in a minority of individuals, the World Health Organization (WHO) recently announced that the International Classification of Diseases, 11th Revision (ICD-11) included gaming disorder (GD) as a syndrome [5,6]. GD refers to the persistent engagement on the internet in playing games despite the psychological distress and the interference with daily activities for more than 12 months [7]. However, there are concerns about the inclusion of GD as one of diseases in the ICD-11 [6,8], in that the objective evidence that showed there were harmful effects of GD was not sufficient (ie, little research examined causality and the persistence of symptoms) [9].

After the announcement by the WHO, GD was reported in the media to result in structural alterations in brain regions based on the results of a cross-sectional study that compared the brain structures of individuals with GD to those of healthy controls; this emphasized the necessity of treatment for GD [10]. Although the tendency of GD was found to be negatively associated with the volume of gray matter (GM) in the prefrontal brain regions that are involved in cognitive control and sensorimotor functioning [11], it is difficult to confirm the causality of the association in the cross-sectional studies. Moreover, unlike the focus on GD, playing video games was positively associated with cognitive function [12-15]. Video game players, compared to non-video game players, showed more integrated white matter (WM) in motor and visual pathways [14] and higher levels of activation in the frontoparietal brain regions to detect visual stimulus despite the comparable cognitive performance [15]. Playing video games for a longer duration was also associated with thicker cortices in the brain regions for attention, navigation, visuomotor function, and the resolution of ambiguity (eg, the left frontal eye field, the left dorsolateral prefrontal cortex [DLPFC], and the bilateral entorhinal cortex) [12,13]. That is, while the association of GD with alterations in brain regions was more focused, playing video games was also associated with cognitive enhancement.

Furthermore, there are individuals who play video games extensively for more than 10 hours a day without reporting disrupted lifestyles (eg, a disrupted sleep-wake cycle) [16]; these individuals are called pro gamers. They refer to a group of people who belong to a team through a contract and who make economic profits by taking part in e-sports competitions [17]. The mean age of pro gamers in major leagues was reported to be 22 years [18]. Although statistics for their mean age of

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retirement were not available, more than half of pro gamers reported that their retirement was dependent on their judgment of their performances in competitions [17]. Since cognitive-motor speed (ie, the speed at which the cognitive process initiates actions) was found to start to decline at 24 years in a sample of StarCraft II players who were aged between 16 and 44 years old, regardless of their expertise level [19], pro gamers were assumed to retire at 25 to 27 years of age.

Taken together, playing video games for a longer duration did not result in the development of GD, and only a minority of people reported the development of GD [6,7]. Unlike negative opinions in the media toward video games and playing video games, playing them was associated with cognitive enhancement (eg, Zhang et al [14] and Richlan et al [15]). Video games were also suggested as a potential tool for clinical intervention for individuals with mental disorders (eg, Alzheimer disease) [20]. Thus, it is necessary to explore the association between video game playing and alterations in brain regions in a more objective manner. Moreover, despite the comparable amount of video game experience between individuals with GD and pro gamers who play video games extensively without any symptoms of GD (eg, higher impulsivity for gaming) [16], more studies have been conducted that focused on individuals with GD, and more review studies about GD have been conducted (eg, Leeman and Potenza [21] and Wei et al [22]). Since pro gamers, in addition to individuals with GD, are a population of interest for investigating the association between extensive video gaming and changes in cognitive function, reviewing studies that recruited pro gamers would deepen the understanding and effects of playing video games extensively.

Objective

This systematic review aimed to explore the association between extensive video game playing and changes in cognitive function. That is, this study reviewed brain-imaging studies that included pro gamers and/or individuals with GD.

Methods

Search Strategy

Literature searches were conducted in two databases: PubMed and Web of Science. Studies about pro gamers were searched for with the following search terms, without a restriction on the date: "pro-gamers," "pro video game players," "action video game experts," "video gaming experts," and "long-term video game players." Studies about individuals with GD were searched for with the following search terms, with date restrictions: "(Internet) gaming disorder," "(Internet) gaming addiction," and "(online) video game addiction." As many studies about GD have been conducted, only studies that were published since 2013 were included in the results of the literature search.

Study Selection

Overview

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [23] were followed in this study. Firstly, duplicates from the search results from the two databases were removed using EndNote X9 (Clarivate Analytics). After the removal of duplicates, the titles and abstracts of the remaining articles were screened to determine if they were eligible for full-text assessment. Secondly, full-text articles were carefully reviewed to determine their eligibility for this review based on selection criteria.

Inclusion Criteria

Inclusion criteria for articles in this review were as follows: (1) original research articles published in English, (2) the use of brain-imaging techniques, and (3) the recruitment of pro gamers and/or individuals with GD. Definitions of pro gamers and GD in this study are as follows:

- Pro gamers are defined as individuals who (1) belong to e-sports teams, (2) are highly experienced video game players without reporting any problematic daily lifestyle behaviors, and/or (3) have won video game playing competitions.
- GD refers to persistent engagement in video game playing despite psychological distress and interference with daily activities [24] for more than 1 year [7].

That is, articles about pro gamers were selected for inclusion when recruited participants met at least one description of pro gamers above. For example, a study that recruited video game experts, who were recognized as top-ranking players [25], was included because the second description of pro gamers was met. The types of video games (eg, StarCraft and League of Legends) were not restricted for the selection. Articles were also selected for the review when recruited participants were confirmed to be diagnosed with GD for more than 12 months or when the stated mean duration of GD symptoms in participants was more than 1 year. In the process of the selection of articles about individuals with GD, the age of the individuals with GD was not restricted. This was because adults, in addition to adolescents, have also shown GD symptoms, despite the report that the prevalence of GD has increased especially in adolescents [26] whose cognitive control is developing [27] with different developmental trajectories of the limbic system and prefrontal cortex (PFC) regions [28].

Exclusion Criteria

Articles were excluded when full texts were not available and when participants in studies did not meet any of the descriptions of pro gamers defined above. Articles were also excluded when they did not confirm that individuals with GD showed GD symptoms for more than 1 year or when they did not present the information of the mean duration of GD.

Data Extraction

The following data were extracted from the selected articles: information about the study (ie, study design, participants, duration of GD, and brain-imaging techniques used) and the brain regions that were associated with extensive video game playing.

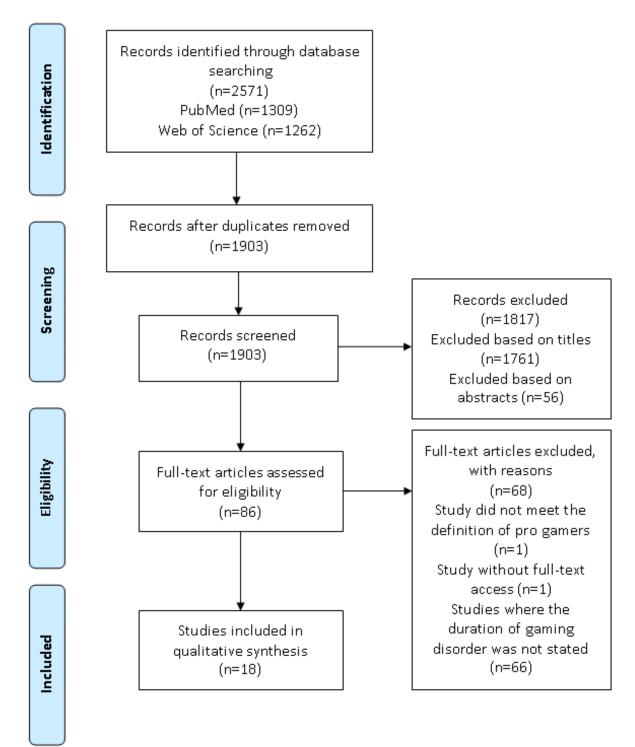
Results

Literature Overview

The searches of PubMed and Web of Science resulted in the identification of 2571 records. After the removal of duplicates, 1903 studies with unique titles were obtained for the screening of titles and abstracts. A total of 1761 studies were removed after the screening of titles, and another 56 studies were removed after the screening of abstracts. After excluding 1817 records, 86 full-text articles were comprehensively reviewed in order to assess their eligibility for inclusion in this review. After conducting assessments based on the inclusion criteria, 68 articles that did not meet the inclusion criteria or did not have full-text access were excluded (Figure 1). Thus, this review included 18 articles. The results of the extracted data from the selected articles are presented in three subsections: (1) information about the study, (2) alterations in brain regions in pro gamers, and (3) alterations in brain regions in individuals with GD.



Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram for the systematic literature review.



Information About the Study

Study Design

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As seen in Table 1 [16,20,25,29-43], 16 studies had a cross-sectional design. One study [16] had a correlational design and one study [25] had a longitudinal design.

 Table 1. Summary of 18 studies included in this review.

Choi et al

Authors; study design	Participant information	Brain-imaging tech- nique	Alterations in brain regions associated with extensive video gaming
Hyun et al [16]; correla- tional	Pro gamers: N=23; all males; mean age 19.8 (SD 1.7) years	Magnetic resonance imaging (MRI)	Cortical thickness in the right superior frontal gyrus, the right superior parietal gyrus, and the right precentral gyrus
Tanaka et al [29]; cross- sectional	 Pro gamers: N=17; all males; mean age 24.1 (SD 2.9) years Age- and educational level-matched control group: N=33; all males; weekly gaming duration was less than 2 hours 	Structural MRI	Gray matter (GM) volume in the right pos- terior parietal cortex
Gong et al [30]; cross- sectional	 Pro gamers: N=27; mean age 23.26 (SD 0.4) years Amateur players: N=30; mean age 22.3 (SD 0.38) years; did not habitually engage in video game playing, and video gaming experience was less than 1 year 	MRI	Functional connectivity (FC) and GM volume in the insular subregions
Gong et al [31]; cross- sectional	 Pro gamers: N=23; all males; mean age 23.3 (SD 4.3) years Amateur players: N=22; all males; mean age 22.3 (SD 3.46) years; video gaming experience was less than 1 year 	Resting-state functional MRI (fMRI)	FC within and between the salience network (SN) and the central executive network (CEN)
Gong et al [20]; cross- sectional	 Pro gamers: N=28; all males; mean age 24.6 (SD 1.4) years Amateurs players: N=30; all males; mean age 24.3 (SD 1.8) years 	Diffusion tensor imag- ing (DTI)	White matter (WM) networks in the pre- frontal network, the limbic system, and the sensorimotor network
Gong et al [25]; longitu- dinal	 Pro gamers: N=20; all males; mean age 21.42 (SD 1.64) years Amateur players: N=20; all males; mean age 22.25 (SD 1.65) years; gaming experience was less than 1.5 years 	Resting-state fMRI at the beginning and end of the study	Amplitude of low-frequency fluctuation (ALFF) in the brain regions of the default mode network (DMN), the CEN, and the SN
Han et al [32]; cross- sectional	 Individuals with gaming disorder (GD): N=20; all males; mean age 20.9 (SD 2) years; mean duration of gaming disorder 4.9 (SD 0.9) years Pro gamers: N=17; all males; mean age 20.8 (SD 1.5) years Age- and educational level-matched healthy controls (HCs): N=18; all males; mean age 20.9 (SD 2.1) years 	MRI	GM volume in cingulate gyrus, thalamus, and occipitotemporal areas
Ko et al [33]; cross- sectional	 Participants with GD: N=15; mean age 24.67 (SD 3.11) years; mean education duration 15.47 (SD 1.56) years Remission subjects from GD: N=15; mean age 24.8 (SD 2.68) years; mean education duration 15.87 (SD 1.41) years HCs: N=15; mean age 24.47 (SD 2.83) years; mean education duration 16 (SD 1.13) years 	Task-based fMRI (the presentation of neutral vs online game-related screenshots)	The bilateral dorsolateral prefrontal cortex (DLPFC), the precuneus, the left parahip- pocampus, the posterior cingulate, the right anterior cingulate, and the left superior parietal lobe
Yuan et al [34]; cross- sectional	 Adolescents with GD: N=18; n=12 males; mean age 19.4 (SD 3.1) years Age- and gender-matched HCs: N=18; daily gaming duration was less than 2 hours 	MRI	Cortical thickness in the left lateral or- bitofrontal cortex, the insula cortex, lingual gyrus, the right postcentral gyrus, the en- torhinal cortex, the inferior parietal cortex, the left precentral cortex, the middle tempo- ral cortices, the precuneus, the middle frontal cortex, and the inferior temporal cortices



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Authors; study design	Participant information	Brain-imaging tech- nique	Alterations in brain regions associated with extensive video gaming
Yuan et al [35]; cross- sectional	 Participants with GD: N=18; n=12 males; mean age 19.4 (SD 3.1) years Age- and gender-matched HCs: N=18; n=12 males; mean age 19.5 (SD 2.8) years; daily gaming duration was less than 2 hours 	Resting-state fMRI	ALFF in brain regions, including major re- gions of the DMN
Ko et al [36]; cross- sectional	 Male subjects with GD: N=26; mean age 24.58 (SD 3.23) years Male HCs: N=23; mean age 24.35 (SD 2.12) years 	Task-state fMRI (go/no-go task)	Activation in the frontostriatal network
Chen et al [37]; cross- sectional	 Individuals with GD: N=15; all males; mean age 24.67 (SD 3.12) years HCs: N=25; all males; mean age 24.47 (SD 2.83) years 	Task-state fMRI (go/no-go task)	Activation in the right supplementary motor area (SMA) or pre-SMA
Ko et al [38]; cross- sectional	 Male adults with GD: N=30; mean age 23.57 (SD 2.5) years Age- and educational level-matched HCs: N=30; mean age 24.23 (SD 2.47) years 	Resting-state fMRI	 GM density in bilateral amygdala FC of amygdala with the left DLPFC, the orbitofrontal lobe (OFL), and the contralateral insula
Cai et al [39]; cross- sectional	 Individuals with GD: N=27; n=23 males; mean age 17.9 (SD 0.9) years Age-, gender-, and educational level-matched HCs: N=30; n=22 males; mean age 18.3 (SD 1.6) years 	MRI	The volume in the striatum
Chen et al [40]; cross- sectional	 Individuals with GD: N=28; all males; mean age 23.64 (SD 2.54) years Age- and educational level-matched HCs: N=28; all males; mean age 24.14 (SD 2.53) years 	Resting-state fMRI	FC between the left insula and the left DLPFC and OFL, and between interhemi- spheric insula
Jin et al [41]; cross-sec- tional	 College students with GD: N=25; n=16 males; mean age 19.12 (SD 1.05) years Age- and gender-matched HCs: N=21; n=14 males; mean age 18.76 (SD 1.81) years 	Resting-state fMRI	 GM volume in the prefrontal regions and the right SMA FC of prefrontal regions with temporal and occipital regions, and between several regions, including the bilateral caudate, the thalamus, the putamen, the insular cortex, and the right SMA
Yuan et al [42]; cross- sectional	 Individuals with GD: N=43; n=32 males; age range 16-22 years; primary internet activity was to play League of Legends Age- and gender-matched HCs: N=44; n=34 males; age range 15-23 years 	Resting-state fMRI	 Volume in the striatum Resting-state FC within the dorsal and ventral striatum networks
Zhai et al [43]; cross- sectional	 Subjects with GD: N=16; n=11 males; mean age 19.1 (SD 1.3) years; primary internet activ- ity was to play League of Legends Age- and gender-matched HCs: N=16; n=11 males; mean age 18.4 (SD 1.9) years 	DTI	The global and local efficiency of WM networks

Participants

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Among the included 18 articles, six articles included pro gamers (Table 1). While pro gamers were compared with amateur video game players who had less gaming experience in five articles [20,25,29-31], one article [16] included pro gamers with varied gaming expertise. One article [32] included both pro gamers and individuals with GD. A total of 11 articles [33-43] included individuals with GD (Table 1). While one article [33] recruited

a remission group in addition to individuals with GD and healthy controls, 10 articles recruited individuals with GD and healthy controls. Moreover, six articles [34,35,39,41-43] included female participants.

Brain-Imaging Techniques

Two studies used diffusion tensor imaging and six studies used magnetic resonance imaging to investigate the alterations in brain regions associated with extensive video game playing.

Seven studies used resting-state functional magnetic resonance imaging (fMRI) and three studies used task-state fMRI. Tasks that were used in the studies included the presentation of gaming cues [33] and tasks to measure cognitive control [36,37] (Table 1).

Alterations in Brain Regions in Pro Gamers

As seen in Table 1, pro gamers showed structural alterations in brain regions that were different from those in amateur players and individuals with GD. Pro gamers showed higher GM volume in the left cingulate gyrus [32], the right posterior parietal cortex (PPC) [29], and insula subregions, including the left long insular gyrus and central insular sulcus [30], compared to amateur players. The GM volume in the left cingulate gyrus was also higher in pro gamers than in individuals with GD [32]. Moreover, pro gamers showed decreased GM volume in some brain regions, including in the left middle occipital gyrus and the right inferior temporal gyrus, compared to healthy controls [32]. The GM volume in the left thalamus was lower in pro gamers than in individuals with GD [32]. Moreover, the pro gamers with longer career lengths were shown to have a thicker cortex in the right superior frontal gyrus, right superior parietal gyrus, and right precentral gyrus, and the pro gamers who won more in the competitions were shown to have a thicker PFC [16].

Pro gamers also showed functional alterations in brain regions. They showed increased amplitude of low-frequency fluctuation (ALFF) in brain regions of the default mode network (DMN), the central executive network (CEN), and the salience network (SN) compared to amateur players [25]. That is, pro gamers showed increased ALFF in the posterior cingulate cortex (PCC), the right angular gyrus, the right DLPFC, the anterior cingulated cortex (ACC), and the right anterior insula [25]. The WM network in the prefrontal regions, the limbic system, and the sensorimotor network was also more integrated in pro gamers, compared to amateur players [20]. Moreover, pro gamers, compared to amateur players, showed more functionally connected networks, not only between anterior and posterior insula subregions [30] but also within and between the SN and CEN [31].

Alterations in Brain Regions in Individuals With GD

Individuals with GD showed structural alterations compared to healthy controls and pro gamers (Table 1). Compared to both pro gamers and healthy controls, individuals with GD showed increased GM volume in the left thalamus [32]. Compared to healthy controls, individuals with GD showed increased volume in the striatum (ie, right caudate and right nucleus accumbens [NAc]) [39,42]; they also had a thicker cortex in the left precentral cortex, the middle temporal cortices, the precuneus, the middle frontal cortex, and the inferior temporal cortices [34]. Moreover, individuals with GD showed decreased GM volume in some brain regions compared to healthy controls. Individuals with GD were found to have decreased GM volume in the amygdala [38], the temporal-occipital cortex (ie, the right middle occipital gyrus and the left inferior occipital gyrus) [32], the prefrontal regions (ie, the bilateral DLPFC, the orbitofrontal cortex [OFC], and the ACC), and the right supplementary motor area (SMA) [41]. The cortical thickness in the left lateral OFC,

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the insula cortex, the lingual gyrus, the right postcentral gyrus, the entorhinal cortex, and the inferior parietal cortex was also found to be decreased in individuals with GD compared to healthy controls [34].

Individuals with GD showed functional changes in brain regions in the resting state compared to healthy controls. The short path length in individuals with GD was found to be increased [43]. Individuals with GD, compared to healthy controls, also showed increased ALFF in the left medial OFC, the left precuneus, the left SMA, the right parahippocampal gyrus, and the bilateral middle cingulate cortex [35]. Moreover, individuals with GD showed increases in the resting-state functional connectivity (FC), not only between the bilateral amygdala and the contralateral insula [38] but also between the bilateral insula [40].

Individuals with GD showed decreased resting-state activation or FC in some brain regions. The global and local efficiency of WM networks was found to be reduced in individuals with GD [43]. The FC between prefrontal regions (ie, ACC, OFC, and DLPFC) and temporal and occipital regions (ie, pallidum, thalamus, caudate, and putamen) also decreased in individuals with GD compared to healthy controls [41]. Moreover, individuals with GD, compared to healthy controls, showed both reduced FC in the dorsal and ventral striatum networks (ie, FC between the right caudate and the DLPFC, and FC between the right NAc and the OFC) [42] and decreased FC of the left insula with the left DLPFC and the orbitofrontal lobe (OFL) [40]. The FC of the bilateral amygdala with the left DLPFC and the FC of the right amygdala with the OFL were found to be decreased in individuals with GD [38].

Additionally, studies that used task-based fMRI showed that individuals with GD showed increased activation in the frontostriatal network (ie, bilateral OFL, ACC, left putamen, right DLPFC, and middle temporal lobe) [36] but decreased activation in the right SMA or pre-SMA [37] compared to healthy controls in the task that required inhibition. Furthermore, when gaming cues were presented, individuals with GD showed higher activation in the bilateral DLPFC, the precuneus, the left parahippocampus, the posterior cingulate, the right anterior cingulate, and the left superior parietal lobe compared to healthy controls [33]. Individuals with GD also showed higher activation in the right DLPFC, the left parahippocampus, and the left middle temporal gyrus in response to gaming cues compared to the remission group of participants [33].

Discussion

Overview

This review aimed to explore the association between extensive video game playing and changes in cognitive functions by focusing on pro gamers and individuals with GD. That is, this study systematically reviewed the brain-imaging studies that included pro gamers and/or individuals with GD. By following PRISMA guidelines, 18 studies were included in this review. Based on selected studies, it was found that pro gamers and individuals with GD showed different structural and functional

alterations in brain regions, despite the comparable level of gaming engagement.

Primary Results of the Studies Including Pro Gamers

Results showed both increased and decreased GM volume in brain regions of pro gamers. Pro gamers, compared to both healthy controls and individuals with GD, showed a thicker cortex in the left cingulate cortex, which is involved in the maintenance of attention and control over executive functioning [32]. Pro gamers also showed structural enhancement in brain regions that are involved in visual working memory, attention, and sensorimotor function (eg, the right PPC and insular subregions) compared to amateur video game players [29,30]. The increased GM volume in the right PPC was positively associated with better visual working memory performance in pro gamers [29], and the increased GM volume in insular subregions was suggested to contribute to functional integration within insular regions [30]. However, pro gamers showed decreased GM volume in occipitotemporal regions for visual processing (eg, the left middle occipital gyrus) compared to amateur players, and they showed decreased GM volume in the left thalamus, which is involved in reward processing, compared to individuals with GD [32]. These structural alterations in pro gamers suggested that pro gamers did not show impaired reward processing but showed enhanced cognitive function (eg, cognitive control and visual working memory), along with reduced cortical thickness in brain regions that are involved in the processing of visual stimuli. Moreover, since pro gamers-who reported longer video game experience or higher rates of winning in competitions-were found to show a thicker cortex in frontal regions for cognitive flexibility (eg, the right superior frontal gyrus) [16], it was suggested that gaming expertise seemed to modulate the association between extensive video game experience and cognitive enhancement in pro gamers.

Results also showed functional enhancement in brain regions of pro gamers. Pro gamers showed more functional integration between anterior and posterior insular subregions [30] and within and between the SN and the CEN [31]. That is, the attention and sensorimotor functions were more coordinated in pro gamers [30], and they showed improvement in the ability to process information [31]. The plasticity of WM networks in brain regions for sensorimotor function and cognitive control (eg, the sensorimotor network and the prefrontal network) was also more enhanced in pro gamers compared to amateur players [20]. Pro gamers were found to integrate information more efficiently by showing nodal and global enhancement in WM networks [20]. Moreover, it was found that activation in the DMN (eg, PCC), the CEN (eg, the right DLPFC), and the SN (eg, the ACC), which was higher in pro gamers than in amateur players at the beginning of the study, decreased after the pro gamers were asked not to play video games for 1 year [25]. The results of that longitudinal study suggested that extensive video game playing seemed to enhance the development of brain regions [25]. Consistent with structural alterations in pro gamers, when compared to amateur players, pro gamers showed functional enhancements within and between the brain regions that are involved in attention, visual processing, sensorimotor function, and cognitive control.

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Primary Results of the Studies Including Individuals With GD

Individuals with GD were found to show structural alterations in frontostriatal regions. While the cortical thickness of the brain regions that were associated with executive function and decision making (eg, the DLPFC, the OFC, and the amygdala) decreased in those with GD [34,38,41], the volumes of the brain regions for reward processing (eg, the striatum) increased in individuals with GD as compared to healthy controls [39,42]. Individuals with GD also showed increased volumes in the brain region that is involved in the expectation of rewards (ie, the left thalamus) compared to pro gamers [32]. The structural alterations in brain regions of individuals with GD suggested that they showed impairment in executive functioning and higher levels of craving to play video games [34]. In particular, the increased volume in the striatum was found to be associated with impairment of cognitive control [39]. However, individuals with GD showed increased volume in the middle temporal cortex, which is involved in the acquisition of skills, compared to healthy controls [34]. That is, despite impaired cognitive control in individuals with GD, their higher level of video game playing experience, compared to that of healthy controls, was associated with improved skills.

Individuals with GD were found to show not only structural alterations but also functional alterations compared to healthy controls. Individuals with GD showed reduced levels of integration within WM networks [43]. The increased short path length [43] and increased resting-state FC within and between the bilateral insula and the amygdala [38,40] in individuals with GD were found to be associated with a higher level of impulsivity. An increased resting-state activation in certain brain regions (eg, the left medial OFC) [35] was also associated with impairment of cognitive control in individuals with GD. Moreover, the CEN (eg, DLPFC) and the reward circuits (eg, amygdala) in individuals with GD, compared to healthy controls, were found to be less functionally integrated in the resting state [38,40]. That is, the FC within the frontostriatal networks, which are involved in the processing of motivation and cognitive control, was found to decrease in individuals with GD during the resting state [41,42]. It was suggested that they showed both higher levels of impulsivity and impaired cognitive control.

Consistent with the resting-state functional alterations in individuals with GD, the task-state fMRI studies showed impairment of cognitive control in individuals with GD. When the execution of cognitive control was required, individuals with GD showed increased activation in the frontostriatal networks, unlike healthy controls who showed increased activation only in the DLPFC [36]. That is, not only frontal regions but also striatal regions were activated in individuals with GD for response inhibition. However, activation in the brain region that is involved in executing proper behavior (eg, pre-SMA) decreased in individuals with GD in the cognitive control task [37]. Moreover, when the gaming cue was presented, individuals with GD showed increased activation in brain regions that are involved in the processing of affective or salient stimuli and craving (eg, the bilateral DLPFC, the posterior cingulate, and the anterior cingulate) compared to healthy controls [33]. The remission group, who showed lower

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levels of craving video game playing than individuals with GD, also showed higher activation in the brain region for visual attention (ie, the superior parietal lobe), though the difference in activation between the remission group and healthy controls was not significant [33].

Furthermore, there was a difference in structural and functional alterations in brain regions among individuals with GD. Individuals who reported more severe levels of GD showed an increased volume in the NAc, which is involved in the processing of rewards [39]. Individuals who reported having GD for a longer duration showed not only an increased volume in the left precentral gyrus and precuneus but also a decreased volume in the lingual gyrus [34]. They also showed more abnormal resting-state activation in the left medial OFC and the left precuneus [35]. Moreover, the level of self-control in individuals with GD was negatively associated with activation of the bilateral caudate nucleus [36]. These findings suggest that it was plausible that the severity or duration of GD and impaired self-control mediated the association between extensive video game playing and changes in cognitive function.

Taken together, pro gamers and individuals with GD showed different structural and functional alterations in brain regions despite comparable extensive engagement in video game playing. Pro gamers showed enhancement in cognitive function (eg, attention and visuomotor function) and better cognitive control. Unlike pro gamers, individuals with GD showed impairment in cognitive control and higher levels of craving video game playing. They also showed improvement in the acquisition of skills. Moreover, factors that seemed to modulate the association of extensive video game playing with changes in cognitive function (ie, gaming expertise, duration or severity of GD, and level of self-control) were identified. That is, although individuals with GD showed impaired executive functioning, extensive video game playing was associated with enhancement in cognitive function in not only pro gamers but also in those with GD.

Limitations

There were three limitations in this review. The first limitation was the limited number of studies. Only a few studies were identified that included pro gamers. Most studies that included individuals with GD did not consider or state the duration of GD despite its importance. According to the WHO's

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announcement, the diagnosis of GD should be based on the report of symptoms for more than 12 months [7]; only a subgroup of individuals were found to show persistent symptoms of GD over 12 months [44]. That is, more studies should be conducted that include pro gamers and individuals who had reported GD for more than 1 year. The second limitation was the design of the studies. Although one study had a longitudinal design, most included studies had cross-sectional designs. More brain-imaging studies with longitudinal designs should be conducted, as these would be helpful in tracking alterations in brain regions and in understanding causality in the association between extensive video game playing and changes in cognitive function. The last limitation was the comparison group. Most included studies recruited participants who did not habitually play video games as the comparison group. There was a group of highly engaged video game players who were not pro gamers and did not show any symptoms of GD [45]; therefore, comparing alterations in brain regions between individuals with GD and highly engaged video game players or pro gamers would be helpful to deepen the understanding of the effect of video game playing on structural and functional alterations in brain regions and to identify the mediating factors of their association. Further studies should be conducted while considering these limitations.

Conclusions

Pro gamers and individuals with GD showed differences in structural and functional alterations in certain brain regions. While pro gamers showed enhancement in cognitive functions (eg, cognitive control), individuals with GD showed impaired cognitive control despite the acquisition of better skills compared to non-video game players. Mediating factors (eg, the duration of GD) were found to be associated with different alterations of brain regions in pro gamers and individuals with GD. That is, it was suggested that various factors seemed to modulate the association of extensive video game playing with changes in cognitive function. However, a limited number of brain-imaging studies included pro gamers and/or individuals who reported symptoms of GD for more than 1 year. Thus, more studies that include pro gamers and/or individuals with GD, as well as more diverse comparison groups, and ones that longitudinally track alterations in brain regions should be conducted in the future.

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Authors' Contributions

MHP was the principal investigator and was involved in study conception, study design, data capture, data analysis, and interpretation of the results. EC was the primary writer of the manuscript and was involved in study conception, data capture, data analysis, and interpretation of the results. SHS was involved in study conception, data analysis, and editing of the manuscript. JKR, KIJ, YH, and JK were involved in data capture, data analysis, and editing of the manuscript.



Conflicts of Interest

None declared.

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Abbreviations

ACC: anterior cingulate cortex AI: artificial intelligence ALFF: amplitude of low-frequency fluctuation **CEN:** central executive network **DLPFC:** dorsolateral prefrontal cortex DMN: default mode network FC: functional connectivity fMRI: functional magnetic resonance imaging GD: gaming disorder **GM:** gray matter ICD-11: International Classification of Diseases, 11th Revision NAc: nucleus accumbens **OFC:** orbitofrontal cortex **OFL:** orbitofrontal lobe **PCC:** posterior cingulate cortex **PFC:** prefrontal cortex **PHR:** personal health record **PPC:** posterior parietal cortex PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses SMA: supplementary motor area **SN:** salience network WHO: World Health Organization WM: white matter

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Original Paper

Using Visual Guides to Reduce Virtual Reality Sickness in First-Person Shooter Games: Correlation Analysis

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Abstract

Background: The virtual reality (VR) content market is rapidly growing due to an increased supply of VR devices such as head-mounted displays (HMDs), whereas VR sickness (reported to occur while experiencing VR) remains an unsolved problem. The most widely used method of reducing VR sickness is the use of a rest frame that stabilizes the user's viewpoint by providing fixed visual stimuli in VR content (including video). However, the earth-fixed grid and natural independent visual background that are widely used as rest frames cannot maintain VR fidelity, as they reduce the immersion and the presence of the user. A visual guide is a visual element (eg, a crosshair of first-person shooter [FPS]) that induces a user's gaze movement within the VR content while maintaining VR fidelity, whereas there are no studies on the correlation of visual guide with VR sickness.

Objective: This study aimed to analyze the correlation between VR sickness and crosshair, which is widely used as a visual guide in FPS games.

Methods: Eight experimental scenarios were designed and evaluated, including having the visual guide on/off, the game controller on/off, and varying the size and position of the visual guide to determine the effect of visual guide on VR sickness.

Results: The results showed that VR sickness significantly decreased when visual guide was applied in an FPS game. In addition, VR sickness was lower when the visual guide was adjusted to 30% of the aspect ratio and positioned in the head-tracking direction.

Conclusions: The experimental results of this study indicate that the visual guide can achieve VR sickness reduction while maintaining user presence and immersion in the virtual environment. In other words, the use of a visual guide is expected to solve the existing limitation of distributing various types of content due to VR sickness.

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KEYWORDS

virtual reality; motion sickness; VR sickness; visual guide; VR fidelity

Introduction

Recently, virtual reality (VR) content based on head-mounted display (HMD) has been expanded to various industrial fields such as sports, medical care, education, and social network. Moreover, such content has been used in video games. However, most users have experienced "VR sickness" while using HMD-based VR content. VR sickness has symptoms similar to motion sickness, including nausea, oculomotor discomfort, and

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disorientation caused while experiencing an HMD-based VR [1]. To investigate the causes of VR sickness, various theories are being studied in a cognitive science approach. The popular sensory conflict theory [1] proposes that VR sickness is induced by an inconsistency between the visual and the vestibular or proprioceptive senses. In particular, the vection that occurs during the VR experience is the biggest cause of sensory conflict [2-4]. Additionally, the postural instability theory posits that VR sickness is caused by changes in human balance [5]. Furthermore, VR sickness may also be induced by various

individual characteristics, such as age, gender, prior user experience, concentration, medical history, mental rotation, perceptual style, and dominant eye [6].

Until now, various studies have only been partially successful in attempting to reduce HMD-induced VR sickness by focusing on the device and the content. A typical method focusing on the device is the optimization of the delay time caused by head movement tracking response, rendering, image transmission, and display response speed [7]. Studies have also been conducted to reduce VR sickness in device elements such as resolution, frame rate, viewing angle, binocular parallax, and flicker fusion frequency [8-13]. Recent studies have evaluated methods focusing on content. These methods investigated the use of dynamic blurring with retinal tracking [14], optical flow reduction of peripheral vision [15], field of view control [16], and viewpoint snapping [17].

However, there is a disadvantage that these dynamic blurring methods limit the user's experience. Therefore, in other studies, VR sickness has been reduced by adding fixed or dynamic visual stimuli regardless of the motion of objects in the content [18-20]. This visual stimulus includes a rest frame that serves as a reference frame designed to induce a user's effective spatial perception. In particular, VR sickness was reduced by applying a virtual human nose as a rest frame to the content [21]. However, this artificial rest frame could not maintain VR fidelity, as it reduced user presence and immersion and provided a strong sense of heterogeneity to the user. VR sickness has further been reduced using the earth-fixed grid or the natural independent visual background (IVB) with rest frames, whereas it did not increase the presence and immersion of the user [22,23]. Particularly, VR sickness in first-person shooter (FPS)

games was reduced when cockpits were added to the IVB, while the VR fidelity of the users was disturbed [24].

To overcome the problem of IVB, we discuss another visual element applied to VR FPS games called the *visual guide*, which refers to a visual element that induces a user's gaze movement within VR content. To our knowledge, there is no study investigating the effect of visual guide on the reduction of VR sickness while maintaining VR fidelity in VR FPS games. Therefore, in this study, we investigated how VR sickness reduction is affected by visual guide in FPS games. To do this, we performed experiments on a VR FPS game consisting of eight scenarios, including visual guide on/off, game controller on/off, and varying the size and position of the visual guide.

Methods

Visual Guide Design in VR FPS Games

In this section, we describe the visual guide used in this study. In VR FPS games, crosshairs, character path indicators, and maps are used as visual guides to provide situational awareness for the user to spatially determine their position in a virtual environment. In this study, we used crosshair as a visual guide to induce a user's gaze movement while maintaining VR fidelity in a space-environment FPS game. Crosshair is a 2D image composed of color, shape, line thickness, depth, size, and position elements. Figure 1 shows an example of crosshair used in the VR FPS game. The brilliant color, complex shape, bold line, and depth of a visual guide can reduce the presence and immersion of the user by increasing the visual stimulation [18]. Therefore, these elements are fixed, and they are designed as a white, circle, 1.0 px, and 0, respectively by referring to commercial VR FPS games. Table 1 shows various crosshair in commercial VR FPS games.

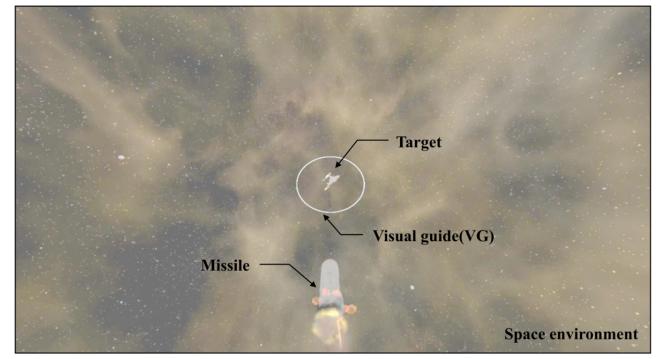


Figure 1. Example of crosshair used in the virtual reality first-person shooter game. HMD: head-mounted display; SSQ: Simulator Sickness Questionnaire.

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Table 1. Various crosshair in commercial virtual reality (VR) first-person shooter (FPS) games.

No.	Name	Crosshair image
1	Super Stardust Ultra VR	×
2	End Space VR	×
3	Elite: Dangerous	×
4	Gunjack	×
5	Sublevel Zero	×
6	VR Galaxy Wars	×
7	Fusion Wars	×
8	EVE: Valkyrie	×
9	Rez Infinite	×
10	EVERSPACE	×

The size and position of the visual guide is considered a variable for VR sickness measurements. Therefore, we designed it as a variable. First, the size was designed to be 0%, 10%, 30%, and 50% of the size of the aspect ratio (with 0% implying that there is no visual guide). Second, the position was synchronized to "none," "head-tracking direction with HMD (H)," "movement direction with game controller (G)," and "head-tracking direction with HMD and movement direction with game controller (H & G)." That is, if the position is "none," then there is no visual guide. If the position is "H," then the position of the visual guide is synchronized with the head-tracking direction by the HMD operation. If the position is "G," then the position of the visual guide is synchronized in the direction of forwarding movement, pitch, yaw, and roll rotation by the game controller operation. Finally, if the position is "H & G," then the position of the visual guide is synchronized with the head-tracking direction by the HMD operation and the direction of forwarding movement, pitch, yaw, and roll by the game controller operation.

Experiments

In this section, we describe the experimental environment and methods used to examine the effect of visual guide on VR sickness. The experimental environment consisted of the participant, experiment device, and experimental content.

We used a paired t test method to analyze the results. This requires the experimental results to approximate the normal distribution. Therefore, the minimum sample size was set to 30 to satisfy a central limit theorem [25]. Eventually, 32 individuals (male: 23, female: 9) participated in the experiment.

All the participants were in their twenties without any HMD VR experience, and none had a medical history of hearing or

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balancing disorder. We received an institutional review board approval for testing of VR sickness by KOREATECH.

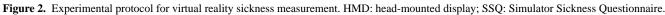
Before performing the experiment, each participant was administered a preliminary questionnaire (M1) comprising the Simulator sickness Questionnaire (SSQ) items, such as measurement, reliability, validity, score interpretation, etc [26,27], to evaluate their current motion sickness state. After the SSQ (M1) was completed, the participant wore the HMD, and the experiment was initiated.

The experimental equipment used was a head-tracking interface device HTC VIVE HMD and an Xbox One Wireless Controller. With these devices, the participants played the VR FPS game and answered the SSQ. The game controller has several functionalities including forward movement; rotation based on pitch, yaw and roll axes; missile launch targeting; and selection of answers in the SSQ. Experimental content is a VR FPS game in space environment because it easily causes VR sickness due to multiaxis movement. The user uses the HMD and the game controller operations to trace the enemy target and score it with the missile.

The experimental protocol consisted of preliminary experiment (M2), eight experimental scenarios (S1–S8), SSQ, and rest videos. Figure 2 shows the experimental protocol for VR sickness measurement. In the preliminary experiment (M2), the participants were taught how to operate the HMD and the game controller. The eight experimental scenarios were designed to measure VR sickness. If a participant is exposed to VR content for a long time, the VR sickness level will potentially increase. [28] Therefore, each scenario was composed of content of 60 s for the safety of the participants. These eight experimental

scenarios were designed to have the visual guide on/off, the game controller on/off, and to vary sizes and positions of the visual guide to determine its effect on VR sickness. Table 2 shows the features of these eight scenarios.

In addition, the experimental scenarios were randomly placed and used to ensure reliability. For 240 s after each experimental scenario (including M2) ended, participants entered SSQ and watched the rest video to relax VR sickness. All participants were equally exposed to this rest video. When the experiment was completed, the SSQ data for the eight scenarios were automatically saved. From the VR sickness measurement experiment, preexperimental SSQ data (M1) and postexperimental SSQ data (S1-S8) were collected for each participant.



HMD Wisual guide(VG) M2, S1-S8 SSQ Rest

SSQ & Rest

	¥		÷		÷		¥		÷		÷		÷		÷		÷
120s	240s	60s	240s	60s	240s	60s	240s	60s	240s	60s	240s	60s	240s	60s	240s	60s	240s
M2		S1		S2		S3		S4		S5		S6		S7		S8	

Table 2. Features of eight scenarios used in the experiment.

Feature	S 1	S2	S 3	S4	S 5	S 6	S 7	S 8
Game controller	Off	On	On	On	On	On	On	On
Visual guide size (%)	0	0	0	10	30	50	30	30
Visual guide position	None	None	None	H ^a	Н	Н	G ^b	H & G ^c

^aH: head-tracking direction with head-mounted display.

^bG: movement direction with game controller.

^cH & G: head-tracking direction with head-mounted display and movement direction with game controller.

Using these experimental protocols, we conducted two experiments to examine the effect of the visual guide on VR sickness. Experiment I investigated the effect of visual guide on/off on VR sickness. In the first step of experiment I, we investigated the effect of VR sickness when the visual guide is on/off with the game controller off. Thus, the SSQ data of S1 and S2 were used for the comparison of VR sickness. Figure 3 shows the S1 and S2 used in the first step of experiment I.

In the second step of experiment I, we investigated the effect of visual guide on/off with the game controller on. Thus, the SSQ data of S3 and S5 were used for the comparison of VR sickness. Figure 4 shows the S3 and S5 used in the second step of experiment I. Experiment II investigated the effects of the visual guide's size and position on VR sickness. In the first step of experiment II, we investigated the effect of the visual guide's size with the game controller on. Thus, the SSQ data of S4, S5, and S6 and the SSQ data of S3 were used for the comparison of VR sickness. Figure 5 shows the S3, S4, S5, and S6 used in the first step of experiment II.

In the second step of experiment II, we investigated the effect of the visual guide's position with the game controller on. Thus, the SSQ data of S5, S7, and S8 using a visual guide with different positions at 30% of the size of the aspect ratio and the SSQ data of S3 were used for comparison of VR sickness. Figure 6 shows the shows S3, S5, S7, and S8 used in the second step of experiment II.

Figure 3. S1 and S2 used in the first step of experiment I. VG: visual guide.

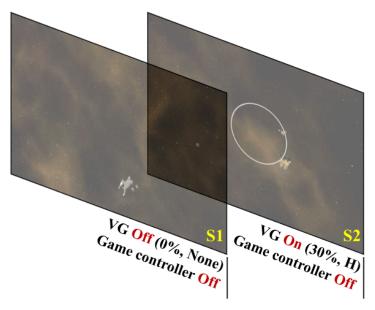


Figure 4. S3 and S5 used in the second step of experiment I. VG: visual guide.

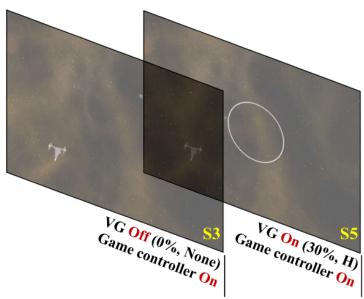




Figure 5. S3, S4, S5, and S6 used in the first step of experiment II. VG: visual guide.

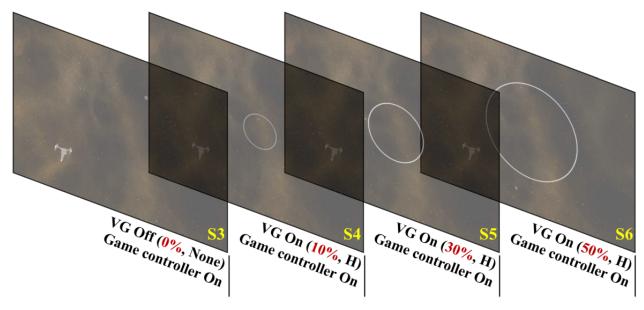
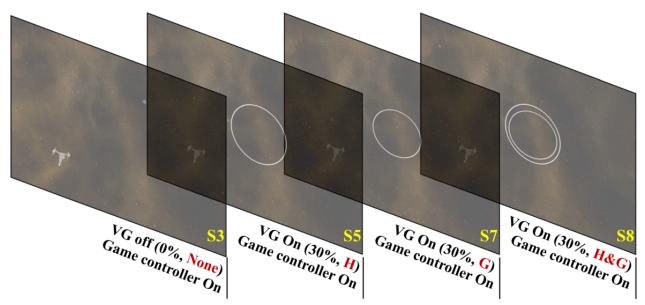


Figure 6. S3, S5, S7, and S8 used in the second step of Experiment II. VG: visual guide.



Results

Overview

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First, we compared the SSQ preexperiment (M1) and postexperiment (S1-S8) data to verify that the experimental protocol for VR sickness measurement was well designed. From the paired *t* test results, a significant difference was observed in VR sickness between M1 and S1-S8. Significantly higher nausea and disorientation symptoms were noted in S1-S8 than in M1. Hence, we confirmed that the participants had experienced nausea and disorientation. In addition, oculomotor discomfort in S1-S8 did not significantly increase because many participants had eye fatigue from M1. From the different SSQ values before and after VR exposure, the increase in the values of nausea and disorientation symptoms of the participants was

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confirmed. It was concluded that the scenarios for the VR sickness experiment were appropriately produced.

Experiment I: Effects of Visual Guide On/Off

In the first step of experiment I, the results of the paired t test showed no significant difference in VR sickness with respect to visual guide on/off when game controller was off; there was a negligible difference in nausea, oculomotor discomfort, disorientation, and total score values. In other words, there was no effect of visual guide with game controller off (watching video) on VR sickness. Table 3 shows the results of the paired t test of visual guide on/off with game controller off. Figure 7 shows the results of the first step of experiment I (ie, difference in VR sickness with respect to visual guide on/off with game controller off).

In the second step of Experiment I, the paired t test showed a significant difference in VR sickness with visual guide on/off and game controller on: nausea and total score values were significantly decreased, whereas oculomotor discomfort and disorientation values had no significant differences. Table 4

shows the results of the paired *t* test of visual guide on/off with the game controller on. Figure 8 shows the results of the second step of Experiment I (difference in VR sickness of visual guide on/off with game controller on).

Table 3. Results of the paired t test of the visual guide on/off with game controller off.

Scenario (state)	Simula	Simulator Sickness Questionnaire											
	Nausea	l		Oculon	Oculomotor discomfort			Disorientation			Total score		
	Score	t (df)	P value	Score	t (df)	P value	Score	t (df)	P value	Score	t (df)	P value	
S1 (visual guide off)	8.65	N/A ^a	N/A	12.08	N/A	N/A	17.84	N/A	N/A	14.14	N/A	N/A	
S2 (visual guide on)	8.65	0 (31)	>.99	13.50	649 (31)	.52	16.97	.360 (31)	.72	14.61	235 (31)	.82	

^aN/A: not applicable.

Figure 7. Results of the first step of experiment I (difference in virtual reality sickness with respect to visual guide on/off with game controller off). SSQ: Simulator Sickness Questionnaire; VG: visual guide.

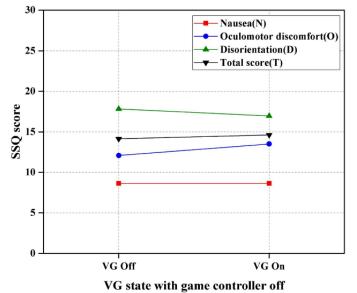


Table 4. Results of the paired *t* test of the visual guide on/off with game controller on.

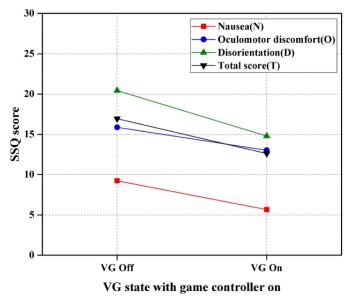
Scenario (state)	Simul	Simulator Sickness Questionnaire										
	Nausea			Oculomotor discomfort			Disorientation			Total score		
	Score	t (df)	P value	Score	t (df)	P value	Score	t (df)	P value	Score	t(df)	P value
S3 (visual guide off)	9.24	N/A ^a	N/A	15.87	N/A	N/A	20.45	N/A	N/A	16.95	N/A	N/A
S5 (visual guide on)	5.66	2.547 (31)	.02 ^b	13.03	1.359 (31)	.18	14.79	1.815 (31)	.08	12.62	2.183 (31)	.04

^aN/A: not applicable.

^bItalicized values indicate statistical significance.



Figure 8. Results of the second step of experiment I (difference in virtual reality sickness of visual guide on/off with game controller on). SSQ: Simulator Sickness Questionnaire; VG: visual guide.



Experiment II: Effect of Visual Guide Size and Position

In the first step of Experiment II, the paired *t* test showed that there was a significant difference in VR sickness with the size of visual guide used in S5: nausea and total score values were significantly decreased, whereas oculomotor discomfort and disorientation values had no significant differences. However, there was no significant difference in VR sickness with the size of visual guide used in S4 and S6. Table 5 shows the results of the paired *t* test of the visual guide size with the game controller on. As shown in Figure 9, VR sickness was lower than that observed with other sizes when the visual guide was 30% of the size of the aspect ratio. Figure 9 shows the results of the first step of Experiment II (ie, difference in VR sickness with respect to the visual guide size when the game controller was on).

In the second step of Experiment II, the paired t test showed that there was a significant difference in VR sickness with the position of visual guide used in S5: nausea and total score values were significantly decreased, whereas oculomotor discomfort and disorientation values had no significant differences. However, there was no significant difference in VR sickness with the position of the visual guide used in S7 and S8. Table 6 shows the results of the paired t test of the visual guide position with the game controller on. As shown in Figure 10, VR sickness was lower than that observed with other positions when visual guide was in the head-tracking direction. Figure 10 shows the results of the second step of Experiment II (ie, difference in VR sickness with respect to visual guide position when the game controller is on).

Table 5.	Results of th	e paired t test of	visual guide size	with game controller on.
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Scenario (size)	Simulat	Simulator Sickness Questionnaire											
	Nausea				Oculomotor discomfort			Disorientation			Total score		
	Score	t (df)	P value	Score	t(df)	P value	Score	t (df)	P value	Score	t (df)	P value	
S3 (0%)	9.24	N/A ^a	N/A	15.87	N/A	N/A	20.45	N/A	N/A	16.95	N/A	N/A	
S4 (10%)	7.45	1.063 (31)	.296	12.55	1.422 (31)	.17	16.53	1.359 (31)	.18	13.56	1.674 (31)	.10	
S5 (30%)	5.66	2.547 (31)	.02 ^b	13.03	1.359 (31)	.18	14.79	1.815 (31)	.08	12.62	2.183 (31)	.04	
S6 (50%)	7.16	0.980 (31)	.34	12.79	1.200 (31)	.24	15.23	1.615 (31)	.12	13.21	1.447 (31)	.16	

^aN/A: not applicable.

^bItalicized values indicate statistical significance.



Figure 9. Results of the first step of experiment II (difference in virtual reality sickness with respect to visual guide size when game controller was on). SSQ: Simulator Sickness Questionnaire; VG: visual guide.

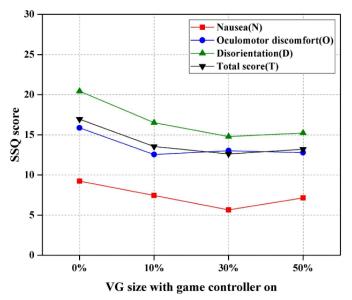


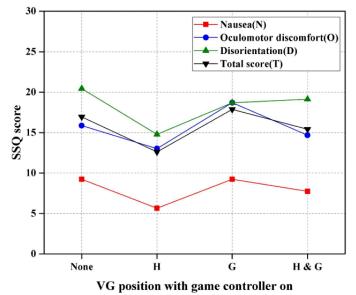
Table 6. Results of the paired t test of the visual guide position with game controller on.

Scenario (position)	Simu	imulator Sickness Questionnaire											
	Nause	ea		Oculo	Oculomotor discomfort			Disorientation			Total score		
	Score	t (df)	P value	Score	t (df)	P value	Score	t (df)	P value	Score	t (df)	P value	
S3 (none)	9.24	N/A ^a	N/A	15.87	N/A	N/A	20.45	N/A	N/A	16.95	N/A	N/A	
S5 (H)	5.66	2.547 (31)	.02 ^b	13.03	1.359 (31)	18	14.79	1.815 (31)	.08	12.62	2.183 (31)	.04	
S7 (G)	9.24	0 (31)	>.99	18.71	-1.099 (31)	.28	18.71	0.436 (31)	.67	17.88	-0.323 (31)	.75	
S8 (H & G)	7.75	0.645 (31)	.52	14.69	0.456 (31)	.65	19.14	0.317 (31)	.75	15.43	0.517 (31)	.61	

^aN/A: not applicable.

^bItalicized values indicate statistical significance.

Figure 10. Results of the second step of Experiment II (difference in virtual reality sickness with respect to visual guide position when game controller is on). SSQ: Simulator Sickness Questionnaire; VG: visual guide.



XSL•FO

Discussion

Principal Findings

In this study, we analyzed the correlation between VR sickness and crosshair, which is widely used as a visual guide in an FPS game. To do this, eight scenarios were designed: visual guide on/off, game controller on/off, and various sizes and positions of visual guide. Experiments were performed using a protocol that consisted of the abovementioned eight scenarios, SSQ, and rest video. Results of Experiment I showed no reduction of VR sickness of the visual guide when the game controller was not operated, whereas there was a reduction when the game controller was operated. While the user operated the HMD and the game controller in the game, the user's gaze movement was synchronized with the motion of the visual guide, thereby reducing VR sickness. The results suggest that visual guide can reduce VR sickness caused by sensory conflicts between content and users when manipulating content. It can be interpreted that visual guide should be used effectively to reduce VR sickness because most VR content requires a game controller. Results of experiment II confirmed a difference in VR sickness with respect to the size and position of the visual guide with game controller operation. VR sickness according to sizes 10% and 50% and positions G and H & G of the visual guide was not significant, whereas VR sickness according to size 30% and position H of the visual guide was significant. Moreover, VR sickness was lower when the visual guide was 30% of the size of the aspect ratio and positioned in the head-tracking direction compared with other sizes and positions. The various sizes of the visual guide reduced nausea, oculomotor discomfort, disorientation symptom, and total score when compared to scenarios when a visual guide was not used. In particular, the visual guide at 30% the size of the aspect ratio further reduced these symptoms to a larger extent than other sizes. The visual guide at 50% of the size of the aspect ratio reduced the disorientation symptom, showing that disorientation was minimized due to the high synergy with the gaze movement when the visual guide size increased. However, if the size of the visual guide increases, the VR fidelity cannot be maintained because it lowers the immersion and presence of the user. The visual guide positioned in the head-tracking direction reduced the symptoms of nausea, oculomotor discomfort, disorientation, and total score more than other positions. As mentioned above, crosshair was the visual guide function to reduce VR sickness, as well as maintain VR fidelity in FPS games.

When recruiting participants, we tried to keep the number of men and women the same. As a result, the number of male (n=23) participants exceeded the number of female (n=9) participants recruited. This may have affected the results of the experiments, as it is reported that men are stronger than women with regard to motion sickness [29]. Therefore, the effects of the proposed method in a same-gender ratio environment should be included in further study.

Conclusions

In this study, we used an experimental protocol consisting of scenarios such as visual guide on/off, game controller on/off, and various sizes and positions of the visual guide to analyze the correlation between VR sickness and crosshair that is widely used as a visual guide in FPS games. VR sickness was found to be significantly correlated with visual guide on/off, and the use of a visual guide was very effective in reducing VR sickness when using a game controller. VR sickness was reduced by synchronizing the user's gaze movement to the motion of the visual guide while operating the HMD and game controller within the game. In addition, VR sickness reduced when the visual guide was 30% of the size of the aspect ratio and positioned in the head-tracking direction. From these findings, it is confirmed that using a visual guide can be an effective method to reduce VR sickness. The experimental results of this study indicate that the visual guide can achieve VR sickness reduction while maintaining user presence and immersion in the virtual environment. In other words, the use of visual guide is expected to solve the existing difficulty in disseminating various VR content due to VR sickness.

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Conflicts of Interest

None declared.

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Abbreviations

FPS: first-person shooter
G: movement direction with game controller
H: head-tracking direction with head-mounted display
H & G: head-tracking direction with head-mounted display and movement direction with game controller
HMD: head-mounted display
IITP: Institute for Information & Communications Technology Promotion
IVB: independent visual background
MSIT: Ministry of Science and ICT
SSQ: Simulator Sickness Questionnaire
VR: virtual reality

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