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Contents

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Editorial

Digital Mental Health and COVID-19: Using Technology Today to Accelerate the Curve on Access and Quality Tomorrow

John Torous[1], MD, MBI; Keris Jän Myrick[2], MS, MBA; Natali Rauseo-Ricupero[1], LCSW; Joseph Firth[3], PhD

[1]Division of Digital Psychiatry, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA, United States
[2]Los Angeles County Department of Mental Health, Los Angeles, CA, United States
[3]Division of Psychology and Mental Health, University of Manchester, Manchester, United Kingdom

Corresponding Author:
John Torous, MD, MBI
Division of Digital Psychiatry
Beth Israel Deaconess Medical Center
Harvard Medical School
Rabb 2, 330 Brookline Ave
Boston, MA, 02215
United States
Phone: 1 61766700
Email: jtorous@bidmc.harvard.edu

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Abstract

As interest in and use of telehealth during the COVID-19 global pandemic increase, the potential of digital health to increase access and quality of mental health is becoming clear. Although the world today must "flatten the curve" of spread of the virus, we argue that now is the time to "accelerate and bend the curve" on digital health. Increased investments in digital health today will yield unprecedented access to high-quality mental health care. Focusing on personal experiences and projects from our diverse authorship team, we share selected examples of digital health innovations while acknowledging that no single piece can discuss all the impressive global efforts past and present. Exploring the success of telehealth during the present crisis and how technologies like apps can soon play a larger role, we discuss the need for workforce training, high-quality evidence, and digital equity among other factors critical for bending the curve further.

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KEYWORDS

digital health; emergency response; telehealth; apps

The COVID-19 crisis and global pandemic has highlighted the role of telehealth and digital tools like apps to offer care in times of need. Many clinicians and patients alike are now realizing the full potential of these digital tools, as they are forced to, for the first time, utilize them to connect in a time when in-person and face-to-face visits are impossible. Harnessing this surge in interest, enthusiasm, and acceptance has immediately been recognized as an opportunity for the field [1]. Thus, the field's next steps will also be critical in ensuring digital health is used today to deliver the best care during the current crisis, ready for any resulting mental health spike following the immediate crisis, and prepared to support future crises as well as care as usual.

In this perspective piece, we draw largely from our team's experience with digital health and recognize the impressive global innovation and research in this space that cannot be captured in any single piece [2-9].

Telehealth is the right solution to deliver mental health care in today's crisis. The only established contraindication to telehealth is a patient not wishing to partake. The temporary waiving of numerous rules and regulations around telehealth by the US government on March 17, 2020, was unprecedented [10]. It was made possible because of the strong and clear evidence base for the efficacy of telehealth and decades of high-quality research [11]. Our Boston team is already using telehealth to

see patients during this current crisis, and feedback from patients as well as colleagues who are just starting to use telehealth suggests that this may be the new normal for many.

Digital therapy programs that can offer courses of evidence-based therapies also have a role in the crisis, given their unique potential for scalability. However, issues of real-world engagement with these programs [12] and high risk of bias in many studies [13] warrant caution in ensuring that plans for encouraging and maintaining meaningful engagement are in place before purchasing these programs or services. Workflow integration issues are also critical to consider when beginning to utilize these types of programs in care settings, and lack of attention here can lead to low uptake and support by both patients and staff [14,15]. New innovations in augmented and virtual reality systems hold great promise [16], but are not yet easily scalable or accessible to all for use in this current crisis.

Tools like apps also have an important role, given their availability and scalability, but with similar caveats. Current evidence for apps for behavior change remains limited [17], and self-help for mental health remains equally limited [18]. Although companies will boast about positive outcomes from randomized controlled trials [19], results from higher-quality studies with valid comparisons groups, proper statistical analysis, and low risk of bias do not tell the same story [18,20]. This is not to say that mobile technologies do not have a role in care. Rather, they possess a tremendous and still largely untapped potential to augment and extend care. Our team in Boston uses mobile apps to better understand the unique lived experience of each patient [21] in both our research as well as our digital clinic. Using apps in conjunction with current care has been shown to greatly increase the efficacy of app interventions [18]; in addition, the sensor, survey, and digital phenotyping data can be used to make more informed, data-driven, and evidence-based decisions about care. Our (JT and NRR) experiences of running a novel "digital clinic" in Boston offering such hybrid care confirm the theoretical advantages with real-world benefits. Now, bringing app data into telehealth visits offers a practical means for patients to share data of their lived experience during this crisis (eg, changing exercise and stress levels or response to new medications) and practice new therapy skills between sessions.

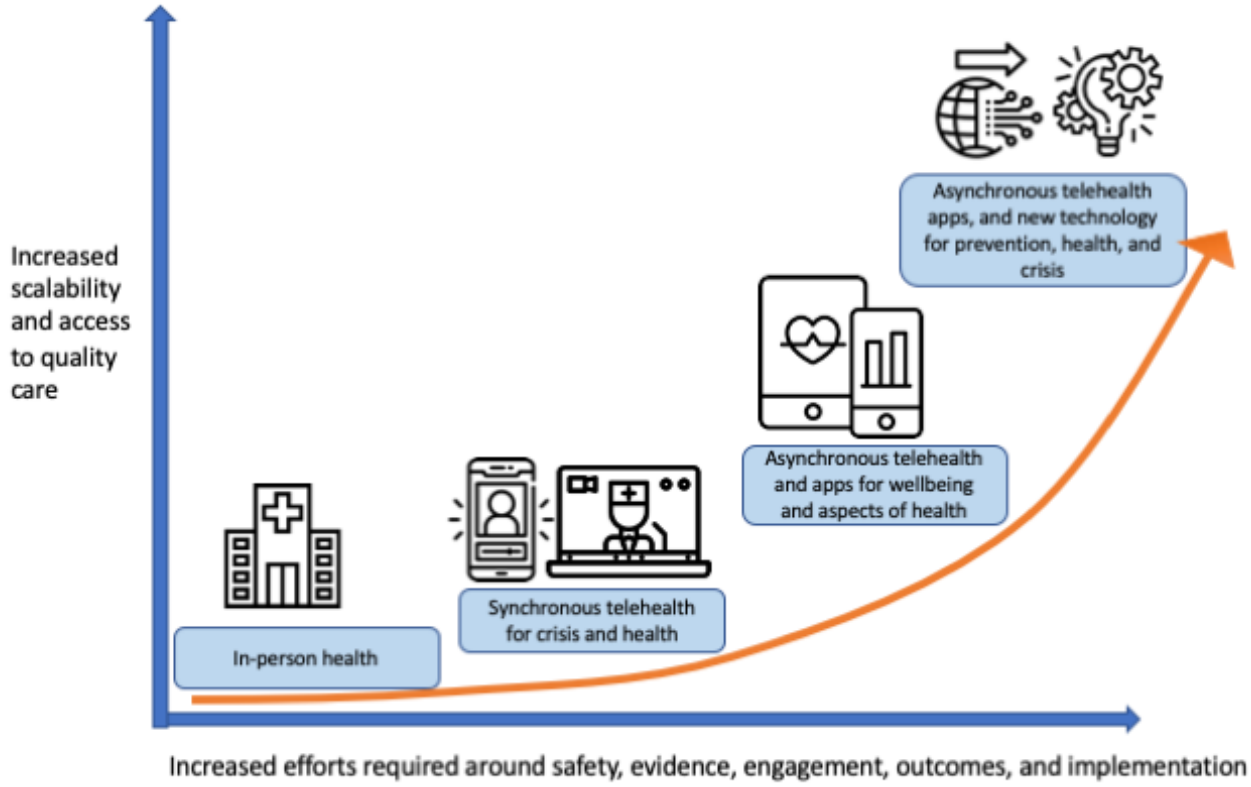
In our experience, the most effective apps are the ones that can be customized to each patient and fit with their personal care goals and needs as well as apps for peer support. Our team is fortunate in that we have created our own app tool (freely available and open source) [22] that we often utilize in research and care, but we realize that different apps are often needed for different situations. Picking from those different apps is challenging as many offer little protection of user data, make exaggerated claims, may be ineffective, and often are quickly abandoned because of usability issues [18,23,24]. Thus, careful attention is warranted when recommending such apps to patients [25]. Thus, relying on static lists of "top apps" or others' scoring systems for selecting apps is often unhelpful and even dangerous, given how out of date these recommendations are [26]. Although many app-evaluation tools exist, our research and development of the American Psychiatric Association's app evaluation framework offers a practical and ready-to-use resource today for both patients and clinicians [27].

One underdeveloped area for digital therapy and mental health apps is the remote delivery of "lifestyle interventions." There is now increasing evidence that lifestyle factors such as physical exercise, sleep, and healthy diet play an important role in self-management of mental health conditions [28]. Consideration of these lifestyle factors for mental health may be particularly important during periods of isolation/prolonged home time, due to the adverse psychological effects of reduced exercise [29] or prolonged sedentary behavior [30], and the ongoing debate about certain types of screen time and social media usage (with quality of online interactions mattering more than time) [31]. Social distancing (which is actually physical space distancing) and self-quarantine will place millions of people at higher risk of disruption to lifestyles that likely benefited their mental health. Nonetheless, digital technologies and smartphone apps may also present a novel platform for the remote delivery of lifestyle interventions [32]. However, there is still a great need for further research to establish how this can be done in an engaging and effective way, to reach those with mental illness.

Looking beyond the immediate consequences of infection with the virus and the mental health impact of self-quarantine and social distancing, a second mental health crisis looms. In times of economic recession, there is often high prevalence of mental health disorders, misuse of substances (or substance use disorder), and deaths from suicide [33]. The need for more mental health services will tax an already overburdened health care system, and digital solutions will be called upon again. Learning from decades of prior research and experience, hybrid solutions that offer a blend of face-to-face and online or app-based treatment will be the most effective solution [14,18].

Ensuring the field advances from the recent interest and use in digital health to further accelerate access and quality of care beyond these immediate and imminent crises is the next challenge. The efforts reducing implementation barriers to video visits (also known as synchronous telehealth) during this current crisis highlight the potential to bend the curve on access to care (Figure 1). Further efforts and investments will be required to now have more access and quality as the field aims to fully utilize technologies like apps and beyond. Investing in the evidence, outcomes, workforce, engagement, and ethical uses of these newer technologies and innovations will allow them to bend the curve and truly deliver on their full potential, just as we are seeing telehealth today benefiting from its legacy of prior investments.

Figure 1. Bending the curve further on access and quality of care will require increased efforts around safety, evidence, engagement, outcomes, and implementation. However, these increased efforts will yield greater returns at each step. The COVID-19 crisis has (at least temporarily) removed implementation barriers to synchronous telehealth through regulatory changes, and the evidence, safety, and engagement were already in place before. The next steps to use apps toward asynchronous telehealth will require continued effort but yield even greater increases in access to high-quality care.



Among some of these new efforts required, a critical one is teaching medical professionals, trainees, and peer support specialists how to use digital and mobile technologies for delivering care. Frameworks for competencies already exist [34,35], and a few have already been implemented. Our personal experience in teaching psychiatry residents about mobile mental health in formal didactics has been positive, and there are already many examples of teaching telehealth [36,37]. Training new care team members around digital health, a role we have termed a digital navigator [38], offers opportunities to easily liaison between digital and classical care. Although training does not offer an immediate solution to the current crisis, it creates the workforce and builds the capacity to support increased access to care for the mental health sequelae of the current crisis and readiness for the next.

Training new providers is, however, only half the picture. Ensuring all patients, especially the most vulnerable ones, have the digital literacy and competency to partake in digital care is a matter of equity and social justice. Many people today find it easy to use their smartphone to set reminders, download apps, join video calls, and connect with peers. However, many people do not, and offering training and skills building is critical to ensure digital health actually offers help to those who need it the most [39]. Our Digital Opportunities for Outcomes in Recovery Services (DOORS) program offers 6-8 weeks of group sessions to develop smartphone skills and competences that have been well received by those with serious mental illness [38] and is freely shareable for others to expand upon. Focusing on and developing programs like this one, which ensures everyone is able to connect and receive care, may not have the attention-grabbing status like artificial intelligence and virtual reality, but such programs are likely of more importance now more than ever.

We must also be aware of the disparities that impact people with low income, those receiving public benefits, and cultural and linguistically diverse communities that may not have access to even basic technology including digital mobile technology. Subsidized phone programs such as Lifeline Assistance may have data, speed, and calling limits. As such, the people we serve may have to make choices about what they will download and how they will use their mobile devices, even though greater opportunities exist. Further, we need to understand how people use their mobile devices—from sharing them with family, housemates, and friends to “renting them for a day” to access funds to meet basic needs—as this will impact privacy as well as research if we are not sure whose hands the phone really is in. During this time of self-quarantine and stay-at-home orders, if one is homeless or unstably housed, charging the phone or laptop is a huge barrier as is finding public or library hotspots. For now, and in the future, we need to prepare the workforce to conduct street psychiatry and outreach work in order to carry chargers and portable hotspots and provide treatment via street psychiatry or connecting with peers or outreach workers. Some people still have and use flip phones (non-smartphones), and this population cannot be ignored. For digital mental health to impact those who are most vulnerable we must be vigilant when addressing these disparities. Ensuring digital data collected for mental health purposes is not repurposed and used for

surveillance or sold for profits/marketing is critical, as any lack of trust or transparency in such a system will erode meaningful use. A focus on equity and ethics will ensure digital health truly increases access to care [40].

The COVID-19 crisis and global pandemic may be the defining moment for digital mental health, but what that definition will be remains unknown. Ensuring the right use of telehealth and app tools today in this crisis and investment in people and training to support them tomorrow during the potential mental health fallout of the current crisis as well as readiness for tomorrow can cement the future of digital mental health as simply mental health. Bending the curve in the right direction (Figure 1) will require funding, research, policy changes, training, and equity, but these investments will continue to yield higher returns at every step.

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Conflicts of Interest

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Abbreviations

DOORS: Digital Opportunities for Outcomes in Recovery Services

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Original Paper

Stakeholder Perceptions of Internet-Delivered Cognitive Behavior Therapy as a Treatment Option for Alcohol Misuse: Qualitative Analysis

Heather D Hadjistavropoulos[1], PhD; Kirsten M Gullickson[1], BA; Shelley Adrian-Taylor[1], MA; Andrew Wilhelms[1], BA; Christopher Sundström[1,2], PhD; Marcie Nugent[1], MSW

[1]Online Therapy Unit, Department of Psychology, University of Regina, Regina, SK, Canada

[2]Department of Clinical Neuroscience, Center for Psychiatric Research, Karolinska Institutet, Stockholm, Sweden

Corresponding Author:
Heather D Hadjistavropoulos, PhD
Online Therapy Unit
Department of Psychology
University of Regina
3737 Wascana Parkway
Regina, SK, S4S 0A2
Canada
Phone: 1 306 585 5133
Email: hadjista@uregina.ca

Abstract

Background: Internet-delivered cognitive behavior therapy (ICBT) has been found to be effective for treating alcohol misuse in research trials, but it is not available as part of routine care in Canada. Recent recommendations in the literature highlight the importance of integrating perspectives from both patient and health care stakeholders when ICBT is being implemented in routine practice settings.

Objective: This study aimed to gain an understanding of how ICBT is perceived as a treatment option for alcohol misuse by interviewing diverse stakeholders. Specifically, the objectives were to (1) learn about the perceived advantages and disadvantages of ICBT for alcohol misuse and (2) elicit recommendations to inform implementation efforts in routine practice.

Methods: A total of 30 participants representing six stakeholder groups (ie, patients, family members, academic experts, frontline managers, service providers, and health care decision makers) participated in semistructured interviews. To be included in the study, stakeholders had to reside in Saskatchewan, Canada, and have personal or professional experience with alcohol misuse. Interviews were transcribed verbatim, anonymized, and analyzed using thematic analysis.

Results: Stakeholders identified numerous advantages of ICBT for alcohol misuse (eg, accessibility, convenience, privacy, relevance to technology-based culture, and fit with stepped care) and several disadvantages (eg, lack of internet access and technological literacy, isolation, less accountability, and unfamiliarity with ICBT). Stakeholders also provided valuable insight into factors to consider when implementing ICBT for alcohol misuse in routine practice. In terms of intervention design, stakeholders recommended a 6- to 8-week guided program that uses Web-based advertising, point-of-sale marketing, and large-scale captive audiences to recruit participants. With regard to treatment content, stakeholders recommended that the program focus on harm reduction rather than abstinence; be evidence based; appeal to the diverse residents of Saskatchewan; and use language that is simple, encouraging, and nonjudgmental. Finally, in terms of population characteristics, stakeholders felt that several features of the alcohol misuse population, such as psychiatric comorbidity, readiness for change, and stigma, should be considered when developing an ICBT program for alcohol misuse.

Conclusions: Stakeholders' insights will help maximize the acceptability, appropriateness, and adoption of ICBT for alcohol misuse and in turn contribute to implementation success. The methodology and findings from this study could be of benefit to others who are seeking to implement ICBT in routine practice.

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KEYWORDS

internet intervention; cognitive behavioral therapy; alcohol consumption; stakeholder participation; qualitative research; implementation science

Introduction

Background

Alcohol misuse, defined as alcohol consumption that causes harm to the drinker, others, or society, is prevalent among Canadian adults, affecting 8% of individuals aged 15 years or older; this is higher than the world average of 5.1% [1]. Although there are numerous evidence-based treatments for alcohol misuse, it is known to be undertreated, with less than 15% of patients receiving services [2]. Many individuals refrain from seeking treatment because alcohol misuse is a particularly stigmatized mental disorder [3]. Compared with people with substance-unrelated mental disorders (eg, depression and schizophrenia), individuals with alcohol misuse are perceived as being more responsible for their condition, elicit more social rejection and negative emotions, are more likely to experience structural discrimination, and are less frequently regarded as mentally ill [3]. Other reasons for this treatment gap include client-related barriers (eg, embarrassment, desire to reduce drinking autonomously, and low motivation to change) and treatment-related barriers (eg, not believing that treatment will help, limited time available for treatment, and low proximity to treatment centers) [4].

Internet-delivered cognitive behavior therapy (ICBT) has emerged as an effective form of treatment that increases access to services by overcoming many barriers associated with face-to-face intervention [5]. ICBT is known to be more accessible, affordable, and convenient than traditional face-to-face care. Consequently, there is growing interest in offering ICBT in routine care [6]. ICBT typically involves users completing Web-based lessons on a weekly basis over the course of several months [7]. In recent years, several research groups have studied ICBT for alcohol misuse and promising treatment effects have been reported [8-11]. The overall goal of ICBT for alcohol misuse is typically behavioral change measured in terms of reduction of drinks consumed [11] as opposed to abstinence [9]. The design of ICBT treatments for alcohol misuse can differ in whether users work alone (ie, self-guided) or with a support person (ie, guided). Guided ICBT provides users with support in the form of email, Web-based chat, or brief telephone calls. Self-guided ICBT allows users to complete lessons independently with automated feedback or no contact at all. Previous research has provided preliminary evidence that guided ICBT results in greater reductions in alcohol consumption than self-guided ICBT [8,11].

Despite the mounting evidence supporting the efficacy of ICBT for alcohol misuse, it has yet to be implemented in routine care in Canada. Previous research has outlined numerous outcomes that should be addressed when implementing an intervention in a new setting [12,13]. Three outcomes that should be measured early in the implementation process are acceptability (ie, extent to which the intervention is agreeable, palatable, satisfactory, or useful), appropriateness (ie, perceived fit or compatibility of an intervention with its consumer's needs), and adoption (ie, consumer's intention to use the intervention) [12,13]. One of the recommended methods for assessing acceptability, appropriateness, and adoption is to gather the perspectives of a wide range of stakeholder groups (eg, health care providers and leaders, researchers, patients, and family members) by conducting semistructured interviews or focus groups before implementation [12,13]. Uptake of internet interventions, especially outside of research trials, is known to be far from satisfactory, and involving potential users in the development of such interventions is considered key in increasing use and impact [14]. Recent recommendations in the literature highlight the importance of integrating perspectives from both patient and health care stakeholders in implementation efforts of ICBT [15]; furthermore, several Canadian researchers have recently emphasized the importance of engaging stakeholders when developing and implementing electronic mental health interventions in Canada [16,17].

Considering acceptability, adoption, and appropriateness before implementation serves several purposes. First, it allows researchers to incorporate stakeholder feedback directly into the development of the ICBT program. Second, it ensures the intervention is patient oriented, ie, the intervention is "closely connected to the primary needs of the patients it is meant to serve" [17]. Third, it allows researchers to understand the local context within which the intervention will be delivered and enhance the appeal of the intervention [12,17]. Finally, and perhaps most importantly, it serves to promote implementation success and thus bolster service and treatment outcomes [13,18].

Objectives

The purpose of this study was to interview diverse stakeholders who had personal or professional experience with alcohol misuse to gain a comprehensive understanding of how ICBT is perceived as a treatment option for alcohol misuse. Specifically, our objectives were to (1) learn about the perceived advantages and disadvantages of ICBT for alcohol misuse and (2) elicit recommendations to inform implementation efforts.

Methods

Geographical Context

This study was conducted in Saskatchewan, a landlocked province in Western Canada with a population of 1,098,352 [19]. Saskatchewan is geographically large (approximately 650,000 km^2), with most residents living in the southern prairie half of the province rather than the sparsely populated northern forest region. Most of the population resides in two large cities with over 250,000 people each, but 35.6% of residents live in rural areas, which is substantially higher than the national average of 16.8% [19]. The average age of Saskatchewan residents is 39.1 years, with 64.8% of the population being aged between 15 and 64 years and 18.0% being 65 years or older [19]. Saskatchewan residents are primarily Euro-Canadian, but

there is also a large portion of aboriginal peoples (16.3%; eg, First Nations, Metis, and Inuit) and a growing immigrant population (10.5%) [20].

Health Care System and Clinical Setting

In Saskatchewan and across Canada, medical and mental health care are publicly funded and financed by the government through taxation [21]. Residents can access free mental health care via publicly funded hospitals and community mental health clinics. However, demand for public mental health services exceeds the supply of service providers available, so many residents turn to private mental health services, paid for out of pocket or by private health insurance [22]. The Online Therapy Unit at the University of Regina was created in part to improve Saskatchewan residents' access to mental health care. Since its inception in 2010, the unit has been offering guided ICBT for depression and anxiety to residents of Saskatchewan, and educating mental health providers on the delivery of ICBT, and conducting research on ICBT in routine practice [23]. ICBT services are provided free of charge as a result of funding from the Saskatchewan Ministry of Health.

Of the more than 1000 clients who were screened for ICBT for depression and anxiety in the past year, approximately 20% self-reported alcohol misuse problems, suggesting that there is a need for ICBT for alcohol misuse in Saskatchewan. This anecdotal finding is supported by recent Census data, which suggest that 21.9% of people aged 12 years or older in Saskatchewan report engaging in heavy drinking at least once a month, compared with the Canadian average of 19.5% [19]. In addition, Saskatchewan has the third highest rate of impaired driving and the fifth highest rate of alcohol-related hospitalizations out of all provinces and territories in 2015, at 575 and 345 incidents per 100,000 people, respectively [24]. To meet the alcohol-related treatment needs of residents of Saskatchewan, the Online Therapy Unit is now planning on extending its services to include ICBT for alcohol misuse.

Participants

Participants for this study were individuals from six stakeholder groups: patients (ie, individuals with direct lived experience), family members (ie, individuals with indirect lived experience), academic experts (ie, individuals who teach about or conduct research on alcohol misuse), frontline managers (ie, individuals who manage service providers), service providers (ie, individuals who work directly with patients), and health care decision makers (ie, individuals involved with government policy related to alcohol misuse). To be included in the study, stakeholders had to reside in Saskatchewan and have personal or professional knowledge of alcohol misuse. Our goal was to recruit numerous stakeholders from each group who could provide diverse perspectives on the topic of alcohol misuse. For example, we wanted stakeholders who could represent the perspectives of the urban and rural population and individuals with knowledge of different cultural perspectives. A priori, we hypothesized that a sample size of 20 to 30 stakeholders would be sufficient; however, we intended to continue conducting interviews until we were confident in the saturation of the data [25]. Stakeholders were primarily recruited via convenience sampling. Initial recruitment involved sending out an invitation to participate to alcohol misuse stakeholders known to the Online Therapy Unit (eg, previous ICBT participants and government officials involved in previous projects). Subsequently, snowball sampling was utilized, wherein stakeholders who were interviewed were asked to suggest other individuals who would have an interest in being involved in the study [26].

Procedure

This study obtained approval from the institutional research ethics board. Interested participants were invited to take part in a semistructured interview with research staff members from the Online Therapy Unit in person or via telephone. Individual interviews were chosen over focus groups to maximize scheduling convenience for the stakeholders and because the stakeholders resided in geographically diverse locations across the province. One staff member (AW) was chosen to conduct interviews because of familiarity with alcohol misuse literature, whereas the other staff member (ST) was chosen because of experience in conducting qualitative interviews. The interview was comprised of 15 questions that provided insight into the acceptability, adoption, and appropriateness of ICBT for alcohol misuse in Saskatchewan (see Multimedia Appendix 1 for the interview guide). All interviews were audio-recorded with the permission of the participant. To ensure data quality, some interviews were attended by both staff members, with one member leading the interview and the other observing. Following such interviews, the researchers provided feedback to one another as an ongoing check to ensure that the interview process and interview questions allowed for the collection of open, honest, and impartial sharing of perspectives.

A total of 30 stakeholders were interviewed between October 2018 and January 2019. The participants who were interviewed represented a number of stakeholder groups (see Table 1). The interviews typically included one stakeholder at a time; however, there were three instances where two participants from the same organization preferred to be interviewed together. This resulted in 27 interviews in total. The interviews ranged in length from 18 to 67 min, with the average being 39 min. Five interviews were conducted in person and 22 by telephone. ST led 17 interviews and AW led 10. Eighteen interviews were attended by both staff members. Data collection was discontinued after 27 interviews (with 30 stakeholders) because all stakeholder groups had been adequately represented, and we were satisfied with our level of data saturation [25].

Table 1. Number of stakeholders by group (N=30).

Stakeholder type	Interviewed, n
Patients	7
Family members	3
Health care decision makers	7
Frontline managers	6
Service providers	4
Academic experts	3

Data Analysis

Interview transcripts were transcribed verbatim, anonymized, and entered into QSR International's NVivo 12 qualitative analysis software [27]. A descriptive, inductive approach to thematic analysis was utilized to identify themes within the interview data [28]. AW was responsible for reading each interview transcript closely to obtain an initial impression of the data and engage in open coding, wherein basic codes that represent each unit of meaning were derived. Subsequently, identified codes were discussed with ST to ensure content coverage. Finally, after AW comprehensively coded all the data, several members of the research team (HH, KG, MN, and ST) came together to sort the individual codes into meaningful themes.

Results

Stakeholder Opinions

Stakeholders from all groups (eg, patients, family members, academic experts, frontline managers, service providers, and health care decision makers) resoundingly endorsed the implementation of ICBT for alcohol misuse in Saskatchewan. Moreover, they provided a wealth of information to be considered when developing an ICBT program for alcohol misuse. The results are discussed below, and illustrative stakeholder quotes are provided to enhance reader understanding.

Perceived Advantages and Disadvantages of Internet-Delivered Cognitive Behavior Therapy for Alcohol Misuse

When discussing the immense need for ICBT for alcohol misuse in Saskatchewan, stakeholders highlighted some perceived advantages and disadvantages of an ICBT approach to the treatment of alcohol misuse. The advantages and disadvantages are described in Tables 2 and 3, respectively, along with example stakeholder quotes.

Table 2. Perceived advantages of internet-delivered cognitive behavior therapy for alcohol misuse. ICBT: internet-delivered cognitive behavior therapy.

Advantages	Description	Example quote
Accessibility	ICBT allows clients with alcohol use who live in rural and remote locations to access care that is otherwise limited.	"For people who are in the rural areas I think it [ICBT for alcohol misuse] is hugely advantageous, because getting an addictions counselor in rural areas can be really challenging." [Stakeholder #12, Patient]
Convenience	ICBT allows clients who are limited by cost, transportation, or time constraints to access care.	"There are individuals that have obligations with work or parenting where they are not able to necessarily attend programming during some of the traditional hours that they're offered or even outside of traditional hours, right? So being able to access a program in their home is definitely a need." [Stakeholder #6, Frontline Manager]
Privacy	ICBT allows clients to participate in treatment from a private location, which reduces the chances of experiencing stigma related to alcohol misuse.	"[ICBT for alcohol misuse] is more private, it's not like they have to walk into a public meeting and say "Hi, I'm an alcoholic." That can be very intimidating." [Stakeholder #24, Family Member]
Relevance to technology-based culture	ICBT is congruent with today's technology-based culture.	"Our world is living in that direction [toward technology], so it would make sense to have a service [like ICBT] that's delivered in a way that lots of people can access. Technology is just part of life." [Stakeholder #3, Service Provider]
Fit with stepped care	ICBT fits within a stepped-care model, wherein clients with less severe alcohol misuse can use ICBT, leaving more intensive in-person services for those with more severe alcohol misuse.	"[ICBT] is really the starting part of a step-care approach so that not everybody needs to go to addiction services. Sometimes it's just a matter of gathering information for themselves or for others and I think it could potentially have a role in prevention. It could potentially have an impact on wait times too." [Stakeholder #22, Health Care Decision Maker]

Table 3. Perceived disadvantages of internet-delivered cognitive behavior therapy for alcohol misuse. ICBT: internet-delivered cognitive behavior therapy.

Disadvantages	Description	Example quote
Requires internet access and technological literacy. ICBT: internet-delivered cognitive behavior therapy.	ICBT requires clients to have access to the internet and the knowledge and ability to use a computer, tablet, or mobile phone, which may prohibit some individuals from participating.	"A lot of individuals don't have access to Internet. Oftentimes we see a population who are disadvantaged so they may not have a stable house where they can access a computer to access online ICBT. They may not have access to a phone where they can get it on their mobile." [Stakeholder #2, Health Care Decision Maker]
May foster isolation	ICBT may reinforce isolation that can be associated with alcohol misuse by allowing clients to engage in treatment without leaving home.	"It [addiction] is about disconnection; disconnection with ourselves, disconnection with others. How do you make it [an ICBT program for alcohol misuse] in a way that is not allowing clients to further isolate?" [Stakeholder #25, Academic Expert]
Less accountability	The Web-based nature of ICBT could allow clients to be less accountable for their actions than they would be if they had face-to-face meetings with their service provider or peers.	"It's easier not to be accountable to a computer than it is to an addiction counsellor or an AA group." [Stakeholder #28, Health Care Decision Maker]
Unfamiliarity with ICBT	Clients might not be aware that ICBT is an available treatment option for alcohol misuse.	"Unfamiliarity with this whole resource [ICBT] could be one [disadvantage]." [Stakeholder #15, Frontline Manager]

Factors to Be Considered When Implementing Internet-Delivered Cognitive Behavior Therapy for Alcohol Misuse

Stakeholders provided valuable insight into factors to consider when implementing ICBT for alcohol misuse in Saskatchewan. Three themes emerged from the analysis: (1) intervention design, (2) treatment content, and (3) population considerations (Figure 1).

Figure 1. Factors to consider when implementing internet-delivered cognitive behavior therapy for alcohol misuse.

Intervention Design	Treatment Content	Population Characteristics
• Benefits of therapist assistance • Optimal length of treatment: 6-8 weeks • Diverse recruitment and referral strategies	• Treatment goal: harm-reduction over abstinence • Share evidence-based information and skills • Appeal to diverse population • Encouraging and clear language	• Psychiatric comorbidity • Drinking culture • Varying readiness for change • Stigma • Varying stressors

Intervention Design

Benefits of Guided Internet-Delivered Cognitive Behavior Therapy

The majority of stakeholders suggested that a guided ICBT program would be beneficial because it would allow for greater support, increase accountability, and provide clients with someone to connect with. In terms of the best method of guidance, stakeholders felt that offering email support in combination with telephone follow-ups would be important. However, several stakeholders indicated that it might be helpful for clients to be able to choose the level and type of support that fits their needs (ie, guided vs self-guided, email vs telephone contact). When discussing the value of guidance, one stakeholder explained:

> *I think it [guided ICBT] is a happy medium between having to go see a therapist and having to do it all on your own.* [Stakeholder #26, Patient]

Optimal Length of Treatment: 6 to 8 Weeks

When stakeholders were asked about the ideal length of treatment, responses ranged from 6 to 12 weeks. The majority of stakeholders suggested a 6- to 8-week time frame. Some recommended a longer treatment length of 10 to 12 weeks, but other stakeholders expressed concern that clients would be less likely to commit to a longer treatment period. A number of stakeholders suggested that the length of treatment may need to be altered depending on a number of factors (eg, interest and alcohol misuse severity).

Diverse Recruitment and Referral Strategies

Stakeholders felt that advertising to potential clients on the Web using social media and Web advertisements would be most effective. The value of recruiting via social media was described by one stakeholder who commented:

> *[Facebook] is where everyone is going these days; that's where you're guaranteed to get the best reach. Facebook is really targeted these days in that you can select people who live in Regina who are between*

> *the ages of 14 and 35 who enjoy drinking [...] you can target ads to every single group [related to alcohol], so you can pick out exactly who you need and who's going to be successful in your program just with one click of a button.* [Stakeholder #26, Patient]

Several additional strategies were also recommended, including point-of-sale advertising (ie, advertisements in places where alcohol is sold or consumed such as liquor stores, restaurants, bars, and sporting events) and media advertising (eg, newspaper and radio). With regard to referrals, stakeholders recommended creating a professional referral network to increase coordination of care among alcohol misuse service providers. Specifically, they suggested the exchange of information and referrals with counselors, physicians, community health clinics, social workers, and public education or advocacy groups.

Treatment Content

Treatment Goal: Harm Reduction Over Abstinence

A few stakeholders discussed abstinence and harm reduction approaches to the treatment of alcohol misuse. Stakeholders generally held the perspective that harm reduction was a more appropriate approach, particularly for people who are drinking at mild-to-moderate levels. However, there was also recognition that clients can choose abstinence within a harm reduction model if their goal was to eliminate alcohol consumption altogether. One stakeholder explained:

> *I think that [the idea of abstinence] turns people off, the idea that you can't have something anymore, then that... You know, you almost want it even more because you can't have it.* [Stakeholder #20, Patient]

Sharing Evidence-Based Information and Skills

A number of stakeholders emphasized the importance of including evidence-based information and skills in the ICBT program. They underscored the value of teaching clients what constitutes alcohol misuse and about the low-risk drinking guidelines. They also recommended providing education about the effects of alcohol, especially the physical effects and how to deal with withdrawal. They suggested using language such as *experts say* and *other participants have said* when introducing new skills to underscore that the treatment content is based on existing evidence. One stakeholder highlighted this subtheme when they said:

> *People often don't know how to moderate their drinking. They don't understand what a standard drink is. There is a need for [education] about that.* [Stakeholder #21, Frontline Manager]

Appeal to Diverse Populations

Stakeholders spoke of the importance of gaining the trust of potential clients by delivering content that demonstrates understanding and sensitivity to the diversity that exists among individuals with alcohol misuse in terms of culture, age, and socioeconomic status. Stakeholders indicated that content such as photos, wording, and case stories must be relatable and relevant to individuals from various cultures. Stakeholders also spoke of alcohol misuse as a cross-generational issue and recommended that the content appeal to adults across the life span. Stakeholders finally recommended that the program content be sensitive to socioeconomic diversity, as people struggling with alcohol misuse are likely to range from those who live in poverty to those who are wealthy. This point was illustrated by one stakeholder who commented:

> *We [individuals with alcohol misuse] come from all walks of life. I mean, you could be a doctor, you could be a janitor, you could be a 16-year old kid, you could be a 90-year old grandmother. It could be anybody... like I said, it's all walks of life so it [alcohol misuse] crosses all boundaries.* [Stakeholder #11, Patient]

Encouraging and Clear Language

All stakeholders spoke to the importance language and messaging would play, not only in drawing potential clients to the Online Therapy Unit website but also in keeping them engaged once participating in the program. Stakeholders advised against language or information that is confrontational, difficult to understand, and stigmatizing or has the potential to trigger feelings of hopelessness. Instead, stakeholders spoke of the need to use encouraging, nonjudgmental, and simple language. One stakeholder explained the importance of removing stigmatizing language:

> *I would say if you're looking to hook in people who are moderate drinkers, I would avoid the term "alcoholic," because I think some people would look at that and think, "Well, I'm not an alcoholic, I'm not a drunk, that's not me.*" [Stakeholder #28, Frontline Manager]

Population Considerations

Psychiatric Comorbidity

The majority of stakeholders highlighted the challenge of providing treatment for alcohol misuse in the context of comorbid conditions. Many spoke of the strong connection between alcohol misuse and other mental health conditions, such as anxiety, depression, and trauma. It was suggested that an ICBT program for alcohol misuse take into account and possibly even address comorbid psychiatric conditions. One stakeholder described the link between alcohol misuse and mental illness:

> *The drinking is just a symptom of deeper emotional issues and so a lot of people aren't aware of that in the beginning part of their journey, they think alcohol is the problem, not the fact that they have years of trauma.* [Stakeholder #12, Patient]

Drinking Culture

The vast majority of stakeholders described the impact of drinking culture on alcohol consumption. They explained that alcohol consumption is typically considered an acceptable, normal activity that goes hand in hand with the day-to-day social activities. Thus, they warned that reducing or eliminating alcohol consumption might contribute to feelings of social isolation. They stressed the importance of the ICBT program acknowledging societal drinking culture and preparing clients for reducing their alcohol consumption within this context.

Varying Readiness for Change

Several professional stakeholders described the importance of the ICBT program considering potential clients' readiness to change their drinking behavior. Relatedly, a number of patients and family members discussed denial or lack of recognition of a drinking problem as a reality for some individuals with alcohol misuse. Stakeholders indicated that it may be valuable to conduct an assessment and provide feedback to allow potential clients to understand their level of alcohol misuse and its negative effects; they suggested this may reduce ambivalence about following through with an ICBT program. The importance of addressing readiness for change was described by one stakeholder who stated:

> *That level of motivation to want to change, sometimes that's just not there, so I think getting an accurate assessment of where they are in that stages of change model would be helpful, but even within that, we know that it's cyclical and people can revert back to contemplation or pre-contemplation where that motivation to follow through on a program like this just isn't there.* [Stakeholder #17, Frontline Manager]

Stigma

Several stakeholders talked about the shame and stigma associated with alcohol misuse being a significant barrier to seeking help. In particular, a number of patients and family members spoke of the feeling of not wanting anyone to know they had a problem because if that had become known it may have had negative consequences. Stakeholders suggested the ICBT program be aware of the enormous stigma faced by individuals with alcohol misuse.

Varying Stressors

Stakeholders spoke of the importance of recognizing the variety of stressors that can be experienced by individuals who misuse alcohol. They noted that alcohol consumption can be not only a source of stress but also a way of coping with stress. One stakeholder discussed stress as a social determinant of health:

> *It's important to acknowledge the social determinants of health that have led to or support that abuse. [...] You'd have to talk about what's your housing situation, where are living, do you have a job, etc. [...] Because if you're an alcoholic who lives at home with a family and you have a job, you're in a much, much different situation than someone who's living in a shelter.* [Stakeholder #26, Patient]

Discussion

Principal Findings

This study aimed to interview stakeholders who had personal or professional experience with alcohol misuse to understand their perceptions of ICBT as a treatment option for alcohol misuse in routine practice. Along with a resounding endorsement for implementation, stakeholders shared their perceptions about the advantages and disadvantages of using ICBT to treat alcohol misuse and made numerous recommendations related to intervention design, intervention content, and the population being treated.

The perceived advantages and disadvantages identified by stakeholders were consistent with previous ICBT research [5]. Understanding stakeholders' perceptions of these advantages and disadvantages is helpful as we proceed with implementation efforts. The perceived advantages of ICBT for alcohol misuse—accessibility, convenience, privacy, relevance to technology-based culture, and fit with stepped-care—can be emphasized to potential clients and referral sources during recruitment. One advantage that seems especially relevant to the alcohol misuse population relates to privacy, given the strong stigma experienced by individuals with alcohol misuse [3]. Accordingly, the ability to participate in ICBT from a private location might be of particular value to potential clients with alcohol misuse and thus should be strongly emphasized.

In contrast, the perceived disadvantages of ICBT for alcohol misuse—requires internet access and technological literacy, may foster isolation, less accountability, and unfamiliarity with ICBT—represent areas to be acknowledged and mitigated as implementation proceeds. Perhaps the most addressable disadvantage is unfamiliarity with ICBT. When implementing ICBT for alcohol misuse in routine practice, significant effort can be made to inform potential clients and referral sources about the nature and availability of the treatment. Other disadvantages might be mitigated by incorporating certain features into the ICBT program for alcohol misuse; eg, guided ICBT likely has greater potential to lessen clients' isolation and improve accountability compared with a self-guided approach. In addition, designing a program that is downloadable and can be accessed through a variety of technological devices (eg, computer, tablet, or mobile phone) may benefit those without a home computer or a consistent internet connection.

In terms of intervention design, stakeholders indicated that a guided program with both email and telephone correspondence would be preferable as it would allow for greater support, increased accountability, and human connection. This suggestion is supported by two previous studies that found guided ICBT programs for alcohol misuse to be both more engaging and more effective than self-guided ICBT [8,11]. With regard to treatment content, stakeholders recommended that the treatment goal of the program should be reduction of, rather than abstinence from, alcohol consumption. This treatment goal is also supported by previous research showing the benefits of harm reduction approaches relative to abstinence [29]. Finally, the population characteristics noted by the stakeholders are supported by existing literature. In particular, stakeholders felt that several common features of the alcohol misuse population, such as psychiatric comorbidity and readiness for change, should be taken into account when developing an ICBT program for alcohol misuse. It is well known that alcohol misuse is often comorbid with other mental health disorders [30] and that readiness for change is an important predictor of successful behavior change [31].

Strengths and Limitations

This study has several important strengths. First, to our knowledge, this is the first study related to implementation of

ICBT for alcohol misuse in routine care. It should be stated that the advantages and disadvantages identified in the stakeholder interviews were in line with what has been previously identified in the literature on internet interventions [5]. However, there were several important recommendations provided by the stakeholders that are unique for the alcohol misuse population. These include the promotion of harm reduction rather than abstinence and the importance of taking into account factors such as psychiatric comorbidity and readiness to change when developing the ICBT program. Second, this study is patient oriented, ensuring that a new ICBT program for alcohol misuse will closely reflect the needs and expectations of the alcohol misuse population, thereby maximizing the probability of implementation success. The fact that we included stakeholders from various groups and regions of Saskatchewan ensures that our results represent a wide range of perspectives. Moreover, our confidence in our level of data saturation makes us certain that interviewing additional stakeholders would have resulted in diminishing returns.

Despite its strengths, this study also has several limitations. First, although we expect the findings of this study to be largely applicable to other geographic locations, the inclusion of stakeholders exclusively from Saskatchewan may hamper generalizations to other geographical contexts. Second, with regard to the sample, there may be a selection bias as some stakeholders may have had initial favorable attitudes toward ICBT. For example, 8 out of 30 stakeholders (27%) had professional or personal experience with other ICBT courses being offered by the Online Therapy Unit. Relatedly, the use of snowball sampling increases the risk that stakeholders referred like-minded individuals to participate. In terms of the interview guide, it is conceivable that the semistructured nature of the interview influenced the stakeholders' responses. Specific interview questions may have implicitly encouraged stakeholders to speak to certain topics and not to others. Moreover, the choice to conduct individual interviews rather than focus groups could be regarded as a limitation, as a focus group format could have resulted in broader discussion, enhancing the richness of the results. Finally, as with all qualitative research, it is possible that the researchers' knowledge and previous experience with ICBT and the treatment of alcohol misuse implicitly influenced how the interview content was interpreted. As described by Braun and Clarke [28], "data are not coded in an epistemological vacuum."

Future Directions

The recognizable next step is to move forward with the development and implementation of ICBT for alcohol misuse in routine practice. This will include continuing to assess acceptability, appropriateness, and adoption once the intervention is implemented. Moreover, other implementation outcomes such as feasibility, fidelity, and implementation cost can be measured in addition to service outcomes (eg, effectiveness, efficiency, and timeliness) and client outcomes (eg, satisfaction, functioning, and symptomatology). Attempts should be made to replicate the findings from this study among stakeholders in other geographical locations and practice settings. We encourage researchers interested in implementing ICBT for alcohol misuse (or any other condition) to use our interview guide and analytic procedure as a model. Finally, as ICBT becomes more common in routine care, there is likely to be ongoing value in taking a patient-oriented approach, whereby patient partners are engaged in all aspects of program development and evaluation. Past research suggests that adopting a patient-oriented approach ensures treatment is tailored to the needs of the clients it is meant to serve, which can improve satisfaction and patient outcomes [32].

Conclusions

Conducting semistructured interviews with 30 stakeholders who had personal or professional experience with alcohol misuse provided valuable insights that will inform the development of an ICBT program for alcohol misuse in routine practice. In terms of intervention design, stakeholders recommended a 6- to 8-week guided program. With regard to treatment goals, stakeholders recommended that the program focus on harm reduction rather than abstinence. In terms of population characteristics, stakeholders believed that several features of the alcohol misuse population, such as psychiatric comorbidity and readiness for change, should be taken into account when developing an ICBT program for alcohol misuse. The feedback provided by stakeholders will be used to bolster acceptability, appropriateness, and adoption and in turn contribute to implementation success. The methodology and findings from this study can serve as an example to others who are seeking to deliver ICBT in routine practice.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide.
[DOCX File , 14 KB - mental_v7i3e14698_app1.docx]

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Abbreviations

ICBT: internet-delivered cognitive behavior therapy

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Original Paper

The Mediating Role of Visual Stimuli From Media Use at Bedtime on Psychological Distress and Fatigue in College Students: Cross-Sectional Study

Yuan Guan[1], PhD; Wenjie Duan[2], PhD

[1]Department of Social Work, Guangdong University of Finance, Guangzhou, China

[2]Social and Public Administration School, East China University of Science and Technology, Shanghai, China

Corresponding Author:
Wenjie Duan, PhD
Social and Public Administration School
East China University of Science and Technology
130 Meilong Road
Xuhui District
Shanghai
China
Phone: 86 17269306934
Email: duan.w@outlook.com

Abstract

Background: Empirical research has linked psychological distress with fatigue. However, few studies have analyzed the factors (eg, stimuli from bedtime media use) that affect the relationship between psychological distress and fatigue.

Objective: The aim of this study was to examine whether visual stimuli from bedtime media use mediate the relationship between psychological distress and fatigue among college students.

Methods: The sample included 394 participants (92 males, 302 females) with a mean age of 19.98 years (SD 1.43 years), all of whom were Chinese college students at an occupational university in Sichuan Province, China. Data were collected using a paper-based questionnaire that addressed psychological distress, stimuli from bedtime media use, and fatigue. Mediation analysis was conducted using the PROCESS macro version 2.16.2 for SPSS 22, which provided the 95% CIs.

Results: Both psychological distress (r=.43, *P*<.001) and visual stimuli from bedtime media use (r=.16, *P*<.001) were positively related to fatigue. The association between auditory stimuli from bedtime media use and fatigue was not significant (r=.09, *P*=.08). The relationship between psychological distress and fatigue was partially mediated by visual stimuli from bedtime media use (beta=.01, SE 0.01, 95% CI 0.0023-0.0253).

Conclusions: The findings imply that psychological distress has an indirect effect on fatigue via visual stimuli from bedtime media use. In contrast, auditory stimuli from bedtime media use did not have the same effect. We suggest that college students should reduce bedtime media use, and this could be achieved as part of an overall strategy to improve health. Mobile health apps could be an option to improving young students' health in daily life.

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KEYWORDS

psychological distress; visual stimulus; auditory stimulus; bedtime media use; fatigue

Introduction

Fatigue and Its Influence

Fatigue is a subjective feeling of tiredness or a sustained sense of exhaustion [1,2]. It includes the experience of fatigue and the influence of fatigue on physical, mental, and social aspects of life [1,2]. Fatigue is common among students in China [3]. In a study of 757 Chinese adolescent students in Taiwan, Chen et al [4] found relatively high proportions of fatigue in grades 9 through 12, primarily owing to the pressure students faced related to university entrance exams. Fatigue has a negative influence on students' school performance [5] and health [6]. For example, using data from 60 college-aged students, Palmer [7] found that fatigue had a negative influence on students' learning and cognitive performance. In their study of 109

medical students aged 21-40 years, Hwang et al [8] found that students with clinical fatigue had low scores for physical health and psychological health.

Fatigue and Related Research

Fatigue has attracted considerable research interest in recent years. The large proportions of students who experience fatigue and the serious consequences of fatigue highlight the need to explore the psychological mechanisms that underlie fatigue. Although most of the published studies have attempted to estimate the negative consequence of fatigue, relatively few studies have analyzed the factors influencing fatigue. Some research has focused on the risk factors for fatigue, such as daily activities [9] and daily events [10]. However, only a few studies have investigated the factors influencing fatigue, such as bedtime media use. Using data from 358 university students, Zarghami et al [11] found that using a cell phone after switching off the main bedroom light was associated with fatigue. Also, relatively few studies have explored the relationship between psychological distress, an important influencing factor and intervening variable, and fatigue among college students in China.

Psychological Distress and Fatigue

Psychological distress is a composite concept that describes the negative symptoms of a person's mental health, such as depression, anxiety, or other emotional dysregulation [12,13]. Psychological distress is positively related to fatigue [4,14,15]. Based on one-way ANOVA analysis of data from a cross-sectional survey of 355 first-year rural college students, Hussain et al [16] found that fatigued students experienced higher levels of psychological distress. In a longitudinal study of 243 college students in South Korea, Shim et al [17] found that depression is positively associated with fatigue.

Media Use and Psychological Distress

Despite the association between psychological distress and fatigue, the mediating mechanism related to bedtime media use has not been explored. Research on media use has recently become a hot topic. Media use is prevalent among youth [18,19], especially at bedtime [20]. Psychological distress is related to media use [21-23] and positively influences media use [24,25]. For example, in their study with 923 college students in Jiangxi Province, China, Ye and Zheng [26] found that psychological distress resulted in higher media use. Wills et al [27] found that addictive forms of behavior were related with an inability of adolescents to control their emotions. Failure to control negative emotions leads to increased media use [28]. According to the social cognitive theory, self-regulation is a process in which people control their behaviors [29]. Failure to affective self-react (one of the processes of self-regulation) is associated with negative outcomes, such as addiction to media use [30]. Therefore, people who experience psychological distress tend to use media to comfort themselves and, especially at bedtime, to relieve psychological distress [31]. Meanwhile, according to the uses and gratifications theory [32,33], people achieve gratification when they meet their needs, and using specific types of media provided this gratification [33]. Psychological differences are one factor that drives individuals to gratify their needs [24,33]. Therefore, psychological distress is positively associated with media use [34].

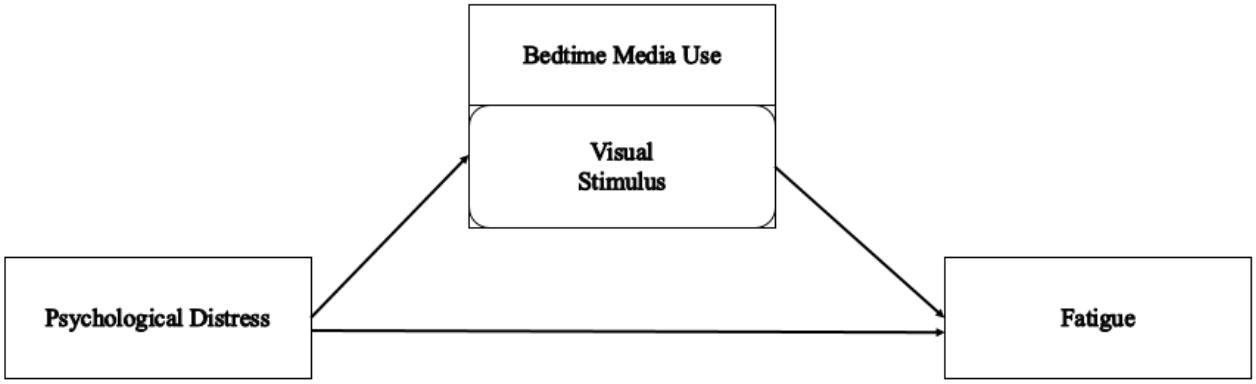
Media Use and Fatigue

Many studies have shown that media use is related to fatigue [20,35-39], and frequent media use results in fatigue [40]. Bedtime media use leads to a later time to fall asleep and displaced sleeping times, which result in fatigue [20]. Moreover, bedtime media use results in irregular sleep [41], disrupting the endocrine system [42]. Students who use media at bedtime may experience two types of stimuli: visual and auditory. Bedtime media use increases the level of external stimuli (visual stimulus and auditory stimulus) at bedtime. Exposure to light at night influences the human biological clock [43,44], and visual stimuli at bedtime influence the neuroendocrine system [45], affecting sleep and resulting in fatigue the following day. Although stimulation at bedtime influences the neuroendocrine system and therefore fatigue [42], few studies have found an association between an auditory stimulus from bedtime media use and fatigue. However, there is limited evidence for an association between listening to music at bedtime and fatigue. With a sample of 844 adults (18-94 years old), Exelmans and Van den Bulck [20] found that listening to music before sleeping increases fatigue. The relationship between an auditory stimulus from bedtime media use and fatigue needs further research.

Hypotheses

In summary, psychological distress has a positive relationship with fatigue. Visual stimuli from bedtime media use have a potential mediating role between psychological distress and fatigue. This study aimed to explore the mediating effect of stimuli from bedtime media use on the relationship between psychological distress and fatigue among Chinese college students. First, we aimed to confirm the results of previous studies by testing the relationship between psychological distress and fatigue. Second, we aimed to extend the existing literature by examining the role of bedtime media use in the relationship between psychological distress and fatigue. We had two hypotheses: (1) psychological distress is positively correlated with fatigue, and (2) visual stimuli from bedtime media use mediate the positive correlation between psychological distress and fatigue. This paper not only provides new insight in this area but also provides practical methods to improve college students' health in China. The theory model is shown in Figure 1.

Figure 1. Theory model of the mediating effect of a visual stimulus from bedtime media on the relationship between psychological distress and fatigue.



Methods

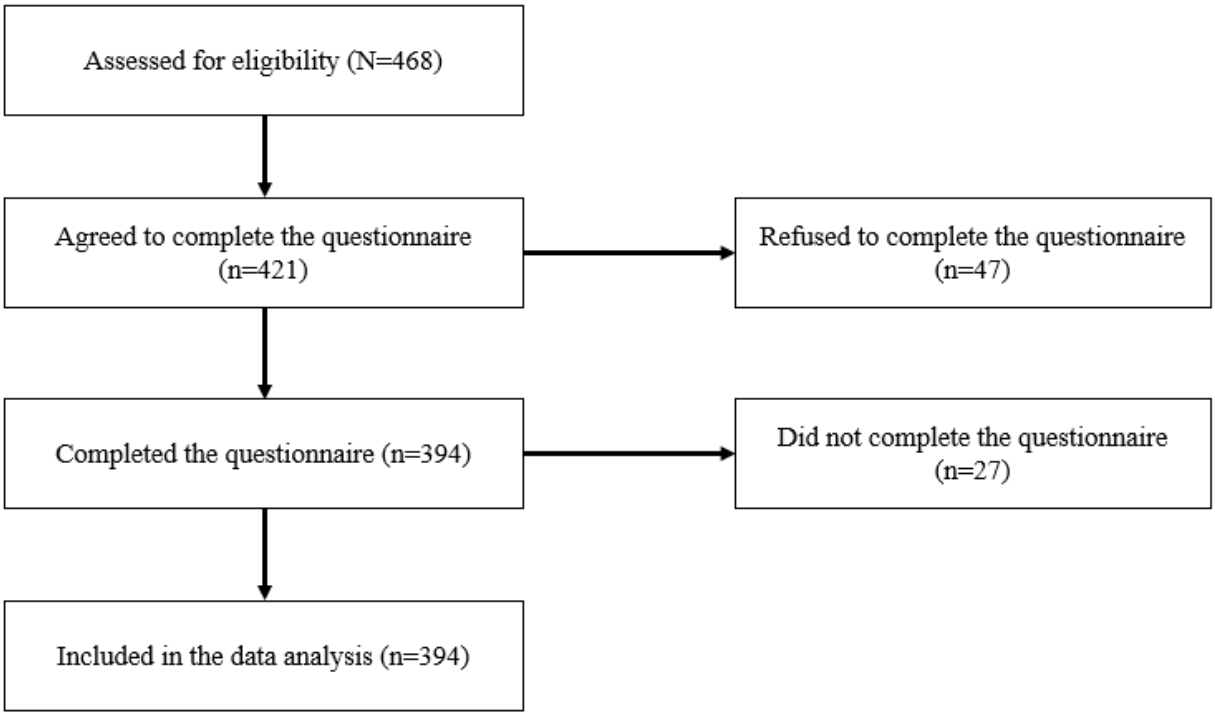
Participants and Procedures

A power analysis was conducted to estimate the minimum sample size using G Power software [46]. The regression model included 5 predictors (sex, age, psychological distress, visual stimulus, and auditory stimulus), the alpha was set at .05, and the observed R^2 in the regression model was 0.21 (Table 1). The minimum sample size was calculated at 158 participants. The power was 0.95, which was an adequate value [47]. The participants were 468 freshmen from an occupational university in Sichuan Province, China. The inclusion criteria were age between 18 and 30 years old and owning a media device for daily use. All participants were asked to complete a questionnaire; 10.0% (47/468) of the participants refused to complete the questionnaire, and 6.4% (27/421) of the remaining participants did not complete the questionnaire. The data were collected in 2016, and 394 completed questionnaires were collected. All data were collected in the form of paper-based questionnaires. The flow chart of eligibility and participation is shown in Figure 2. A normal Q-Q plot and histogram showed that the fatigue scores were approximately normally distributed. The necessary ethical approval was obtained from the Human Research Ethics Committee of the Department of Sociology, Wuhan University, China, and the research was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all the participants.

Table 1. Results from the hierarchical regression analyses of the effects of the demographic variables, psychological distress, and stimuli from bedtime media use on the dependent variable, fatigue.

	Step 1			Step 2			Step 3		
	beta	*t*	*P* value	beta	*t*	*P* value	beta	*t*	*P* value
Constant	47.15	12.68	<.001	46.70	13.80	<.001	45.29	13.14	<.001
Sex (male, female)	–1.61	–2.57	.01	–1.14	–1.99	.047	–1.46	–2.50	.01
Age (years)	0.29	1.56	.12	0.12	0.69	.49	0.09	0.54	.59
Psychological distress				0.25	9.04	<.001	0.24	8.65	<.001
Visual stimuli							0.92	2.59	.01
Auditory stimuli							–0.18	–0.64	.52
R^2	.02			.19			.21		
F statistic	$F_{(2,391)}$=4.34			$F_{(3,390)}$=30.76			$F_{(5,388)}$=20.27		
P value	.01			<.001			<.001		

Figure 2. Flow chart of eligibility and participation.



Measures

Psychological Distress

The Depression Anxiety Stress Scales (DASS) can be used to measure general psychological distress [48]. As a self-reported instrument, the DASS measures the three related psychological states of depression, anxiety, and stress [49]. It is a 4-point scale that asks participants about their experiences in the past week (eg, "I felt that life was meaningless"), with scores ranging from 0 ("This item does not apply to me at all.") to 3 ("This item applies to me very much."). No item is reverse-coded. The short version, DASS-21, has half the questions of the DASS-42 and is suitable for research use rather than clinical use [50]. The total score of the DASS-21 provides a composite/general measure of the negative psychological distress of the general population rather than for people with a specific psychological state [50]. Therefore, the DASS-21 was suitable for this exploratory study, which did not measure the endocrine index as is done in a biomedical experiment. Research has shown that the psychometric properties of the Chinese version of the DASS-21 is acceptable [51]. The Cronbach alpha of the current sample was .89. The total score of the DASS-21 was used to measure psychological distress among college students.

Bedtime Media Use

Based on previous studies [20,38,39,52,53], we asked the respondents how often they used media to help them fall asleep (eg, surfed the internet or watched videos) and about the two types of stimuli (ie, auditory stimulus and visual stimulus) before bedtime. Visual stimuli included playing computer games, watching videos, or surfing the internet on a computer; playing computer games, watching videos, or sending short messages on a smartphone; and reading. Auditory stimuli included listening to music and making phone calls. For example, we asked how often the respondent played computer games to help them fall asleep, with responses on a 6-point scale, from 1=never to 6=always. For the statistical analyses, the mean scores of the 7 visual stimulation activities and the mean scores of the 2 auditory stimulation activities were calculated.

Fatigue

The PROMIS Fatigue Short-Form 7a measures self-reported fatigue using a single total score [1]. The 7 questions (eg, "How often did you experience extreme exhaustion in the past seven days?") each have a possible score from 1 (never) to 5 (always). The Fatigue Short-Form 7a scale is available to use with college students (age ≥18 years), and the Chinese version is available from PROMIS [54]. The psychometric properties of the PROMIS scale have been tested [55]. The Cronbach alpha of fatigue was .78. For the statistical analyses, the total score of the 7 items was transformed to a standardized T score (mean 50 points, SD 10 points) using the coding from PROMIS [54]. As a self-reported instrument, the PROMIS Fatigue Short-Form 7a is available to assess fatigue for people without a clinical condition such as general-population university students.

Data Analysis

The pairwise method was used to handle missing data. First, descriptive statistics and the correlation matrix were calculated. We expected that psychological distress, stimuli from bedtime media use, and fatigue would be positively related to each other. Second, hierarchical regressions were performed using the entry method to explore the roles of psychological distress and stimuli from bedtime media use on fatigue. In the hierarchical regression, fatigue acted as the dependent variable. Demographic variables (ie, age and sex, coded as 1 for male and 0 for female) were entered in step 1, followed by psychological distress in

step 2. The two types of stimuli from bedtime media use were entered in step 3. Third, using the results from the hierarchical regressions, the mediating effect was examined using the PROCESS macro version 2.16.2 for SPSS 20.0 (IBM Corp, Armonk, NY) [56]. Bootstrapping was set at 5000 resamples to provide robust estimates of the 95% CIs of the standardized effects [57]. We examined if the stimuli from bedtime media use mediated the association between psychological distress and fatigue. A model was constructed with psychological distress as the predictor (X), fatigue as the outcome (Y), and visual stimulus from bedtime media use as the mediator (M). Covariates included sex and age. Our model describes path a as the direct effect of the psychological distress regressed on the visual stimuli from bedtime media use. Path b is the direct effect of visual stimuli from bedtime media use regressed on fatigue. Path c is the direct effect of psychological distress regressed on fatigue. Path c' is the mediating effect of psychological distress regressed on fatigue through visual stimuli from bedtime media use (c' = a * b). *P* values are two-tailed, and the statistical significance level was set at $P<.05$.

Results

Sample Characteristics

The mean age was 19.98 years (SD 1.43 years, range 18-26 years), and 76.6% (302/394) of the participants were female.

Bivariate Correlation Analyses

The mean (SD) points for visual stimuli from bedtime media use, the auditory stimuli from bedtime media use, psychological distress, and fatigue were 3.08 points (0.84 points), 3.76 points (1.04 points), 15.19 points (8.89 points), and 52.55 points (5.32 points), respectively. Visual and auditory stimuli from bedtime media use had a significant positive relationship (r=.56, $P<.001$). Psychological distress had a significant positive relationship with fatigue (r=.43, $P<.001$). Psychological distress also had a significant positive relationship with visual stimuli from bedtime media use (r=.13, $P=.009$), while the relationship between psychological distress and auditory stimuli from bedtime media use was not significant (r=.10, $P=.059$). Visual stimuli from bedtime media use had a significant positive relationship with fatigue (r=.16, $P<.001$), while the relationship between auditory stimuli from bedtime media use and fatigue was not significant (r=.09, $P=.08$). Therefore, the effect of visual and auditory stimuli from bedtime media use on psychological distress might differ. And, the two types of stimuli from bedtime media use might have different effects on fatigue.

Hierarchical Regression Analyses

The results of the hierarchical regression analyses are shown in Table 1. All regression equations were statistically significant ($F_{(2,391)}>4.34$, $P<.05$). Psychological distress was positively related to fatigue ($t_{390}=9.04$, $P<.001$). The two types of stimuli from bedtime media use were entered in step 3, and the results showed that visual stimuli had a small yet significant explained variance on fatigue ($t_{388}=2.59$, $P=.01$). The effect of auditory stimuli regressed on fatigue was not significant ($t_{388}=-.64$, $P=.52$). These results support hypothesis 1, that psychological distress and visual stimuli from bedtime media use positively affected fatigue.

Analyses of Mediating Factors

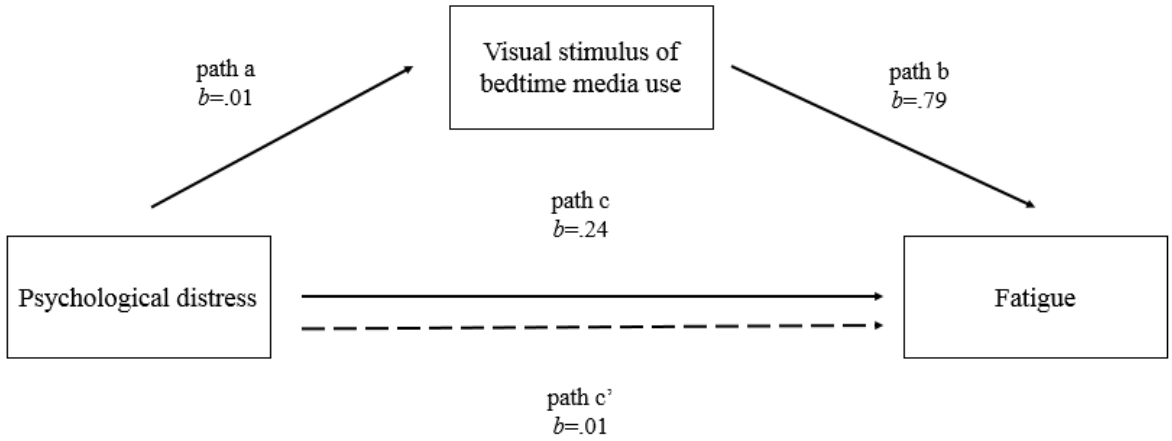
The results of the analyses of the mediating effects of stimuli from bedtime media use are shown in Table 2. As shown in Figure 3, psychological distress was significantly related to visual stimuli from bedtime media use (path a: beta=.01, SE 0.005, $P=.006$). Bedtime media use was significantly correlated with fatigue (path b: beta=.79, SE 0.29, $P=.007$).

Based on the bivariate analysis, psychological distress was correlated with fatigue (path c: beta=.24, SE 0.03, $P<.001$) when controlling for visual stimuli from bedtime media use. Consistent with hypothesis 3, there was an indirect effect of psychological distress on fatigue through the visual stimuli from bedtime media use (path c': beta=.01, bootstrapped SE 0.01, bootstrapped 95% CI 0.0023-0.0253). Therefore, the positive association between psychological distress and fatigue was partially mediated by visual stimuli from bedtime media use.

Table 2. Mediating effect of the visual stimuli from bedtime media use on the relationship between psychological distress and fatigue.

Path	R^2	beta	SE	*P* value	95% CI
Psychological distress and visual stimuli	.05	.01	0.01	.006	0.0039-0.0225
Visual stimuli and fatigue	.21	.79	0.29	.007	0.2152-1.3622
Psychological distress and fatigue (direct effect)		.24	0.03	<.001	0.1842-0.2926
Psychological distress and visual stimuli and fatigue (indirect effect)		.01	0.01		0.0023-0.0253

Figure 3. Direct effects (paths a, b, and c) of psychological distress and visual stimuli from bedtime media use on fatigue and an indirect effect (path c') of psychological distress on fatigue through the visual stimuli from bedtime media use. The control variables were age and sex.



Discussion

Study Objective

To improve college students' health and ability to study efficiently, fatigue should not be neglected, especially when fatigue is associated with psychological health. This study explored the association between psychological distress and fatigue. The mediating mechanism of bedtime media use was also analyzed.

Discussion of Findings Regarding the Hypotheses

In line with our first hypothesis, there was a significant positive association between psychological distress and fatigue, which is consistent with results from previous studies [58-60]. It is conceivable that increasing psychological wellbeing and maintaining a good mood positively affect physiological systems and improve college students' vitality. Psychological interventions may help students maintain mental and physical health and increase their learning efficiency [61].

Supporting our second hypothesis, the association between psychological distress and fatigue was mediated by visual stimuli from bedtime media use. Due to the pressure from learning activities, it is common for young students to have mental health concerns [62]. Media use is a common method to regulate emotion [63]. Students with psychological distress increase their media use as a method for emotional regulation. This makes them feel comfortable and gratified [64]. However, visual stimuli from bedtime media use influence the endocrine system, disrupt the biological clock, and replace sleeping time. This potentially influences fatigue during the day. Students' schedules are restricted by school hours. Students who fall asleep later at night because of media use at bedtime may not compensate by getting up later and therefore not get enough sleep. This results in fatigue the next day. In this study, the relationship between auditory stimuli from bedtime media use and fatigue was not significant. Therefore, the effect of an auditory stimulus from bedtime media use might not be enough to disrupt sleep and cause fatigue among college students.

This paper provides practical strategies to improve the health of college students. First, administrators should consider the negative effect of stimuli from bedtime media use and provide students with an intervention to control bedtime media use. Equally important is students' awareness of ways to promote mental health. Educators who work to improve students' emotion regulatory abilities could teach skills to relieve psychological distress and address habitual excessive bedtime media use, such as through the practice of mindfulness [65]. This would help students improve their sleep quality [66] and decrease fatigue. Second, to reduce fatigue and improve study efficiency among college students, reducing bedtime media use, particularly the use of a smartphone screen, could be a good strategy to relieve psychological distress. Mobile health apps could be a good option to improve college students' health and working efficiency. Some mindfulness training apps, such as Headspace, provide courses to improve health through auditory resources only. App-based mindfulness training positively affects emotional regulation and sleep [67]. It could be a suitable option for college students to improve their health and avoid additional visual stimuli at bedtime.

Limitations and Implications for Future Research

Several limitations of this study should be noted. First, the sex distribution and generalizability need to be considered. Further data are needed to extend the results to students outside of China. Future research should improve the representativeness of the sample. Second, the items to measure media use and the content of media use need improvement, and further

investigation is required. Although there were 7 items to measure visual stimuli from bedtime media use, there were only 2 items to measure auditory stimuli from bedtime media use. This might affect the validity of the results. As a result, future studies should improve the sample and measurements. Third, parents are an important influence on college students' daily behavior and mental health. Future research should consider controlling the effects of parental education level and occupation.

Conclusions

This paper contributes and expands the current research about the effects of stimuli from bedtime media use and psychological distress on fatigue among Chinese college students. Specifically, the results suggest that visual stimuli from bedtime media use can serve as a mediating factor to understand the association between psychological distress and fatigue. Further research should investigate the effects of the type (ie, playing games and social communication) of bedtime media use on mental and physical health.

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Conflicts of Interest

None declared.

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Abbreviations

DASS: Depression Anxiety Stress Scale

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Original Paper

Digital Cognitive Behavioral Therapy for Insomnia for Adolescents With Mental Health Problems: Feasibility Open Trial

Bethany Cliffe[1], BSc, MSc; Abigail Croker[2], BSc; Megan Denne[2], BSc; Jacqueline Smith[2], BSc; Paul Stallard[1], PhD

[1]Department of Health, University of Bath, Bath, United Kingdom

[2]Child and Adolescent Mental Health Service, Oxford Health NHS Foundation Trust, Temple House, Keynsham, United Kingdom

Corresponding Author:
Paul Stallard, PhD
Department of Health
University of Bath
1 West
Claverton Down
Bath, BA2 7AY
United Kingdom
Phone: 44 01225 388388
Email: p.stallard@bath.ac.uk

Abstract

Background: Insomnia in adolescents is common, persistent, and associated with poor mental health including anxiety and depression. Insomnia in adolescents attending child mental health services is seldom directly treated, and the effects of digital cognitive behavioral therapy (CBT) for insomnia (CBTi) on the mental health of adolescents with significant mental health problems are unknown.

Objective: This open study aimed to assess the feasibility of adding supported Web-based CBT for insomnia to the usual care of young people aged 14 to 17 years attending specialist child and adolescent mental health services (CAMHS).

Methods: A total of 39 adolescents with insomnia aged 14 to 17 years attending specialist CAMHS were assessed and offered digital CBTi. The digital intervention was Sleepio, an evidence-based, self-directed, fully automated CBTi that has proven effective in multiple randomized controlled trials with adults. Self-report assessments of sleep (Sleep Condition Indicator [SCI], Insomnia Severity Scale, and Web- or app-based sleep diaries), anxiety (Revised Child Anxiety and Depression Scale [RCADS]), and depression (Mood and Feelings Questionnaire [MFQ]) were completed at baseline and post intervention. Postuse interviews assessed satisfaction with digital CBTi.

Results: Average baseline sleep efficiency was very poor (53%), with participants spending an average of 9.6 hours in bed but only 5.1 hours asleep. All participants scored less than 17 on the SCI, with 92% (36/39) participants scoring 15 or greater on the Insomnia Severity Scale, suggesting clinical insomnia. Of the 39 participants, 36 (92%) scored 27 or greater on the MFQ for major depression and 20 (51%) had clinically elevated symptoms of anxiety. The majority of participants (38/49, 78%) were not having any treatment for their insomnia, with the remaining 25% (12/49) receiving medication. Sleepio was acceptable, with 77% (30/39) of the participants activating their account and 54% (21/39) completing the program. Satisfaction was high, with 84% (16/19) of the participants finding Sleepio helpful, 95% (18/19) indicating that they would recommend it to a friend, and 37% (7/19) expressing a definite preference for a digital intervention. Statistically significant pre-post improvements were found in weekly diaries of sleep efficiency (P=.005) and sleep quality (P=.001) and on measures of sleep (SCI: P=.001 and Insomnia Severity Index: P=.001), low mood (MFQ: P=.03), and anxiety (RCADS: P=.005).

Conclusions: Our study has a number of methodological limitations, particularly the small sample size, absence of a comparison group and no follow-up assessment. Nonetheless, our findings are encouraging and suggest that digital CBTi for young people with mental health problems might offer an acceptable and an effective way to improve both sleep and mental health.

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KEYWORDS

insomnia; internet-based intervention; cognitive therapy; mental health

Introduction

Adolescent Insomnia and Mental Health

Insomnia is a chronic dissatisfaction with sleep quantity or quality, despite an adequate opportunity to sleep [1]. It includes difficulties initiating, maintaining, or returning to sleep, with the sleep disturbance occurring at least three nights per week for 3 months and causing impairment in daytime functioning. It is the most prevalent adolescent sleep disorder, with community surveys identifying up to one-third of adolescents with significant symptoms of insomnia [2]. The mean age of onset of insomnia is 11 years, with symptoms being associated with significant mental health problems and tending to be persistent [3-5]. Associations have been found between insomnia and increased risk of nonsuicidal self-injury [6], poor school performance [7], anxiety, mood disorders, behavioral difficulties, substance use, eating disorders, and suicidality [2].

The mechanisms underlying these relationships are complex and potentially involve sequential, parallel, and interacting biological, psychological, and social systems [8]. Although there is a bidirectional relationship between sleep and mental health [5], there is evidence to suggest that sleep difficulties may precede the development of depression and anxiety [8-10]. Given the common comorbidity of insomnia across mental health diagnoses, interventions directly targeting sleep difficulties could have a positive effect on mental health outcomes [11].

Cognitive Behavioral Therapy for Insomnia

Within an adult population, cognitive behavioral therapy for insomnia (CBTi) is an effective and recommended intervention for insomnia [12]. It is the first line of treatment offered for adults with insomnia and has been shown to be superior to pharmacological treatments in the long term [13]. CBTi involves a range of cognitive and behavioral techniques such as stimulus control, relaxation training, sleep restriction, sleep hygiene, and cognitive techniques to manage worries and intrusive thoughts. Although traditionally provided as a face-to-face intervention, CBTi is also effective when delivered digitally [14,15]. Randomized controlled trials with community cohorts of adults have shown that digital CBTi can improve both sleep and mental health, with reductions in symptoms of anxiety, depression, and psychosis being reported [16-18].

Cognitive Behavioral Therapy for Insomnia for Children and Adolescents

The evidence base for children is more limited, although cognitive and behavioral interventions for insomnia for children in medical settings have shown promising results [19]. However, studies evaluating CBTi within mental health settings with adolescent clinical populations are extremely limited [20]. In a small pilot study, adolescents with a diagnosis of depression and insomnia were provided with 10 sessions of face-to-face CBTi (n=20) or sleep hygiene (n=21) in addition to CBT for depression [21]. Improvements in total time asleep and depression outcomes in the CBTi group were noted at 6 months. Similarly, in an open trial, adolescents (N=46) with depression and insomnia received a group CBTi intervention consisting of five 90-min sessions, which resulted in postintervention improvements in sleep and mood [22].

In terms of digital CBTi with adolescents, a recent systematic review found postintervention improvements in sleep efficiency, quality, total sleep time, and sleep onset latency [23]. However, the authors were only able to identify three studies that met their inclusion criteria, with one of these involving young people aged 19 to 34 years. In the largest study to date, a community study of Dutch adolescents (n=116) found that face-to-face and internet-delivered CBTi were both effective in improving sleep, with improvements being maintained at 1-year follow-up [24,25]. The authors also noted improvements in mental health, with reductions in affective and anxiety symptoms being mediated by improvements in sleep. No studies have yet evaluated the impact of digital CBTi on the sleep and mental health of adolescents with significant mental health problems attending specialist mental health services.

Aims of the Study

The aim of this study was to evaluate the feasibility of adding supported, low-intensity, digital CBTi to the usual care of adolescents with significant mental health problems attending specialist child and adolescent mental health services (CAMHS). To determine feasibility, we collected data on participants' perceived acceptability of Sleepio and assessed any impact on sleep (primary outcome) and mental health (secondary outcome).

Methods

Study Design

This was a pragmatic, pre-post, uncontrolled, mixed method, open feasibility study. A detailed methodology can be found in the study protocol [26].

Participants

The participants were young people aged 14 to 17 years with mental health problems and comorbid symptoms of insomnia. Participants were recruited from child and adolescent mental health outpatient clinics under the Oxford Health National Health Services Foundation Trust across Bath and North East Somerset, Swindon, and Wiltshire.

Exclusion Criteria

Young people were excluded if they presented with active suicidal ideation; they were diagnosed with psychosis; there were safeguarding concerns (ie, the young person had suffered abuse within the last 6 months or was the subject of a safeguarding investigation); and they had a significant developmental disorder (eg, autism), which prevented them from understanding the materials.

Screening

Potential participants were screened by their clinician for sleep efficiency and motivation. Sleep efficiency was chosen as this is also the measure that is used within the digital CBTi Sleepio program to monitor progress and classify sleep. Young people reported the average amount of time they spent in bed and the amount of time spent asleep each night. Their sleep efficiency (time in bed divided by time asleep) was calculated. Adolescent

sleep efficiency in a community sample (N=10,220) of adolescents aged 16 to 18 years was 85% to 88% [27]. A sleep efficiency of 85% or less was, therefore, required for participation.

The young person's motivation to improve their sleep is an important factor that will affect their willingness to engage with sleep programs and to secure long-term sleep change [28,29]. Motivation was assessed by three items relating to problem severity ("At present, sleep is a big problem for me"), desire to change ("I want to change my sleep"), and self-efficacy ("I feel I can change my sleep"). Each item was rated on a 10-point Likert scale ranging from 0 (strongly disagree) to 10 (strongly agree), with a score of 5 or more on each item being required for participation.

Enrollment and Consent

A researcher met with interested individuals (and their parents if aged <16 years) to explain the project. Those aged 14 to 15 years provided signed assent and their parents signed consent. Those aged 16 to 17 years provided signed consent.

Ethics

The study was approved by the South West-Central Bristol Research Ethics Committee (17/SW/0178). Any face-to-face intervention or medication participants were receiving through CAMHS was continued, and their CAMHS clinician continued to take responsibility for the young person's care.

Intervention

Sleepio is an established, fully automated, Web-based, self-administered sleep intervention that has been evaluated with adults [18,30,31]. As this study aimed to assess the acceptability of Sleepio for young people, no developmental adaptations were made to the existing program. The intervention was free to study participants and consisted of 6 sessions, each lasting approximately 20 min, which were released each week. The sessions were accessed via a Web browser on a tablet, desktop, or mobile phone. The program is highly interactive, and content is presented via an animated cartoon therapist (*The Prof*). Participants completed daily Web or app-based sleep diaries throughout the program, with an algorithm personalizing the content of the program to the individual's needs. Sleepio is based on CBTi and incorporates cognitive (paradoxical intention, cognitive restructuring, mindfulness, positive imagery, and putting the day to rest), behavioral (sleep restriction, stimulus control, and relaxation), and educational (sleep hygiene and the process of sleep) components. Participants took an average of 8.5 weeks to complete the program.

Engagement with Web-based self-help mental health programs is variable and is typically lower than that with guided interventions [11]. As Sleepio has not previously been used with this age group, we augmented the programs with brief (up to 15 min), weekly support telephone calls from a trained Sleepio assistant. The support calls were designed to maintain motivation and engagement and followed a similar process to that used by Luik et al [31]. They focused solely on how the material presented in each Sleepio session could be applied to the young person's circumstances and did not address the wider mental health of the young person.

Acceptability of Sleepio

A semistructured interview was undertaken with young people to gather detailed feedback on their experience of Sleepio and their perceived acceptability of it. Qualitative questions assessed how, where, and how often Sleepio was accessed; which techniques and sessions were most useful; experience of using a Web-based program and telephone support; and how the program could be improved. The frequencies of reported themes were summarized, and key quotes were extracted to contextualize the results. In addition, young people rated on a 4-point Likert scale the ease of use, helpfulness, preference over face-to-face meetings, whether sessions were understandable, and if they would recommend Sleepio to a friend. Perceived changes in sleep, mental health, and overall satisfaction were rated on a 10-point Likert scale.

Outcome Measures

Standardized questionnaires were completed at baseline and on completion of the program.

Sleep

Sleep was assessed using the Insomnia Severity Index (ISI) [32] and the Sleep Condition Indicator (SCI) [33]. The ISI is a 7-item self-report measure assessing symptoms of insomnia over a 2-week period on a 5-point scale. The ISI assesses sleep onset, sleep maintenance, early morning awakening problems; sleep dissatisfaction; interference of sleep difficulties with daytime functioning; whether sleep problems are noticed by others; and distress caused by sleep difficulties. The ISI has excellent internal consistency (Cronbach alpha=.91), with a cutoff of 15 or greater identifying 88% of those diagnosed with insomnia [32].

The SCI is an 8-item self-report measure assessing sleep and its impact on daytime functioning over the previous month on a 4-point scale. The SCI assesses sleep continuity (falling and remaining asleep), satisfaction with sleep (quality and troubled by sleeping), severity (nights per week and problem duration), and consequences of poor sleep (impact on personal functioning and performance). The SCI is internally consistent (Cronbach alpha=.86), with a clinical cutoff of less than 17 correctly identifying 89% of those with probable Diagnostic and Statistical Manual of Mental Disorders (DSM), Fifth Edition, insomnia disorder [30,33].

Anxiety

Symptoms of anxiety were assessed using the Revised Child Anxiety and Depression Scale (RCADS) [34]. The RCADS is a 47-item questionnaire assessing DSM, Fourth Edition, criteria for social phobia, separation anxiety, obsessive compulsive disorder, panic disorder, generalized anxiety disorder, and major depressive disorder. Each item is rated on a 4-point Likert scale of frequency ranging from never (0) to always (3), and items are then summed to produce subscale and total anxiety scores. There are age- and gender-related norms for identifying clinically significant scores (*t* scores ≥65).

Depression

Symptoms of depression were assessed using the Mood and Feelings Questionnaire (MFQ) [35]. The MFQ consists of 33 items, each rated as either true (scores 2), sometimes true (scores 1), or not true (scores 0). The MFQ has high criterion validity and correlates well with other measures of depression. A total score of 27 or greater is associated with major depression, 17 to 26 with mild depression, and 16 or less with no mood disorder.

Statistical Analysis

Descriptive statistics summarize the cohort, with group differences being examined by Student's *t* test.

Results

Participant Flow

A total of 50 young people were screened, with one being unable to participate because of becoming homeless. The remaining 49 participants were enrolled and contacted to arrange a baseline assessment. One young person did not respond; 3 participants had other commitments they needed to prioritize; 2 participants no longer wanted to be involved; and the mental health of 2 participants had deteriorated with the sleep of 2 participants improving. Baseline assessments were completed with the remaining 39 participants. Of the 39 participants, 30 (77%) assessed at baseline completed at least one Sleepio session, 22 (56%) completed at least two sessions, 21 (54%) completed at least three sessions, 16 (41%) completed at least five sessions, and 13 (33%) completed at least six sessions. The average number of Sleepio sessions completed was 3.93 (SD 2.16). Postuse assessments were undertaken with 19 of 30 (63%) participants who engaged with the program, and interviews about the experience and acceptability of the program were conducted with 12 of 30 (40%) participants.

Participant Characteristics

The 49 participants enrolled were predominantly female (37/49, 76%), with an average age of 15.6 (SD 1.19) years. The group had poor sleep efficiency (52%, SD 13.59) and spent an average of 9.6 (SD 1.8) hours in bed each night, of which they were asleep for 5.1 (SD 1.6) hours. Self-report ratings out of 10 indicated that sleep was a big problem (mean 8.2, SD 1.6), which they wanted to change (mean 9.1, SD 1.2) and indicated that they felt they were able to change (mean 6.3, SD 1.2).

The primary diagnoses of those enrolled were emotional disorders of anxiety or depression (37/49, 76%), with almost half (22/49, 45%) of the participants reporting a history of self-harm. Pharmacological interventions were prescribed for 51% (25/49) young people, with 37% (18/49) taking selective serotonin reuptake inhibitors (SSRIs; fluoxetine, n=11; sertraline, n=5; and citalopram, n=2) and 25% (12/49) receiving a pharmacological intervention for their sleep (melatonin, n=3; zopiclone, n=1; and circadian, n=8). None of the participants had received a psychological sleep intervention.

There were no differences between those who went on to complete baseline assessments (n=39) and those who did not (n=10) in gender (Levene test indicated unequal variances, so degrees of freedom were adjusted [$t_{19.8}$=1.47; P=.16]), age (t_{47}=−0.04; P=.97), sleep being a big problem (t_{47}=0.22; P=.83), wanting to change sleep (t_{47}=1.47; P=.15), or feeling able to change sleep (t_{47}=1.68; P=.10). There was one difference in sleep (t_{47}=3.35; P=.002), with those who completed baseline assessments spending almost 2 hours more in bed (mean 9.95 hours, SD 1.66) than those who did not (mean 8.05 hours, SD 1.30).

Demographic and assessment data for the 39 participants who completed baseline assessments are summarized in Table 1.

All participants scored less than 17 on the SCI, with 92% (36/39) participants scoring 15 or greater on the Insomnia Severity Scale, suggesting clinical insomnia. Sleep difficulties were regular and chronic, with 95% (37/39) participants reporting problems sleeping for 4 or more nights each week and 69% (27/39) participants reporting difficulties for more than 1 year. Poor sleep severely, or very severely, interfered with everyday functioning (35/39, 90%); caused problems with concentration, productivity, or ability to stay awake (34/39, 87%); and affected mood, energy, or relationships (31/39, 80%). Satisfaction with sleep was poor, with 95% (37/39) participants being severely, or very severely, dissatisfied with their current sleep pattern.

Table 1. Participant demographics and baseline sleep, motivation, anxiety, and depression (N=39).

Characteristic	Values
Age (years), mean (SD)	15.6 (1.21)
Gender, n (%)	
Female	28 (72)
Male	11 (28)
Average number of hours in bed each night, mean (SD)	9.95 (1.66)
Average number of hours asleep per night, mean (SD)	5.15 (1.23)
Average percentage of sleep efficiency=hours asleep/hours in bed, mean (SD)	52.86 (13.56)
Sleep is a big problem—rating out of 10, mean (SD)	8.18 (1.49)
I want to change my sleep—rating out of 10, mean (SD)	8.97 (1.29)
I feel I can change my sleep—rating out of 10, mean (SD)	6.13 (1.08)
Primary diagnosis, n (%)	
Anxiety disorder	11 (28)
Depressive disorder	8 (21)
Mixed anxiety and depressive disorder	13 (33)
Eating disorder	3 (8)
Posttraumatic stress disorder	2 (5)
Autism spectrum disorder	2 (5)
History of self-harm, n (%)	
Yes	18 (46)
No	21 (54)
Currently prescribed medication, n (%)	
Yes	22 (56)
No	17 (44)
Currently prescribed sleep medication, n (%)	
Yes	10 (26)
No	29 (74)
Sleep Condition Indicator, mean (SD)	6.56 (3.04)
Insomnia Severity Index, mean (SD)	19.64 (3.54)
Revised Anxiety and Depression Scale, mean (SD)	
Obsessive compulsive disorder	7.05 (3.76)
Separation anxiety	8.69 (4.78)
Social anxiety	18.82 (6.23)
Generalized anxiety	9.95 (4.21)
Panic disorder	12.79 (6.46)
Depression	20.21 (4.62)
Anxiety total	57.03 (20.26)
Total Revised Child Anxiety and Depression Scale	77.23 (23.52)
Mood and Feeling Questionnaire, mean (SD)	42.05 (11.70)

In terms of mental health, the group presented with significant symptoms of depression and anxiety. On the MFQ, 92% (36/39) participants scored 27 or greater, suggesting major depression. Of the 39 participants, 16 (41%) endorsed the statement "I thought that life wasn't worth living," 15 (39%) endorsed the statement "I thought about death or dying," and 13 (33%) endorsed the statement "I thought about killing myself." Similarly, there were significant symptoms of anxiety. Using

age- and gender-adjusted norms, 51% (20/39) participants scored within the clinical range (*t* score≥70) for the total RCADS, with a further 23% (9/39) participants falling within the borderline range (*t* score=65).

A comparison of baseline data was undertaken for those who completed follow-up assessments (n=18) and those who did not (n=21). There were no differences in age (t_{37}=−0.34; *P*=.73); gender (t_{37}=−0.25; *P*=.81); perception of sleep as a problem (t_{47}=0.52; *P*=.61); desire to change sleep (t_{37}=1.94; *P*=.06); ability to change sleep (t_{37}=−0.46; *P*=.65); or baseline scores on standardized measures of sleep (SCI: t_{37}=0.60; *P*=.55 and ISI: t_{37}=−0.16; *P*=.87), depression (MFQ: t_{37}=0.79; *P*=.44), or anxiety (RCADS: t_{37}=−0.33; *P*=.74).

Acceptability of Sleepio

Semistructured interviews were undertaken with 12 young people. Most young people accessed Sleepio at least once per week (10/12, 83%), via a laptop (10/12, 83%), in their room (11/12, 92%), and on their own (11/12, 92%). Young people were positive about working with the Web-based program (10/12, 83%) and identified a number of benefits. Working on the Web was seen as less stressful (5/12, 42%): “It was less stressful, like I could do it when I wanted” and “made it a little less intimidating cos you’re not talking to someone.” Other benefits were convenience (4/12, 33%): “you could go through it in your own time, there wasn’t any pressure.” Three young people highlighted that they found face-to-face meetings difficult and so welcomed the Web-based intervention: “I am rubbish at speaking to people, it’s exhausting, so I like this.” Of the 2 participants who expressed a preference for face-to-face meetings, both highlighted that they missed the opportunity to ask questions and to seek clarification of the things they did not understand: “face to face is probably better, you can ask questions if you don’t understand.”

The weekly support telephone calls were used by 16 out of the 30 young people who, on average, received a total of 38 min during the course of the program. Of the 14 participants who did not take up the telephone support, 7 dropped out after session 1 compared with 1 of the 16 participants of those who received support. Of those interviewed, 11 out of the 12 young people used the telephone support. Although all the participants found the calls helpful, 3 did not think they were necessary: “I think it would’ve been fine without the phone calls though, because I never had any questions or anything.” The reported benefits of the calls included being able to recap on sessions (9/12, 75%): “I think it was good to just talk over what you’d done.” Five participants welcomed the opportunity to ask questions: “It was good if I had any questions,” with 2 young people finding the calls motivating: “It definitely kept me more motivated to do it cos it’s an actual person.”

In terms of the specific techniques that were helpful, sleep restriction (reducing the amount of time spent in bed to consolidate sleep) was identified most often (6/12, 50%). Although helpful, it was also seen as challenging: “It was hell on earth, but it was useful, it did help definitely.” However, another 3 participants identified sleep restriction less positively, finding it hard to implement: “If I was really tired, I would go to bed before Sleepio said I was supposed to.”

The 15-min rule (ie, if awake for 15 min, get out of bed) was positively endorsed by 5 out of the 12 young people. One young person commented: “I tend to work myself up quite a lot so having the 15 minutes rule if I haven’t slept to just get out of that working myself up thing.” Another young person did not find this helpful and reported the opposite effect: “I kind of gave up with it after a week cos it just stresses you.”

Relaxation was identified as helpful by 4 out of the 12 young people: “Imagery and progressive relaxation were good for taking my mind off of other things.” Another young person did not find progressive relaxation helpful (“It wasn’t that things weren’t useful, they just didn’t work for me”), and one person did not like mindfulness (“mindfulness I didn’t like”). Finally, 2 young people identified thought blocking and 1 identified sleep hygiene as helpful.

In terms of improvements, 3 young people commented about issues with connectivity (“Tiny thing was that it got a bit glitchy at some points when you were doing the sessions”), although all participants noted that this may have been because of their internet connection (“I think it might just have been my rubbish Wi-Fi”). One participant requested sessions to be released earlier rather than waiting a week; another participant requested short-time interval in the sleep diary (5 min blocks instead of 15 min); one participant requested wanting to print out material; and one participant requested sleep diary reminders. Only 1 young person commented on improving the program content and how thought blocking and mindfulness were unhelpful.

Satisfaction and Helpfulness

A total of 19 young people completed Likert ratings of satisfaction and helpfulness. Overall satisfaction, assessed on a 1 to 10 scale, was good (mean 6.89, SD 1.97). Participants found Sleepio easy to use (14/19, 74%) and understand (16/19, 84%), with just under half (9/19, 47%) of the participants definitely finding it helpful and a further 37% (7/19) participants finding it partially helpful. In terms of endorsing Sleepio, only 5% (1/19) participants would not recommend Sleepio to a friend, and 68% (13/19) participants would definitely recommend it.

On a 10-point scale, the mean rating of sleep improvement was 5.58 (SD 2.22), but it was lower, 3.37 (SD 2.54), for perceived improvements in mental health. In terms of delivery, 37% (7/19) participants expressed a definite preference for the Web-based program, with 26% (5/19) participants stating a definite preference for a face-to-face intervention.

Postuse Outcome Data

Pre-post data are summarized in Table 2.

Table 2. Pre- and postdata (N=19).

Psychological measure	Baseline, mean (SD)	Postuse, mean (SD)	95% CI	*P* value
RCADS[a]				
Obsessive compulsive disorder	6.58 (3.44)	5.42 (4.19)	−0.25 to 2.57	.10
Separation anxiety	8.53 (4.39)	6.05 (4.33)	1.22 to 3.73	*.001* [b]
Social anxiety	20.37 (5.64)	18.00 (5.74)	−0.15 to 4.89	.06
Generalized anxiety	10.68 (4.04)	9.74 (4.53)	−0.55 to 2.44	.20
Panic disorder	13.11 (5.50)	11.16 (6.27)	0.11 to 3.79	*.04* [b]
Depression	19.26 (4.81)	15.32 (6.05)	1.45 to 6.45	*.004* [b]
Anxiety total	59.26 (19.01)	50.37 (20.82)	2.59 to 15.20	*.008* [b]
Total RCADS	78.53 (23.06)	65.68 (26.17)	4.35 to 21.33	*.005* [b]
Mood and Feeling Questionnaire	40.53 (13.13)	33.79 (16.34)	0.94 to 12.54	*.03* [b]
Sleep Condition Indicator	6.26 (2.71)	15.11 (7.89)	−12.26 to −5.43	*<.001* [b]
Insomnia Severity Index	19.74 (3.25)	12.47 (6.05)	4.87 to 9.66	*<.001* [b]

[a]RCADS: Revised Child Anxiety and Depression Scale.

[b]Value reached significance.

Sleep

Paired *t* tests identified statistically significant postintervention changes on all measures. Sleep improved as assessed by the SCI (t_{18}=−5.44; *P*<.001) and the ISI (t_{18}=6.36; *P*<.001). Using the recommended cutoffs for identifying significant symptoms of insomnia, there was a significant change in both measures. On the SCI, there was a postintervention reduction from 19 to 10 in those scoring less than 17, and on the ISI, there was a reduction from 19 to 6 in those scoring 15 or greater. Finally, a comparison between the first and the last sleep diaries completed each week identified improvements in sleep quality (t_{23}=−5.81; *P*<.001) and efficiency (t_{24}=3.11; *P*=.005), with 69% of total time in bed spent asleep compared with 54% at baseline.

Mental Health

In terms of mental health, there were postintervention reductions in symptoms of depression (MFQ: t_{18}=2.44; *P*=.03), with a slight postintervention reduction in the number scoring 27 or greater from 16 to 14. There were reductions in anxiety (total RCADS: t_{18}=3.18; *P*=.005), which were particularly marked on the subscales assessing separation anxiety (t_{18}=4.13; *P*<.001), panic (t_{18}=2.22; *P*=.04), and depression (t_{18}=3.32; *P*=.004). The number within the clinical range on the RCADS (*t* score≥70) reduced from 10 to 7, with a reduction from 15 to 7 of those scoring within either the borderline or clinical range (*t* score ≥65).

Discussion

Principal Findings

The adolescents who participated in this open feasibility study were attending specialist CAMHS, and all the adolescents presented with clinical levels of mental health problems. The group presented primarily with affective disorders, self-harm was common, and almost half of the participants were prescribed SSRIs. Insomnia was chronic, severe, and disabling; one-fourth of the participants were receiving a pharmacological intervention for their insomnia, and none of the participants had been offered a psychological intervention. Despite these high levels of psychopathology, our results are encouraging and demonstrate that brief, supported, digital CBTi was acceptable and was associated with reductions in symptoms of insomnia, increased sleep quality and efficiency, and fewer symptoms of anxiety and depression.

It proved feasible to recruit young people with comorbid insomnia from child mental health services. Program adherence was good, with 54% (21/39) of those who started digital CBTi completing more than half of the program sessions. However, this is significantly lower than the rates reported by others assessing digital CBTi with adolescents [24,25]. At baseline, the amount of time spent in bed was the only difference between those who activated their Sleepio account and those who did not. Although a formal comparison of Sleepio completers and noncompleters was not possible because of small numbers, we did observe some trends. Noncompleters were more likely to have a history of self-harm (9/9, 100%), a diagnosis of depression or mixed depression/anxiety (6/9, 67%), and be prescribed medication (5/9, 56%) than completers (self-harm, 7/21, 33%; depression/mixed depression, 9/21, 43%; and medication, 9/21, 43%). This needs to be explored in further studies but may indicate that supported digital CBTi may be more appropriate for adolescents with less complex mental health presentations.

Satisfaction with digital CBTi was high, with 95% (18/19) of the participants recommending digital CBTi to a friend. Of the 19 participants, 7 (37%) expressed a definite preference for the

digital program, noting advantages of convenience, less stress, and an alternative nonverbal intervention. The advantage of a nonverbal delivery model was particularly highlighted during interviews by those who found face-to-face interventions difficult. However, 26% (5/19) of participants stated a definite preference for a face-to-face intervention as opposed to a digital intervention. Interviews with 2 young people who expressed this preference highlighted how they missed the interactive opportunity to ask questions. Further research is required to explore treatment preferences, and although digital sleep interventions may not be the first choice for all adolescents, our results suggest that some will have a clear preference for digital delivery.

In terms of program content, 9 of the 12 participants interviewed specifically commented about sleep restriction. Sleep restriction is a core component of CBTi, although there is considerable variation in the way the sleep window is calculated [36]. In our study, we did not make any developmental modifications and used the existing algorithm of the adult Sleepio program. Most (6/9, 67%) of the participants identified sleep restriction as helpful although challenging, with the remaining 3 of 9 participants reporting that they were unable to fully implement these techniques. We do not know whether this would have been easier to implement if sleep restriction was more specifically adapted for this younger age group. Although this should be explored in future studies, our preliminary findings suggest that the unmodified program did result in significant improvements in sleep efficiency and quality.

The digital intervention was low intensity, delivered in just over 2 hours, alongside the young person's usual face-to-face mental health intervention. Telephone support from a trained graduate psychologist required an average of 38 min per participant and was viewed positively by most young people. In particular, they welcomed the usefulness of recapping on the session content and how they could apply the ideas to their situation. The motivational aspects of the support calls were identified by 2 young people, with others being unsure whether the support calls were necessary. However, the calls may have helped with initial engagement. Half of those (7/14) who did not take up the support call dropped out after session 1 compared with only 6% (1/16) of those who received the support. With such a small sample, it is unclear whether those who used telephone support were more motivated than those who did not. This suggests the need for a flexible approach where different levels of support may be required to engage with and complete digital interventions.

Our results are consistent with those undertaken with adults where Web-based CBTi has improved both sleep and mental health [16-18,30,37-40]. These findings are also consistent with community studies where Web-based CBTi for adolescents with a primary diagnosis of insomnia showed improvements in mental health outcomes including affective and anxiety symptoms [24,25]. Studies evaluating the use of CBTi with clinical groups are extremely limited, although findings from pilot studies have shown that face-to-face CBTi resulted in improvements in both sleep and mental health [21,22]. However, to our knowledge, this is the first study evaluating digital CBTi with adolescents with mental health problems attending specialist child mental health services. Despite the high levels of mental health psychopathology, postintervention assessments demonstrated that low-intensity digital CBTi was associated with improvements in sleep, anxiety, and depression. If substantiated in a robust, comparative, randomized controlled trial, digital CBTi may offer an accessible, low-cost, less stigmatizing way of providing mental health interventions for adolescents.

Limitations

Although encouraging, our study suffers from a number of limitations that need to be acknowledged. First, our study was a small open feasibility study with no comparison group. Although our results are consistent with others, we do not know whether the improvements we report are because of Sleepio or the face-to-face CAMHS intervention the young person received. Second, digital CBTi involved telephone support, and it is possible that this contact may have confounded the results we report. Although feedback from young people identified that these calls remained focused on the CBTi session content, it is possible that this may have had a secondary effect on the outcomes we report. Third, our group was self-selected and highly motivated and may not, therefore, be representative of those attending child mental health services. Although a limitation, this nonetheless suggests that there is a group of motivated young people with chronic insomnia attending child mental health services who might benefit from the addition of digital CBTi. Fourth, we relied on self-reports and did not have any objective measures of sleep (eg, actigraphy) or undertake any follow-up assessments. Self-reports may suffer from recall bias and tend to overestimate total sleep compared with actigraphy [41]. Finally, we added digital CBTi to the usual care of young people already attending CAMHS, and we cannot generalize these findings outside of this setting.

Conclusions

These results suggest that the unmodified Sleepio digital CBTi intervention is feasible to deliver to young people with significant mental health problems attending specialist mental health services. Digital CBTi was acceptable, with a number of young people expressing a preference for non–face-to-face interventions. Pre-post improvements in sleep, anxiety, and depression are encouraging and support the undertaking of a robust, suitably powered, randomized controlled trial to compare the effectiveness and cost-effectiveness of digital CBTi on the sleep and mental health of young people with identified mental health problems. This could be a 2-arm (supported digital CBTi vs usual CAMHS care) or a 3-arm (supported digital CBTi vs self-guided CBTi vs usual care) trial. This low-intensity intervention has the potential to be cost-effective and could be incorporated into a stepped care pathway where a brief digital CBTi could be provided before pharmacological interventions.

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Authors' Contributions

PS is the grant holder and principal investigator for the project. PS conceptualized the study design and drafted the manuscript. MD, AC, and JS provided telephone support, and BC undertook pre- and postassessments. All authors read, contributed to, and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CAMHS: Child and Adolescent Mental Health Services
CBT: cognitive behavioral therapy
CBTi: cognitive behavioral therapy for insomnia
DSM: Diagnostic and Statistical Manual of Mental Disorders
ISI: Insomnia Severity Index
MFQ: Mood and Feelings Questionnaire
RCADS: Revised Child Anxiety and Depression Scale
SCI: Sleep Condition Indicator
SSRI: selective serotonin reuptake inhibitor

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Original Paper

Efficacy of a Virtual Reality Biofeedback Game (DEEP) to Reduce Anxiety and Disruptive Classroom Behavior: Single-Case Study

Rineke Bossenbroek[1], MSc; Aniek Wols[1], MSc; Joanneke Weerdmeester[1], MSc; Anna Lichtwarck-Aschoff[1], PhD; Isabela Granic[1], PhD; Marieke M J W van Rooij[1], PhD

Behavioural Science Institute, Radboud University, Nijmegen, Netherlands

Corresponding Author:
Rineke Bossenbroek, MSc
Behavioural Science Institute
Radboud University
PO Box 9104
Nijmegen, 6500 HE
Netherlands
Phone: 31 243612638
Email: r.bossenbroek@pwo.ru.nl

Abstract

Background: Many adolescents in special education are affected by anxiety in addition to their behavioral problems. Anxiety leads to substantial long-term problems and may underlie disruptive behaviors in the classroom as a result of the individual's inability to tolerate anxiety-provoking situations. Thus, interventions in special needs schools that help adolescents cope with anxiety and, in turn, diminish disruptive classroom behaviors are needed.

Objective: This study aimed to evaluate the effect of a virtual reality biofeedback game, DEEP, on daily levels of state-anxiety and disruptive classroom behavior in a clinical sample. In addition, the study also aimed to examine the duration of the calm or relaxed state after playing DEEP.

Methods: A total of 8 adolescents attending a special secondary school for students with behavioral and psychiatric problems participated in a single-case experimental ABAB study. Over a 4-week period, participants completed 6 DEEP sessions. In addition, momentary assessments (ie, 3 times a day) of self-reported state-anxiety and teacher-reported classroom behavior were collected throughout all A and B phases.

Results: From analyzing the individual profiles, it was found that 6 participants showed reductions in anxiety, and 5 participants showed reductions in disruptive classroom behaviors after the introduction of DEEP. On a group level, results showed a small but significant reduction of anxiety (d=–0.29) and a small, nonsignificant reduction of disruptive classroom behavior (d=−0.16) on days when participants played DEEP. Moreover, it was found that the calm or relaxed state of participants after playing DEEP lasted for about 2 hours on average.

Conclusions: This study demonstrates the potential of the game, DEEP, as an intervention for anxiety and disruptive classroom behavior in a special school setting. Future research is needed to fully optimize and personalize DEEP as an intervention for the heterogeneous special school population.

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KEYWORDS

anxiety; disruptive behavior; single-case study; applied game; serious games; special education; attention-deficit/hyperactivity disorder (ADHD); autism spectrum disorder (ASD); adolescents

Introduction

Background

Adolescents attending schools for special education in the Netherlands (called "cluster 4 schools") are characterized by profound behavioral and psychiatric problems [1], such as autism spectrum disorder (ASD), attention-deficit/hyperactivity disorder (ADHD), and oppositional defiant disorder. In addition, 27% to 32% of the Dutch heterogeneous special school population exhibits clinical levels of anxiety [2], indicated by high comorbidity rates between anxiety and ASD (40%) [3] and ADHD (25%) [4]. Anxiety symptoms significantly interfere

with adolescents' mental health, academic achievement, and social functioning [5]. Moreover, anxiety may underlie disruptive behaviors in the classroom, such as acting out spontaneously or expressing worries frequently, as a result of the individual's inability to tolerate anxiety-provoking situations [6]. Individuals suffering from anxiety often have trouble regulating their behaviors in those situations because of underdeveloped self-regulation skills [7]. Clearly, interventions in special needs schools that help adolescents cope with anxiety and, in turn, diminish disruptive classroom behaviors are needed.

Conventional school-based interventions for anxiety are usually based on cognitive behavioral therapy (CBT) [8]. However, these conventional approaches pose limitations with regard to the special school population, as they often do not take the presence of comorbid disorders into consideration. For example, children with ASD may find it difficult to learn CBT skills such as cognitive restructuring because of their cognitive and social impairments [9]. Children with ADHD might also feel uncomfortable in talk therapies because higher-order abstractions may be challenging for them [10]. Moreover, conventional approaches entail challenges in their form of delivery because children are often not motivated to attend the didactic-based sessions nor to complete the homework assignments [11]. Within the school setting in particular, clinicians often fail to match interventions to the child's readiness or motivation for change and hence struggle to keep students engaged [12,13]. Another limitation of CBT includes the use of decontextualized exercises that do not fully represent the authentic emotional and physical experiences associated with anxiety [14], limiting the transfer of the learned skills to other contexts (eg, the classroom setting). Finally, school clinicians have limited time to successfully deliver CBT [13,15]. As a result of these limitations and challenges, conventional school-based programs for anxiety often yield disappointing outcomes, with small-to-moderate effect sizes and intervention effects that do not sustain over time (see Mychailyszyn et al [16] and Werner-Seidler et al [17] for meta-analyses). Taking these limitations together, alternative interventions for anxiety need to be considered.

A promising alternative approach to enhance mental health among children and adolescents is the use of video games. A recent review showed that video games provide youths with immersive emotional experiences, teaching them new forms of emotional, cognitive, and behavioral strategies [14]. Video games may have the potential to address each of the limitations discussed. First, video games may be suitable for the heterogeneous special school population as they provide the player with visual aids and structured sensory information, an important prerequisite in treating anxiety in children with ASD [9,18]. Moreover, video games may impose less load on working memory capacities compared with the verbal reasoning required in CBT, which is an important requirement to treat anxiety in children with ADHD [19]. Second, video games hold great potential to intrinsically motivate and engage children, thereby addressing one of the most challenging tasks faced by (school) clinicians [20]. Third, video games provide youths with an opportunity to practice anxiety regulation skills until they are automatized and can be transferred to situations outside of the game [14]. Finally, a potential benefit of video games is their relatively low cost compared with traditionally delivered mental health interventions [21], thereby addressing the limited resources of clinicians in school settings. Overall, video games hold great promise as a novel intervention approach for adolescents with anxiety in the special school setting.

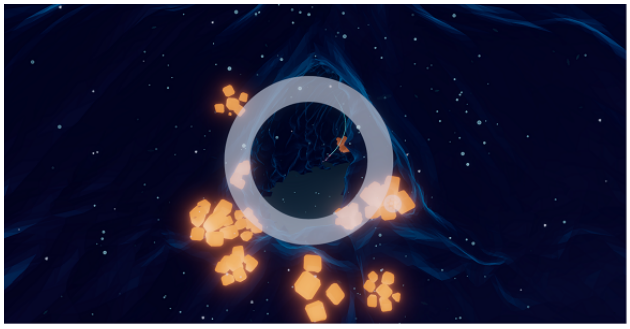
DEEP

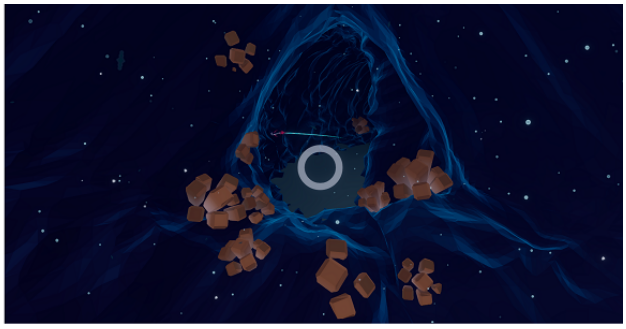
Recently, a virtual reality biofeedback game (DEEP) was developed as a potential intervention to reduce anxiety in youths [22]. In DEEP, players explore an underwater fantasy world by using their own breathing to control their movement. Players wear a belt with a stretch sensor around their waist just below their diaphragm. This sensor measures the expansion of the diaphragm associated with breathing, providing input to control in-game movement: the slower and deeper players breathe through their diaphragm, the better they can move around in the underwater world. The game aims to provide a relaxing and immersive experience for the player; there are no in-game goals to attain. DEEP targets a fundamental causal mechanism that contributes to the development and maintenance of anxiety symptoms: *physiological reactivity*. Anxious youths tend to experience hyperarousal (eg, rapid breathing or increased heart rate) in response to stressors [23]. The body's physiological response interacts with negative cognitive biases (eg, focus on threat-relevant information [24]) to produce the negative affective states that characterize anxiety [25,26]. Thus, the ability to regulate physiological arousal may modify the interaction with negative cognitive biases, resulting in a positive change in the affective state.

The mechanism through which DEEP teaches players how to regulate physiological responses is diaphragmatic breathing [27]. Diaphragmatic breathing is the act of initiating breath into the lungs from contraction of the diaphragm muscle rather than the rib cage, which facilitates breathing efficiency and efficient exhalation [28,29]. Diaphragmatic breathing at a slow pace has been shown to evoke a relaxation response of the autonomic nervous system [30]. Hence, diaphragmatic breathing is commonly used as a relaxation technique in evidence-based treatments for anxiety [29,31].

The breathing exercises incorporated in DEEP are based on biofeedback, which is defined as the process of feeding information back to the individual about one's physiological state to gain awareness and control over physiological processes [32]. Biofeedback is an effective evidence-based therapeutic technique for regulating anxiety (see Schoenberg et al [33] and Weerdmeester et al [34] for recent reviews). In DEEP, biofeedback mechanics are applied in various ways. First, players receive feedback about their stage of breathing by their way of movement: when players inhale, an upward (when close to the ground) or a forward force is applied; when players exhale, these forces are strengthened. Second, players receive feedback about their breathing through visual cues. A circle is shown in the players' visual field that expands with inhalation and contracts with exhalation (Figure 1). Finally, players' breathing is mirrored by elements in the environment (eg, plants) that change in color, size, or movement accordingly. See Multimedia Appendix 1 for a short video of DEEP.

Figure 1. Visual circle that is depicted in the players' visual field corresponding to an inhalation (left) and exhalation peak (right).





Previous Research and Remaining Questions

Preliminary evidence for the efficacy of DEEP as an intervention for anxiety has been demonstrated in a recent pilot study [22]. In a sample of 86 typically developing children, DEEP reduced levels of state-anxiety directly after playing the game for 7 min. However, knowledge about the duration of the calm or relaxed state after playing DEEP is lacking, and it is also unknown if playing DEEP can reduce levels of state-anxiety in a clinical sample.

Next to the potential of DEEP as an intervention for anxiety, an additional yet uncertain beneficial effect of DEEP could be an improvement in the ability to regulate disruptive classroom behaviors. Previous research has shown that traditionally delivered deep-breathing exercises reduced rates of disruptive classroom behaviors (assessed by blind independent observers) among youths attending a special school for students with behavioral problems [35]. Moreover, a game-based intervention incorporating deep-breathing techniques and biofeedback has been found to significantly decrease self-reported externalizing behaviors of adolescents in residential youth care [36,37]. There may be two ways in which DEEP could potentially affect adolescents' behaviors. First, playing DEEP may reduce disruptive classroom behaviors through its effect on anxiety levels. Disruptive behaviors of anxious youths are often driven by the individual's inability to escape or avoid anxiety-provoking situations [6,38]. Not being able to withdraw from or avoid those situations (ie, blocking of the individual's goals) may increase levels of frustration, which could result in subsequent externalizing behaviors [38,39]. Thus, if adolescents feel more relaxed and less anxious after playing DEEP, they may handle any subsequent anxiety-provoking situation better and feel less frustrated about being unable to escape. The diminished frustration may in turn make them less prone to show disruptive behaviors in the classroom.

Second, playing DEEP could potentially reduce disruptive behaviors through its effect on interoceptive awareness: the ability to recognize internal physiological states [40]. Playing DEEP might bring about increased interoceptive awareness as players are continuously informed about their breathing while playing. Heightened interoception might in turn enable adolescents to mobilize self-regulation resources as individuals who are able to focus on their body's response to anxiety might recognize more quickly that control is needed [41]. Next to an efficient mobilization of self-regulation resources, previous research has shown that a better perception of one's bodily signals may facilitate the use of adaptive emotion regulation strategies [42]. Those skills might empower adolescents to control their disruptive behaviors in the classroom.

Design and Hypotheses

Our primary aim in this study was to investigate the effect of DEEP on daily levels of state-anxiety and disruptive classroom behavior in a clinical sample. It was expected that playing DEEP would reduce both participants' state-anxiety and disruptive classroom behavior. Second, we explored the duration of the calm or relaxed state of participants after playing DEEP. No specific hypotheses were formed as this is the first study examining the duration of the effect of playing DEEP. To meet the research aims, we conducted a single-case experimental design (SCED) study in a special school setting. The SCED methodology was particularly appropriate because it allowed us to evaluate the efficacy of an intervention for individuals with heterogeneous characteristics (as is the case in special education [43,44]). This study followed an ABAB design, in which participants' state-anxiety and disruptive classroom behavior in the absence of the intervention (A or baseline-withdrawal phase) were compared with participants' state-anxiety and disruptive behavior during the intervention (B or intervention phase).

Disruptive classroom behavior outcomes were personalized per adolescent as difficulties to regulate oneself may manifest differently in each individual. This idiographic assessment approach may provide insight into whether the intervention is impacting the problems that teachers frequently observe and consider most important [45]. The Single-Case Reporting Guideline in Behavioural Interventions [46] was used to report this study.

Methods

Participants

Participants were 8 adolescents (mean age 14.67, SD 1.83 years) attending a secondary special school for students with behavioral and psychiatric problems in the northern part of the Netherlands. Adolescents were considered eligible for the study if teachers had the impression that the adolescent showed symptoms of anxiety, displayed disruptive behaviors in the classroom, and could handle the burden of completing momentary questionnaires (ie, 3 times a day). In total, teachers put forward 10 eligible adolescents. A school clinician contacted the parents of those 10 adolescents by phone to inform them about the study goals and to invite their child for participation. A total of 8

adolescents and their parents expressed their interest to participate in the study. The research team contacted these parents by phone to provide detailed information about the study's procedure. All adolescents and their parents provided initial verbal consent and received an information and consent letter. Parental written informed consent was sent by mail. Individual demographic characteristics including participants' age, gender, educational level, pretest trait-anxiety score, diagnoses, current medication, and treatment are provided in Table 1. All participants were of Dutch descent.

Table 1. Individualized description of participants' demographics at pretest.

Participant	Age (years)	Gender	Educational level	Trait-anxiety scores[a]	Diagnoses[b]	Current medication	Current treatment
1	12.94	Male	Lower secondary vocational education	44	ADHD[c] and ASD[d]	Methylphenidate	None
2	12.91	Male	Lower secondary vocational education	31	ADHD and ASD	Atomoxetine	None
3	13.90	Male	Lower and higher secondary vocation	37	ADHD and ASD	Methylphenidate	Psychotherapy
4	13.03	Male	Lower and higher secondary vocation	22	RAD[e], ODD[f], and ADHD	None	Psychomotor therapy
5	16.48	Male	Middle level vocational education	47	ASD	None	None
6	17.34	Male	Lower secondary education	36	ASD	None	Ambulatory care offered by the school clinicians
7	16.52	Male	Lower secondary education	36	ADHD and ASD	Methylphenidate[g]	Psychotherapy
8	14.22	Female	Lower secondary education	27	ASD, PD[h], SAD[i], and ED[j]	None	None

[a]To gain a general impression of adolescents' predisposition toward anxiety, the trait-scale of the State-Trait Anxiety Inventory for Children [47] was assessed at pretest. Trait-anxiety scores can range from 20 to 60, with higher scores reflecting higher levels of trait-anxiety. Previous research suggests that children with subclinical and clinical levels of anxiety score on average 32.8 (SD 7.2) and 35.8 (SD 8.1) on the trait-scale, respectively [48,49].

[b]Diagnoses were derived from the electronic school database by the school clinician.

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

[d]ASD: autism spectrum disorder.

[e]RAD: reactive attachment disorder.

[f]ODD: oppositional defiant disorder.

[g]Participant 7 stopped taking medication on day 18, 19, and 20 of the study.

[h]PD: personality disorder.

[i]SAD: social anxiety disorder.

[j]ED: eating disorder.

Design

This study followed an ABAB withdrawal or reversal design, with baseline (A_0), intervention (B), and withdrawal or no intervention (A_1) phases. A and B phases were alternated several times over a period of 4 weeks (ie, 20 schooldays in total). All participants started with the A_0 baseline phase, which lasted for 5 or 6 days. After the baseline phase, the first intervention period (ie, B phase) began. The B phases usually lasted for 1 day, in which participants completed 1 DEEP session in the morning. However, some participants played DEEP on 2 subsequent days because the planned DEEP sessions did not synchronize with the participants' schedule. The intervention days (ie, B phases) were alternated with withdrawal days, in which participants did not play DEEP (ie, A_1 phases). All participants completed 6 DEEP sessions throughout the study period, except for participant 8 who completed 5 DEEP sessions because of illness. Another exception to this design was participant 5, who was doing an internship outside of the school for 2 days a week. Therefore, he participated in the study 3 days a week for 8 subsequent weeks (ie, 24 schooldays in total).

Throughout all phases, state-anxiety and disruptive classroom behavior were assessed with paper-and-pencil questionnaires 3 times per day. Adolescents reported their state-anxiety around 10:00 AM, 12:00 PM, and 2:00 PM. However, during B phases, participants filled in the first state-anxiety questionnaire directly after the DEEP session (between 8:45 AM and 10:15 AM). Teachers reported what they had observed about participants' disruptive classroom behavior in the past 2 hours around 10:20 AM, 12:25 PM, and 2:30 PM. During B phases, teachers reported what they had observed about participants' behavior *after* participants came back from the DEEP session. Therefore,

4 assessments around 10:20 AM were missing because, in those cases, the participant finished the DEEP session around 10:15 AM.

Participant 4 was observed by 3 teachers: 1 teacher observed for 4 days a week, 1 teacher observed for 1 day a week, and 1 teacher observed for 2 days in total when one of the other 2 teachers was ill. Participants 6 and 7 were classmates and were also observed by 2 teachers: 1 teacher observed for 4 days a week, and the other observed for 1 day a week. The remaining participants were observed by a single teacher. Participants 1 and 2 were classmates, so their behavior was observed by the same teacher.

Procedure

At the start of the study, interviews with the teachers were held to discuss specific disruptive classroom behaviors of each participant. On the basis of their input, a personalized questionnaire about each participant's disruptive behavior was developed. Afterward, participants filled in questionnaires regarding their demographics and trait-anxiety at pretest. Then, participants completed the ABAB study that lasted for 4 weeks. The study procedure was followed twice; in the first block, participants 1 to 4 participated, and in the second block, participants 6 to 8 participated. Participant 5 participated in both blocks. After participation, participants and their teachers both received a monetary compensation of €25.00. A total of 2 teachers received a monetary compensation of €37.50 because they had observed 2 adolescents for 4 or 5 days a week. Ethical approval for this study was obtained from the Radboud University Ethics Committee Social Sciences (ECSW-2017-038R1).

Measures

State-Anxiety

Adolescents' state-anxiety was assessed with the 6-item short form of the state scale of the Dutch State-Trait Anxiety Inventory (STAI) [50,51]. The 6 items reflect how calm, tense, upset, relaxed, content, or worried one feels at the moment. To ensure that the questionnaire would match the cognitive abilities of the sample, the questionnaire was adapted to a visual analog scale, consisting of a line of 10.0 cm. State-anxiety scores could therefore range between 0.0 (eg, not tense) and 10.0 (very tense). Item 1, 4, and 5 were recoded, and a mean score across all items was calculated, with higher values indicating more anxious feelings. The state scale of the STAI has shown good reliability and acceptable validity among various populations, including adolescents ([52,53]; for short form: [51,54]), and internal consistency was good (Cronbach alpha=.78) in this study.

Disruptive Classroom Behavior

On the basis of the interviews with the teachers, 2 or 3 disruptive behaviors were defined per participant (Table 2). During the ABAB study, teachers indicated how often those behaviors occurred in the past 2 hours by rating the items on a 6-point Likert scale: 0=*never*, 1=*rarely*, 2=*sometimes*, 3=*often*, 4=*very often*, and 5=*almost always*. Items 1 and 2 from participant 8 were recoded as the desired effect for this participant would be an increase in behavior rather than a decrease.

Table 2. Disruptive classroom behaviors of each participant, indicated by their teacher.

Participant	Behavior 1	Behavior 2	Behavior 3
1	Clears throat or sniffs nose	Asks for confirmation[a]	Gets off the chair and walks out of the classroom
2	Talks (loudly) out of turn	Asks for confirmation[a]	Gets off the chair and walks around the classroom
3	Taps fingers on the table or chair leg	Plays with or pulls hair	Gets off the chair and walks around or out of the classroom
4	Talks out of turn	Gets off the chair and walks around the classroom	Asks for confirmation[a]
5	Looks around during an independent work hour	Talks or laughs with classmates during an independent work hour	Asks for confirmation[a]
6	Shouts or talks loudly	Talks out of turn	N/A[b]
7	Looks around during an independent work hour	Asks for confirmation[a]	N/A
8	Asks a question[c]	Makes contact with classmates[c]	N/A

[a]For example: "Am I doing this right?" and "What are we going to do now?".

[b]N/A: not applicable, because the teachers mentioned only 2 disruptive classroom behaviors for these participants.

[c]The desired effect for participant 8 was an increase in behavior rather than a decrease.

Intervention

Participants completed DEEP sessions in a separate room at school. Upon arrival, participants first sat in a turnaround desk chair after which the DEEP breathing belt was placed around the abdomen. The DEEP belt contains an Arduino-compatible FLORA wearable electronic platform [55] that opens Arduino software [56] to keep track of real-time belt values. Afterward, the HTC Vive VR headset was adjusted to fit each player, and headphones were plugged in for the games' music. Before starting the game, participants were instructed that they could move in the game by breathing deeply through their belly and

by turning around in their chair. Finally, DEEP was started on a laptop, and a timer was started to keep track of time. Participants could play DEEP for 15 min but were allowed to stop earlier if they wanted to. On average, participants played DEEP for 12.41 (SD 3.76) min.

Analyses

Means and standard deviations of A_0, B, and A_1 phase assessments of state-anxiety were calculated for each participant. In addition, the percentage of data points exceeding the median (PEM [57]) was computed for each participant. These scores reflect the percentage of data points in the B phases below the median of the A_0 baseline phase. Afterward, a recent review [58] was used to choose the most appropriate analyses for the state-anxiety data.

To gain a general impression of the data, a visual analysis was performed involving the examination of trend (for the A_0 baseline phase only), variability, and level [59]. Visual analysis was necessary to assess if the data pattern corresponded to what is expected from a baseline (ie, no stable upward or downward trend) and effective intervention (ie, less variability in B phases compared with the A_0 baseline phase; reduction of the level of anxiety over the course of the intervention [58]). To assess if baseline data showed no stable upward or downward trend, trend stability envelopes [60] were calculated for each participant via a Web-based calculator [61]. Lane and Gast [60] proposed that stable trends are present when at least 80% of the data points fall within the envelope defined by the split-middle trend line plus or minus 25% of the baseline median. To compare variability in the B phases with variability in the A_0 baseline phase, the median absolute deviation (MAD) was computed for participants' A_0 baseline phase and the B phases. To calculate the MAD of the B phases, data points of all B phases were merged together for each participant. The MAD was calculated on the 6 STAI items instead of participants' mean anxiety to optimally represent participants' variability.

To assess changes in level, a visual analysis usually focuses on mean score differences between phases [59]. However, this strategy has some limitations. First, mean score differences between phases do not take the presence of potential carryover effects into consideration, which refers to the continued impact of an intervention on subsequent (A_1) phases [62]. Especially when adolescents have played DEEP several times, the intervention may have an irreversible effect on adolescents' breathing skills. Second, the ABAB design consisted of several relatively short phases that also differed in length, making mean score comparisons between phases questionable. As such, it was decided to examine if participants' level of anxiety decreased over time, regardless of phase, thereby keeping the temporal structure of the data intact. Levels of anxiety were classified with recursive partitioning, which is a data-driven approach that uses regression trees to identify segments of a time-series (of at least two data points) that have a stable mean value [63]. Recursive partitioning was performed with the ts_levels function of the casnet package (version 0.1.3, developed by Hasselman [64]) in R [65].

After the visual analysis, nonoverlap of all pairs (NAP [66]) was calculated, which reflects the proportion of NAP comparisons across A and B phases. NAP was calculated as the area under the curve percentage from a receiver operating characteristic analysis in IBM SPSS Statistics 21. NAP ranges of 0 to 0.65 are considered as weak effects, 0.66 to 0.92 as medium effects, and greater than 0.92 as strong effects [66]. The first NAP analysis included all A and B phases. To account for potential carryover effects, a second NAP analysis was conducted comparing the data points in the A_0 baseline phase only with the data points in the B phases.

Finally, the between-case standardized mean difference (BC-SMD [67]) was computed to give an overall quantitative summary of the magnitude of change from A to B phases on a group level. The BC-SMD is an effect size designed specifically for SCED studies and can be compared with effect sizes for between-group designs. Moreover, the BC-SMD accounts for repeated intraindividual assessments and between- and within-case variances and includes a correction for a small sample bias [68,69]. The BC-SMD assumes that the outcome measurement is normally distributed and that there are no clear baseline trends [70]. A total of 4 separate BC-SMD quantifications were obtained. First, an overall change in level from all A to B phases was computed. Afterward, to investigate the duration of the effect of each DEEP session, we obtained overall changes in level from A to B phases measured around 10:00 AM, 12:00 PM, and 2:00 PM separately. The BC-SMD was calculated via a Web-based calculator, developed by Pustejovsky (version 0.3.1 [71]). Restricted maximum likelihood estimation was used to generate the design-comparable model effect size as it is the most flexible estimation model [72]. A random effect for treatment level was specified, which permits the treatment effect to vary across cases. Effect sizes of 0.20, 0.50, or 0.80 were interpreted as small, medium, or large effect sizes, respectively [73].

The same procedure, as described earlier, was repeated for classroom behavior. As NAP scores revealed the same pattern of results for all observed behaviors within the majority of participants, it was decided to only report the results of behavior 1 of each participant. However, for participants 2 and 3, behavior 2 was reported, and for participant 5, behavior 3 was reported because these were the only behaviors that showed medium effects for these participants; all other behaviors of these participants showed no effect.

In terms of missingness, 133 (27.0%) out of the 492 state-anxiety assessments were missing for reasons such as practical lessons, national holidays, or illness. Furthermore, 161 (32.7%) out of the 492 disruptive classroom behavior assessments were missing because of the absence of the adolescent (eg, practical lessons in front of another teacher) or lack of time. We decided not to use imputation strategies, as these percentages of missing data may not affect the quality of statistical inferences [74]. Moreover, the BC-SMD is a robust analysis strategy as it accounts for missing observations [70].

Results

Anxiety

Descriptive Statistics

Table 3 presents means and SDs on A_0, B, and A_1 phase assessments of anxiety and PEM scores for each participant. Overall, participants reported a mean anxiety of 3.32 (SD 1.81) in the A_0 baseline phase, 2.35 (SD 1.48) in the B phases, and 2.30 (SD 1.31) in the A_1 phases. Thus, participants' mean anxiety scores fell within one-third of the full range of the scale in all phases. The findings indicate that participants' anxiety scores may have declined over the course of the intervention. The minor difference between the participant's anxiety in A_1 and B phases suggests that carryover effects may have occurred. PEM scores ranged between 61% (11/18) and 100% (17/17), indicating that most assessments of anxiety were lower on the days of DEEP sessions compared with the A_0 baseline phase.

Table 3. Means and standard deviations of anxiety by phase and percentage of data points exceeding the median scores for each participant.

Participant	A_0 baseline phase, mean (SD)	B phases, mean (SD)	A_1 phases, mean (SD)	Data points exceeding the median, n (%)
1	5.49 (2.24)	3.32 (1.79)	3.55 (1.47)	11 (92)
2	1.95 (1.59)	1.19 (1.60)	0.91 (1.07)	12 (80)
3	3.17 (1.68)	1.52 (0.90)	1.79 (1.02)	17 (100)
4	1.98 (0.56)	1.68 (0.33)	2.21 (0.71)	14 (82)
5	4.11 (1.45)	2.75 (1.78)	1.95 (0.51)	12 (86)
6	2.91 (1.49)	2.52 (1.16)	3.45 (1.13)	11 (61)
7	3.30 (1.29)	2.62 (1.27)	2.40 (0.99)	14 (78)
8	3.73 (0.99)	3.58 (1.21)	4.00 (1.19)	10 (67)

Visual Analysis

Each participant's mean anxiety score is represented graphically in Figure 2. Trend stability envelopes revealed no stable upward or downward baseline trend for all participants (Table 4). The MADs showed that the variability in the B phases compared with the A_0 baseline phase seemed to decrease for half of the participants (ie, participants 2, 3, 4, and 7; Table 4). In contrast, the data patterns of the other half (ie, participants 1, 5, 6, and 8) did not correspond to what is expected from an effective intervention as the variability in anxiety during the B phases compared with the A_0 baseline phase increased or remained the same.

Finally, the changes in levels of anxiety that were identified by recursive partitioning are represented in Figure 2. Anxiety scores seemed to decrease for half of the participants (ie, participants 1, 3, 5, and 7) over the course of the intervention. However, scores of participant 7 should be interpreted cautiously as the decrease in anxiety seemed to correspond with the days he stopped taking his medication. A potential floor effect was detected for participant 2. This floor effect was considered as a desired effect as the levels of anxiety stabilized over the course of the intervention for this participant. No changes in anxiety level were identified for participants 4, 6, and 8 (Table 4).

Figure 2. The effect of DEEP on anxiety for 8 adolescents. Every 3 data points represent 1 day (measured around 10:00 AM, 12:00 PM, and 2:00 PM). The dashed and stepped lines represent the relatively stable anxiety levels that were identified using recursive partitioning.

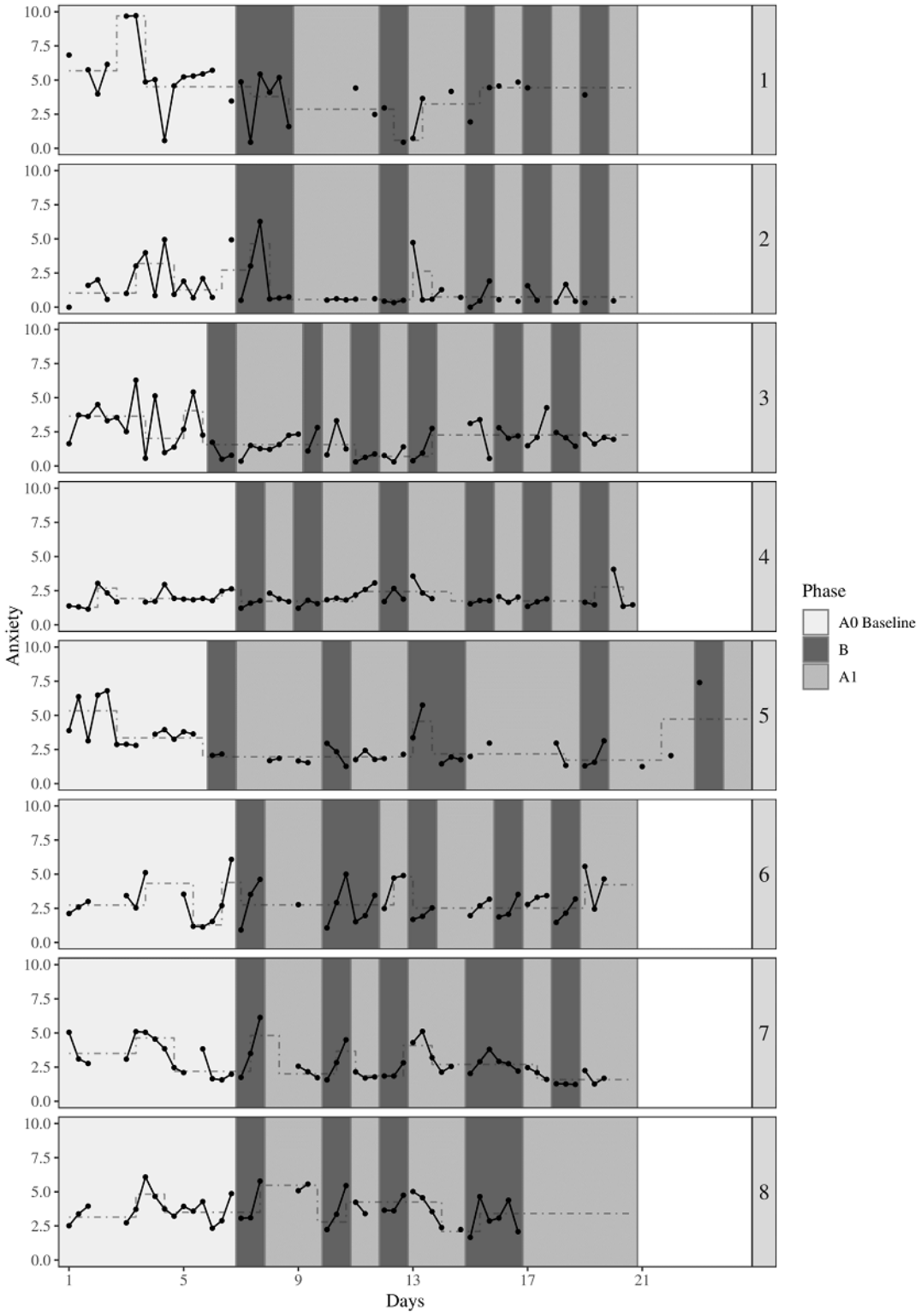


Table 4. Results from visual analysis (baseline trend, variability, and change in level) and nonoverlap of all pairs on anxiety.

Participant	A_0 baseline trend	Variability		Change in level	Comparison: A vs B		Comparison: A_0 baseline vs B	
	Slope (% of data points within envelope)	MAD[a] A_0 phase	MAD B phases		NAP[b]	95% CI[c]	NAP	95% CI[c]
1	−0.11 (67)	3.41	3.85	Seems to decrease	0.72[d]	0.55-0.89	0.82[d]	0.66-0.98
2	0.04 (20)	0.59	0.30	Potential floor effect	0.63	0.45-0.82	0.74[d]	0.55-0.93
3	−0.16 (47)	2.82	1.04	Seems to decrease	0.66[d]	0.51-0.81	0.80[d]	0.64-0.96
4	0.03 (63)	2.97	1.63	No change in level	0.75[d]	0.61-0.88	0.68[d]	0.49-0.87
5	−0.21 (38)	1.48	1.48	Seems to decrease	0.58	0.39-0.77	0.81[d]	0.63-0.98
6	−0.11 (33)	1.85	2.00	No change in level	0.65	0.48-0.83	0.59	0.37-0.80
7	−0.35 (43)	2.00	1.63	Partly decreases	0.55	0.38-0.72	0.67[d]	0.48-0.86
8	−0.02 (60)	2.52	3.56	No change in level	0.58	0.39-0.77	0.56	0.35-0.77

[a]MAD: median absolute deviation.

[b]NAP: nonoverlap of all pairs.

[c]Confidence intervals are asymptotic.

[d]Medium effect.

Nonoverlap of All Pairs

NAP scores including all A and B phases are presented in Table 4. Participants 1, 3, and 4 showed changes in the medium range, indicating that their anxiety scores were lower during the B phases compared with the A phases. Regarding NAP scores including A_0 baseline and B phases only participants 1, 2, 3, 4, 5, and 7 showed changes in the medium range. Carryover effects may have occurred for participants 2, 5, and 7 as they showed medium effects in the A_0 baseline vs B phase comparison but no effect in the A vs B comparison.

Between-Case Standardized Mean Difference

The assumptions of normality and absence of clear baseline trends were tested and met. Therefore, the BC-SMD analysis was deemed appropriate. The overall A vs B comparison yielded an effect size of d=−0.29 (SE 0.11; 95% CI −0.51 to −0.08). This d statistic indicates a small but significant reduction of anxiety with the introduction of DEEP [73]. The A vs B comparison yielded a value of d=−0.43 (SE 0.15; 95% CI −0.74 to −0.15) for the data measured around 10:00 AM, a value of d=−0.34 (SE 0.17; 95% CI −0.68 to −0.02) for the data measured around 12:00 PM, and a value of d=−0.02 (SE 0.17; 95% CI −0.34 to 0.30) for the data measured around 2:00 PM. These d statistics indicate a medium significant reduction of anxiety directly after gameplay, a small but significant reduction 2 hours after gameplay, and no reduction 4 hours after gameplay (see Multimedia Appendix 2 for a graphical representation). Thus, the calm or relaxed state of participants after a DEEP session lasted for 2 hours on average.

Disruptive Classroom Behavior

Descriptive Statistics

Table 5 presents means and SDs on A_0, B, and A_1 phase assessments of disruptive classroom behavior and PEM scores for each participant. Overall, participants reported a mean disruptive classroom behavior score of 2.60 (SD 1.72) in the A_0 baseline phase, 2.11 (SD 1.53) in the B phases, and 2.21 (SD 1.49) in the A_1 phases. These findings indicate a small decrease in participants' disruptive classroom behavior during the intervention. The minor difference between participants' classroom behavior in A_1 and B phases suggests that carryover effects may have occurred. PEM scores ranged between 0% (0/11) and 77% (10/13), indicating that the effect of DEEP on classroom behavior varied between participants.

Table 5. Means and standard deviations of disruptive classroom behavior by phase and percentage of data points exceeding the median scores for each participant.

Participant	A_0 baseline phase, mean (SD)	B phases, mean (SD)	A_1 phases, mean (SD)	Data points exceeding the median, n (%)
1 - behavior 1	0.46 (0.66)	0.91 (1.14)	1.17 (1.64)	0 (0)
2 - behavior 2	2.23 (1.30)	1.38 (0.65)	1.06 (0.68)	7 (54)
3 - behavior 2	2.93 (0.83)	2.27 (0.96)	2.23 (0.75)	8 (53)
4 - behavior 1	3.00 (1.10)	1.31 (1.25)	2.50 (1.58)	10 (77)
5 - behavior 3	1.93 (0.62)	1.21 (0.80)	1.63 (0.50)	8 (57)
6 - behavior 1	2.00 (1.26)	2.38 (0.89)	2.14 (0.86)	2 (13)
7 - behavior 1	2.22 (1.20)	2.40 (1.30)	2.64 (0.50)	3 (20)
8 - behavior 1	6.00 (0.00)	5.27 (0.47)	5.78 (0.44)	8 (73)

Visual Analysis

Each participants' classroom behavior score is represented graphically in Figure 3. Trend stability envelopes revealed no stable upward or downward baseline trend for all participants (Table 6). The MADs showed that the variability in the B phases compared with the A_0 baseline phase decreased only for participant 6. However, this finding should be interpreted cautiously as the level of disruptive behavior for this participant seemed to increase over the course of the intervention. The data pattern of all other participants did not correspond to what is expected from an effective intervention as variability in disruptive behaviors in the B phases compared with the A_0 baseline phase increased or remained the same (Table 6).

Finally, the changes in relatively stable levels of disruptive classroom behavior that were identified by recursive partitioning are represented in Figure 3. Desired effects were found for half of the participants (ie, participants 2, 4, 5, and 8) as their disruptive behavior seemed to decrease over the course of the intervention. All other participants did not show any desirable effects in terms of their behavior (Table 6).

Figure 3. The effect of DEEP on disruptive classroom behavior for 8 adolescents. Every 3 data points represent 1 day (measured around 10:20 AM, 12:25 PM, and 2:30 PM). The dashed and stepped lines represent the relatively stable disruptive classroom behavior levels that were identified using recursive partitioning.

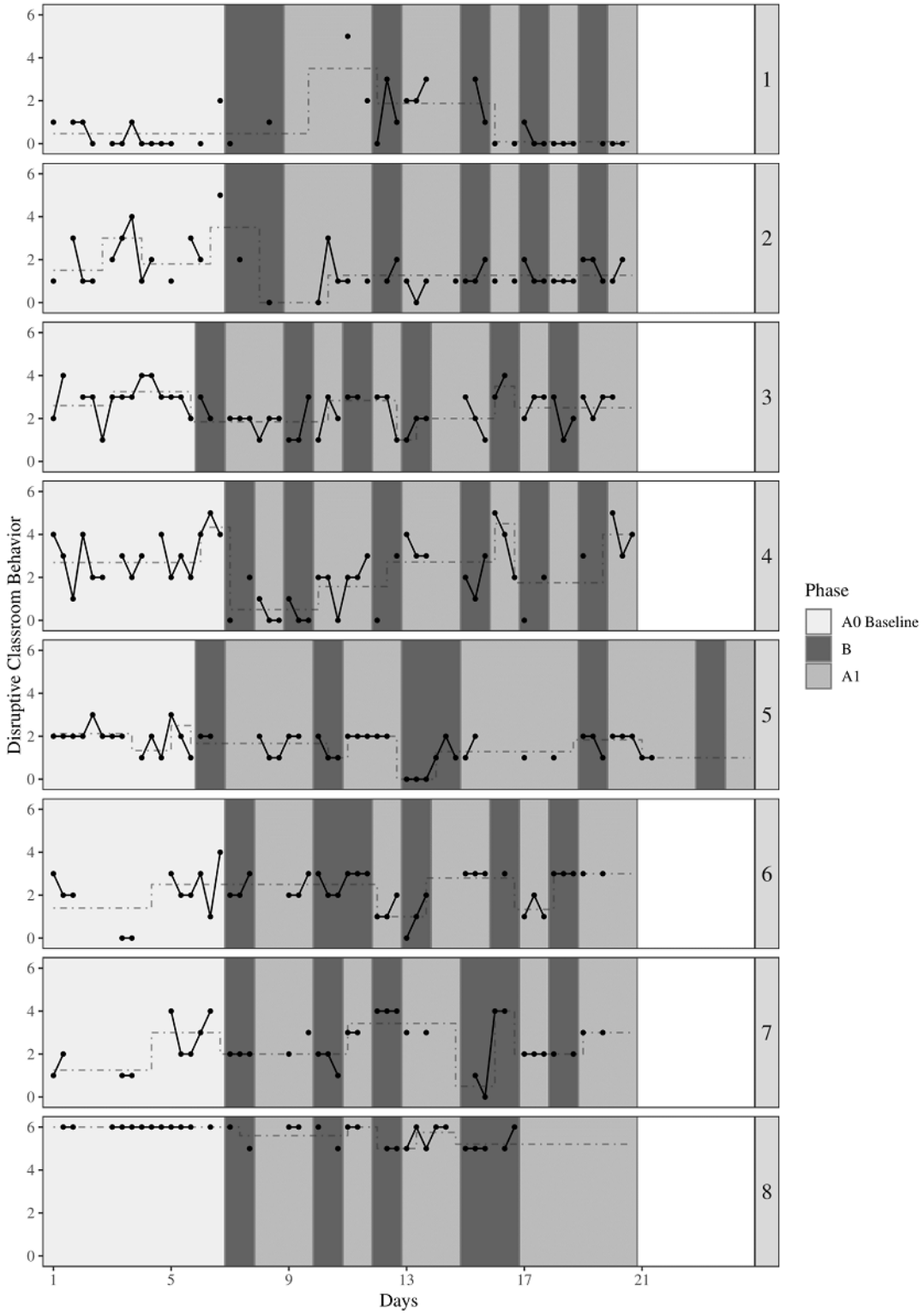


Table 6. Results from visual analysis (baseline trend, variability, and change in level) and nonoverlap of all pairs on disruptive classroom behavior.

Participant	A_0 baseline trend	Variability		Change in level	Comparison: A vs B		Comparison: A_0 baseline vs B	
	Slope (% of data points within envelope)	MAD[a] A_0 phase	MAD B phases		NAP[b]	95% CI[c]	NAP	95% CI[c]
1 - behavior 1	−0.07 (0)	0.00	1.48	Partly increases	0.45	0.24-0.65	0.40	0.16-0.63
2 - behavior 2	0.07 (38)	1.48	1.48	Seems to decrease	0.50	0.31-0.68	0.68[d]	0.47-0.89
3 - behavior 2	0.00 (57)	0.00	1.48	No change in level	0.57	0.40-0.75	0.69[d]	0.50-0.89
4 - behavior 1	0.12 (44)	1.48	1.48	Partly decreases	0.77[d]	0.62-0.91	0.83[d]	0.68-0.98
5 - behavior 3	0.00 (64)	0.00	1.48	Partly decreases	0.68[d]	0.50-0.86	0.73[d]	0.55-0.92
6 - behavior 1	0.00 (36)	1.48	0.00	Seems to increase	0.41	0.23-0.59	0.40	0.17-0.63
7 - behavior 1	0.30 (67)	1.48	1.48	No change in level	0.52	0.31-0.73	0.45	0.21-0.69
8 - behavior 1	0.00 (100)	0.00	0.00	Seems to decrease	0.82[d]	0.64-0.99	0.86[d]	0.70-1.00

[a]MAD: median absolute deviation.

[b]NAP: nonoverlap of all pairs.

[c]Confidence intervals are asymptotic.

[d]Medium effect.

Nonoverlap of All Pairs

NAP scores including all A and B phases are presented in Table 6. Participants 4, 5, and 8 showed changes in the medium range, indicating that their disruptive classroom behavior scores were lower during the B phases compared with the A phases. Regarding NAP scores including A_0 baseline and B phases only, participants 2, 3, 4, 5, and 8 showed changes in the medium range. Carryover effects in terms of participants' classroom behavior may have occurred for participants 2 and 3, as they showed medium effects in the A_0 baseline vs B comparison but no effect in the A vs B comparison.

Between-Case Standardized Mean Difference

The assumptions of normality and absence of clear baseline trends were tested and met. The overall A vs B comparison of the BC-SMD analysis yielded a value of d=−0.16 (SE 0.12; 95% CI −0.39 to 0.05), indicative of a small, nonsignificant reduction of participants' disruptive behavior with the introduction of DEEP [73].

Discussion

Principal Findings

This SCED study evaluated the efficacy of the virtual reality biofeedback game, DEEP, as an intervention to reduce anxiety and disruptive classroom behaviors in adolescents in a special school setting. The primary aim of the study was to test the effect of playing DEEP on daily levels of state-anxiety and disruptive classroom behavior. On a group level, results indicated a small-sized reduction of state-anxiety after the introduction of DEEP. On the individual level, strong evidence was found for 5 out of 8 participants as their NAP scores indicated a medium-sized reduction and their level of anxiety seemed to decrease over the course of the intervention. Moderate evidence was found for 1 participant, as NAP scores indicated a medium-sized reduction, but no change was found in the level of anxiety. In terms of disruptive classroom behavior, a small, nonsignificant reduction was found on the group level. On the individual level, strong evidence was found for 4 out of 8 participants as their NAP scores indicated a medium-sized reduction and their level of disruptive behavior seemed to decrease. Moderate evidence was found for 1 participant as the NAP score indicated a medium change, but no change was found in the level of disruptive behavior. The secondary aim of our study was to investigate the duration of the calm or relaxed state of participants after playing DEEP. Results indicated that, on average, the effect of playing DEEP lasted for 2 hours.

The Effect of DEEP on State-Anxiety

In line with our hypothesis, the current findings indicate that, on a group level, DEEP reduces daily levels of state-anxiety. These results corroborate the previous pilot study conducted by Van Rooij et al [22], who found that playing DEEP for 7 min reduced levels of state-anxiety directly after the game. This study adds that DEEP also holds potential as an intervention for anxiety in adolescents with various disorders such as ADHD or ASD. Even though the direct effects of the evidence-based clinical techniques (ie, diaphragmatic breathing and biofeedback) incorporated in DEEP require further investigation, the techniques may have enabled individuals to gain awareness about and control over their diaphragmatic breathing, enabling them to regulate or dampen high arousal levels [27].

This study is the first study examining the duration of the effect of DEEP on state-anxiety and found that, on average, the calm or relaxed state of participants after playing DEEP lasted for 2 hours. This duration indicates that the effect of playing DEEP does not persist through the whole school day but may be particularly valuable to use in specific anxiety-provoking situations in class, such as during exams or when giving a speech. Although this study provides insight into the duration

of the effect of DEEP on a group level, insight into individual variability in the duration of the effect is lacking. The NAP and visual analysis strategies used in this study are not suitable to analyze the duration of an effect on an individual level. It is possible that some individuals mainly reported reduced levels of state-anxiety directly after gameplay, whereas others still felt calmer or more relaxed at the end of a day playing DEEP. In addition, it is unknown if there are differences in the duration of the effect of DEEP between the 6 sessions. Participant 6, for example, showed a steep increase in anxiety during the day after the first and second DEEP session but seemed to feel calm or relaxed for a longer period after the last couple of DEEP sessions (Figure 2). Future studies could use more assessments per day and multilevel modeling techniques such as the N-of-1 randomized controlled trial methodology [75] to identify differences in the duration of the effect of DEEP between individuals and to investigate if the duration of the effect of DEEP might change over the course of the sessions within each individual.

The Effect of DEEP on Disruptive Classroom Behavior

Analyses yielded mixed results for the efficacy of DEEP to reduce levels of disruptive classroom behavior. The results partly confirmed our hypothesis as 5 out of 8 individuals showed a reduction of disruptive classroom behavior after the introduction of DEEP. DEEP may have affected participants' behavior in various ways. First, as high levels of anxiety may underlie escape-driven disruptive behaviors [6,38], participants in our study may have felt less anxious after playing DEEP and, as a result, were less prone to show disruptive behaviors in the classroom. Participant 5, for example, reported reduced levels of state-anxiety and was less likely to ask his teacher for constant confirmation on the days of DEEP sessions. Although findings need to be interpreted cautiously, participant 5 may have felt more relaxed after playing DEEP, enabling him to allow worrisome thoughts to pass through his mind (as hypothesized by Hayes et al [76]), which in turn may have led to a decreased need for constant confirmation from his teacher.

Second, DEEP may have reduced participants' disruptive behavior through its effect on interoceptive awareness. Although empirical evidence is yet lacking, it is likely that participants' interoceptive awareness improved over the course of the intervention because participants were continuously informed about their stage of breathing while playing DEEP. It has been theorized that increased interoceptive awareness may enable individuals to mobilize self-regulation resources [41], which are needed to regulate one's behavior. Participants that benefited from DEEP in terms of their behavior may have been increasingly aware of their bodies and physiological responses, which may have enabled them to regulate their emotions and behavior in the classroom. To illustrate, after the intervention period, participant 8 noted that she learned to "...pay attention to my breathing more often, for example when I stress about an exam. It happened once, for an English exam. I tried to breathe in and out more deeply." Supposedly, this participant became more aware of her bodily response to stress and tried to regulate heightened arousal levels by breathing. This self-regulation strategy may have helped her to cope with stressful situations in class, resulting in an increase in her participation (eg, asking questions to the teacher) in the classroom. Nevertheless, these explanations remain speculative; future studies are warranted to examine the underlying mechanisms (eg, interoceptive awareness and self-regulation) by which DEEP might affect disruptive behaviors.

Contrary to our hypothesis, we found a small, nonsignificant effect of DEEP on disruptive behavior on a group level. The 3 participants that did not seem to benefit from DEEP in terms of their behavior may have cancelled out the effect of the participants that did, leading to an unobservable effect on a group level. There are several possible explanations why DEEP did not affect the behaviors of those participants. First, anxiety may not have been the cause of disruptive behaviors in the classroom for these individuals. Rather, neurological deficits in individuals with ADHD or ASD that are associated with attention-related problems [77-79] may have caused the disruptive behaviors of the individuals that did not improve. Hence, DEEP may not have been targeting the underlying mechanisms responsible for the disruptive behaviors of these adolescents. Second, there may have been individual differences in the extent to which participants were actually engaging with the diaphragmatic breathing mechanic while playing DEEP. Some individuals may not have developed the skill to breathe through their diaphragm, limiting them in their ability to regulate their behaviors in the classroom. Future studies are encouraged to investigate if individual profiles in learning diaphragmatic breathing skills (as measured by in-game diaphragm expansions) might underlie changes in disruptive behavior [22].

Strengths, Limitations, and Future Directions

A clear strength of this investigation is that the study was conducted in a special school setting, thereby addressing ecological validity issues relevant to the school setting. Another strength is that we used an SCED, which is a suitable design to test interventions in the heterogeneous special school population [43,44]. In addition, the study followed all external validity recommendations for SCED studies as described in the Risk of Bias in *N*-of-1 Trials (RoBiNT [80]).

Regarding the RoBiNt recommendations for internal validity, not all recommendations were carried out. First of all, we did not randomize the beginning of the study phases. We explicitly chose not to randomize the conditions because of constraints of the school setting (eg, scheduling conflicts) and characteristics of the target group (eg, in need of structure). In terms of sampling of the target behaviors, the required minimum of 3 data points in each study phase [80] was not always met because of missing data. Another limitation was that neither participants nor teachers were blinded to the study phases as the intervention required that participants leave the classroom to play DEEP in a separate room. The lack of blinding may have caused bias in teacher and child reports as they knew DEEP was supposed to reduce anxiety and disruptive classroom behaviors. In addition, inter-rater reliability measures of the target behaviors were not computed as no blinded assessors were used. The study was also limited because the behaviors of participants 4, 6, and 7 were assessed by multiple teachers, thereby reducing the reliability of those observations. Future studies may benefit from blinded assessors to reduce bias, and it is also

recommended to tailor the units of measurement to the specific disruptive behaviors as some of the disruptive behaviors identified in this study would be better suited to rate or frequency measures rather than duration.

Although this study provided initial insight into the efficacy of DEEP in a special school setting, future research is needed to fully optimize DEEP as an intervention for this heterogeneous population. The intervention effects of DEEP could be optimized using a parametric analysis of the optimal amount of play time for a given individual [81]. Moreover, the active intervention elements of DEEP (eg, diaphragmatic breathing and biofeedback) that are necessary to produce behavior change should be determined in future studies. Although there are problems in terms of specificity when using physiological measures, adding physiological measures to detect changes in arousal during and after playing DEEP may also help uncover the potential working mechanism of DEEP. In addition, the conditions under which DEEP may be most successful for certain individuals could be established by replicating the current single-case study in new settings. Some individuals may benefit most from playing DEEP right before (eg, exams) or after (eg, quarrels) stressful events, whereas others may show optimal effects when they play DEEP at fixed times. Finally, larger group studies and replicated single-case research may yield variables that moderate intervention outcomes such as trait-anxiety scores, comorbid disorders, age, and gender, which could be used to personalize DEEP.

Implications

The aforementioned limitations notwithstanding, this study has important implications for clinical practice. Although it should be noted that findings need to be interpreted cautiously in a study of this type, this study demonstrated the potential of DEEP as an intervention to reduce daily levels of state-anxiety and disruptive classroom behavior in a special school setting. The results implicate the clinical techniques of diaphragmatic breathing and biofeedback in treating individuals with anxiety. Moreover, the results demonstrate that an applied game incorporating those techniques can be used either in isolation or as an add-on to existing interventions in a clinical sample. On overage, our results showed that the calm or relaxed state of participants after playing DEEP lasted for 2 hours. Therefore, school clinicians are recommended to tailor implementation strategies of DEEP to the individual with different needs early or later in the day, considering individual variation in the duration of the effect of DEEP. The implementation of game-based interventions might be a promising avenue for the special school setting, as video games can be tailored to the diverse needs and learning paces of the heterogeneous special school population.

This study also has strong implications for future research on behavioral health interventions. This study demonstrated that there are individual differences in the extent to which an applied game to enhance mental health is effective. Therefore, we need to tailor behavioral interventions to the personal needs of different individuals. Although the randomized controlled trial may be the golden standard in behavioral health intervention research, this costly and time-invasive method is limited because of a lack of attention paid to individual differences [82,83]. We advocate the use of SCED research to optimize health interventions through ongoing tailoring and testing [81]. Single-case designs provide an excellent opportunity to dynamically and efficiently assess the most promising intervention elements through systematic replication of single-case experiments [81]. Moreover, single-case designs may enhance our understanding of the conditions under which interventions are most successful by replicating single-case studies in new settings, thereby also establishing its generality. Knowledge derived from a body of SCED research about certain demographic and diagnostic variables, generality, and the conditions that may influence intervention outcomes may eventually enable (school) clinicians to personalize behavioral health interventions to the unique characteristics of the individual.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
DEEP trailer.
[MP4 File (MP4 Video), 185651 KB - mental_v7i3e16066_app1.mp4]

Multimedia Appendix 2
Participants' mean anxiety scores measured around 10:00 AM, 12:00 PM, or 2:00 PM, split out by phases.
[PNG File , 10 KB - mental_v7i3e16066_app2.png]

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
ASD: autism spectrum disorder
BC-SMD: between-case standardized mean difference
CBT: cognitive behavioral therapy
MAD: median absolute deviation
NAP: nonoverlap of all pairs
PEM: percentage of data points exceeding the median
RoBiNT: Risk of Bias in N-of-1 Trials
SCED: single-case experimental design
STAI: State-Trait Anxiety Inventory

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Original Paper

Reflective and Reflexive Stress Responses of Older Adults to Three Gaming Experiences In Relation to Their Cognitive Abilities: Mixed Methods Crossover Study

Najmeh Khalili-Mahani[1,2], DPhil, MEng; Atousa Assadi[1], MEng; Kate Li[1], BSc; Mahsa Mirgholami[1], MSc; Marie-Eve Rivard[1], MSc; Habib Benali[1], DPhil; Kim Sawchuk[3], DPhil; Bob De Schutter[4], DPhil

[1]PERFORM Centre, Concordia University, Montreal, QC, Canada

[2]McGill Centre for Integrative Neuroscience, Montreal Neurological Institute, McGill University, Montreal, QC, Canada

[3]Department of Communications, Concordia University, Montreal, QC, Canada

[4]Armstrong Institute for Interactive Media Studies, Miami University, Oxford, OH, United States

Corresponding Author:
Najmeh Khalili-Mahani, DPhil, MEng
PERFORM Centre
Concordia University
Montreal, QC,
Canada
Phone: 1 5148482424 ext 5370
Email: najmeh.khalili-mahani@concordia.ca

Abstract

Background: The gamification of digital health provisions for older adults (eg, for rehabilitation) is a growing trend; however, many older adults are not familiar with digital games. This lack of experience could cause stress and thus impede participants' motivations to adopt these technologies.

Objective: This crossover longitudinal multifactorial study aimed to examine the interactions between game difficulty, appraisal, cognitive ability, and physiological and cognitive responses that indicate game stress using the Affective Game Planning for Health Applications framework.

Methods: A total of 18 volunteers (mean age 71 years, SD 4.5; 12 women) completed a three-session study to evaluate different genres of games in increasing order of difficulty (S_1-BrainGame, S_2-CarRace, and S_3-Exergame). Each session included an identical sequence of activities (t_1-Baseline, t_2-Picture encode, t_3-Play, t_4-Stroop test, t_5-Play, and t_6-Picture recall), a repeated sampling of salivary cortisol, and time-tagged ambulatory data from a wrist-worn device. Generalized estimating equations were used to investigate the effect of session×activity or session×activity×cognitive ability on physiology and cognitive performance. Scores derived from the Montreal Cognitive Assessment (MoCA) test were used to define cognitive ability (MoCA-high: MoCA>27, n=11/18). Kruskal-Wallis tests were used to test session or session×group effects on the scores of the postgame appraisal questionnaire.

Results: Session×activity effects were significant on all ambulatory measures (χ^2_{10}>20; P<.001) other than cortisol (P=.37). Compared with S_1 and S_2, S_3 was associated with approximately 10 bpm higher heart rate (P<.001) and approximately 5 muS higher electrodermal activity (P<.001), which were both independent of the movement caused by the exergame. Compared with S_1, we measured a moderate but statistically significant drop in the rate of hits in immediate recall and rate of delayed recall in S_3. The low-MoCA group did not differ from the high-MoCA group in general characteristics (age, general self-efficacy, and perceived stress) but was more likely to agree with statements such as *digital games are too hard to learn*. In addition, the low-MoCA group was more likely to dislike the gaming experience and find it useless, uninteresting, and visually more intense (χ^2_1>4; P<.04). Group differences in ambulatory signals did not reach statistical significance; however, the rate of cortisol decline with respect to the baseline was significantly larger in the low-MoCA group.

Conclusions: Our results show that the experience of playing digital games was not stressful for our participants. Comparatively, the neurophysiological effects of exergame were more pronounced in the low-MoCA group, suggesting greater potential of this

genre of games for cognitive and physical stimulation by gamified interventions; however, the need for enjoyment of this type of challenging game must be addressed.

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KEYWORDS

silver gaming; serious games; stress; cognitive training; brain training games; exercise games; ICT

Introduction

Background

Playing digital games is quickly becoming a common pastime for many older adults [1,2]. Games are pleasurable activities when they offer a balanced mixture of challenge, reward, and competition. Playing games together is a social activity that may mitigate feelings of isolation. Playing games alone offers relaxation and distraction. Digital games have several potential advantages: they may offer higher sensory stimulation by their visual and sound effects; they may challenge executive and motor skills, visual attention, and speed of reaction in decision making; and they can also be customized in interface or level of difficulty. Research indicates that many older adults are onboard with *serious* digital play [3-7]. To develop serious games (ie, games in which the intention is to benefit tangibly from game play and attempt to deliver cognitive, emotional, or rehabilitation training to older adults) is a growing trend [8-15].

Although emerging data suggest that digital playing can improve cognitive, physical, and emotional health in older adults [16-23], the results are not conclusive. Currently, there are two dominant research streams addressing the complexity of developing serious games for seniors: (1) game designers evaluate the effectiveness of a game in terms of accessibility and meaningful and enjoyable play [6,24-32], and (2) health researchers focus mainly on their cognitive [33-36] or specific motor-related effects [19,25,37-49] in controlled trials. An empirical framework to evaluate the efficacy of different game-based health interventions that bridges these two fields is much needed [50,51].

At present, the inadequate design of computer games and low accessibility of game technologies are the major impediments to their adoption by seniors [42,52,53]. Successful games foster time-on-task and promote more effective learning because they raise motivation and arouse players' interest, for instance, by providing instantaneous and informative feedback, intrinsic rewards, and features that allow players to self-assess and adjust the levels of game difficulty to their skills [54]. These neurological signals may transfer to positive psychological effects such as enjoyment and challenge resulting from gameplaying [55]. Several studies have shown that in general, more seniors prefer the ease and pleasure of casual games (preferably with an intellectual component) over more cognitively demanding action games [3,56,57]. However, interindividual variations in game perception and motivation are important factors that engender the game-playing experience [58,59]. Thus, while digital games are increasingly prevalent among the seniors who are offered access to digital devices, many seniors are not familiar with or accustomed to digital game playing. As such, the mere promise of functional enhancement through such activities may not suffice to motivate them to overcome the barriers of unfamiliarity with the technology, if they have access to that technology. Inserting a *for-health* computerized intervention, even if ludic, may still introduce stress either because it seems too difficult to master and thus underlines their disabilities, or because it is an unfamiliar and burdensome imposition on their lifestyle. Therefore, it is important to ask whether the adoption of proscribed gamified interventions for older adults may be too stressful.

Objectives

This study aimed to address the question on whether the adoption of proscribed gamified interventions for older adults may be too stressful. To that end, a hybrid data/model-driven mixed methods framework for Affective Game Planning for Health Applications (AGPHA) was proposed [60]. AGPHA builds on the theory of appraisal and coping by Lazarus (summarized in Figure 1) and emphasizes that motivational, relational, and cognitive factors determine individual differences in perception of, and ability to cope with, new challenges (for an ontology by Lazarus, see [61]). These differences may manifest as quantifiable variations in the stress system of the body, including marked changes in cortisol response and autonomic signals such as heart rate (HR), skin conductance, and gut reflexes. These physiological reactions are the body's nonspecific response to the perception of stress [62], and usually the intensity of these responses depends on an individual's biological and psychological coping resources [63].

Figure 1 shows our adaptation of the theory by Lazarus [61]. When presented with a challenge, an individual's primary appraisal determines its relevance, threat, and benefits. If it is irrelevant, the individual can ignore it. If it is threatening, they have to respond to it. If the challenge is beneficial, they may choose to respond to it. In case of games for health, the challenge is not threatening to one's health, but if the games are introduced in the context of health care or cognitive fitness, they can be challenging to an individual's self-esteem because the player may feel pressured to learn the game and perform well. How an individual responds to the game challenge will depend on the individual's coping style and their cognitive, emotional, or physiological reserves. If they have a negative attitude toward the game, they might avoid it, or feel stressed by trying it. However, if they have a positive attitude, or an investment (such as expectation that it will improve cognitive function), then they will try to learn and overcome the challenges of the game. This is when the player enters the secondary stage of appraisal. In the secondary stage of appraisal, if the challenge is feasible, then the player may experience what is termed as *flow*; otherwise, it becomes *stressful*. Again, at the secondary appraisal, the personality and cognitive and physical reserves

of the individual play a role in moderating the magnitude of the stress response and the behavioral outcome (in this case, playing further or giving up).

In the context of gamified strategies for cognitive training or testing, the complex relationship between stress and cognition deserves attention. It is well established that physiological stress responses modulate the function of central cognitive structures such as the hippocampus and the prefrontal cortex [64,65]. Stress interferes with learning through myriad cognitive processes, especially attention, reward processing, and decision making [66,67], which are important for habitual and complex activities that define an individual's adaptation strategies in the course of life. Actual or perceived decline in cognitive abilities can influence a senior's primary and secondary appraisal of the game and discourage them to try. Diminished cognitive abilities can make the game more challenging and thus lead to more pronounced physiological stress responses, which might cause health-related side effects that need to be monitored or avoided. It is also possible that excessive game stress would lead to distraction or memory failure, thereby impeding learning and skill development, which are important for motivation to replay.

Therefore, in evaluating whether games are stressful or not, AGPHA asks three central questions:

1. What are the characteristics of individuals who choose to play?
2. Is the playing experience quantifiably stressful?
3. Which intra- or intersubject factors (eg, appraisal, cognitive abilities, health status) predict variations in game-related stress, game-learning, and retention?

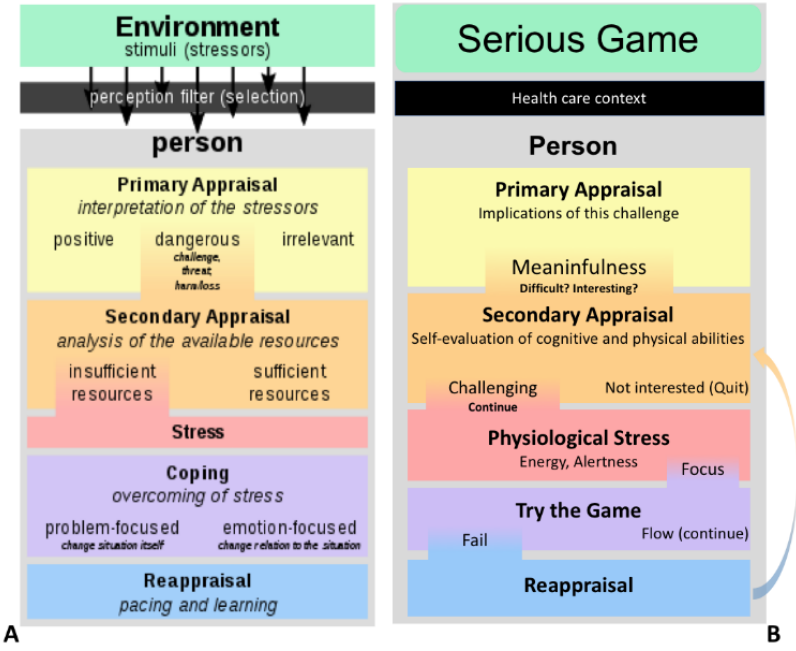
Study Aims and Hypotheses

In this study, we provide an example of deploying the AGPHA framework to investigate the relation between game stress and cognitive abilities of the senior game players, introduced to three unfamiliar gaming experiences. In this study, we have tested the following hypotheses:

1. Playing unknown digital games will be stressful to older adults.
2. Game difficulty and general cognitive abilities predict a quantifiable increase in reflexive (ie, variations caused in physiological or neuropsychological function) and reflective (ie, subjective evaluation of the postgame experience) stress responses.

This study includes the following elements: (1) a survey element to allow us to understand the biases related to individual characteristics that attract older adults to the topic of gamified cognitive enhancement, (2) a within-subject factor (three genres of presumably cognitive enhancing games: brain training, car racing, and exercise gaming) that allows us to introduce variations in the phenomenology of gaming experience, (3) a between-subject factor (cognitive ability determined by the Montreal Cognitive Assessment [MoCA]) that allows us to investigate intersubject variations in game experience, and (4) two categories of reflexive (cortisol, ambulatory signals, and neuropsychological tests) and reflective (postgame evaluation of the game-play experience based on intrinsic motivation) outcome measures that would allow us to compare the sensitivity of objective biomarkers against subjective ratings.

Figure 1. (A) Diagram of Lazarus and Folkman's Transactional Theory of Stress (Source: Wikipedia, Philipp Guttmann), (B) our adaptation of Lazarus's model to be tested in the Affective Game Planning for Health Applications framework.



Methods

Participant Recruitment

We adopted a snowball survey method to recruit potential participants and assess the characteristics of seniors who showed interest in the topic of gamified approaches to cognitive enhancement. With approval from the institutional review board, we targeted a general mailing list of the PERFORM Centre; this list consisted of individuals interested in volunteering for preventative health studies. We invited individuals older than 65 years to participate in *Finding Better Games for Older Adults: An Objective Assessment of Interactions Between Appraisal, Arousal and Cognitive Benefits of Electronic Playing.* The recruitment period lasted approximately 2 months. The survey asked questions about how they evaluated game-related activities in relation to a range of other activities (eg, gaming vs exercising, or talking with people rather than playing). The survey also included the General Self-Efficacy Scale (a 10-item scale) [68]; University of California, Los Angeles (UCLA) Loneliness Scale [69]; and Perceived Stress Scale (9-item scale [70]) to control for confounding chronic stress or tendency to become more easily stressed. We also asked participants to self-evaluate their state of mental and physical wellness as *good*, *bad*, or *could be better*.

Study Sample

Those who completed the survey and could commit to three 120-min tests in our research facility were invited to participate in the follow-up experiments. On the basis of previous work [71], we estimated a sample of 20 participants sufficient to provide pilot data with 80% power to detect a difference of 0.17 (log [Cortisol nmol/mL]) in response to a psychological stress challenge between the study arms with an SD of 0.26 and one-tailed paired *t* test (P=.05, where more difficult games were expected to cause higher stress). We performed medical screening using the Physical Activity Readiness Questionnaire (PAR-Q+) to rule out hazards such as movement disorders that would increase the risk of falling, epileptic seizures, and visual impairments that would prohibit participants from playing digital games safely. Participants were required to be capable of walking continuously for 20 min; literate; and able to watch a television, a computer, and an iPad screen. Before participation, they signed an informed consent approved by the institutional ethics review board. They were free to discontinue the study at any moment. No financial compensation was offered.

Experimental Design

Aim 1 was to determine whether novel gaming experiences induce a psychophysiological stress response, and whether there is a relation between appraisal of the game experience and psychophysiological measures. Aim 2 was to determine whether differences in cognitive abilities predict variations in game-related stress. Cognitive abilities were assessed by MoCA Original 7.0, a 30-point standardized outcome measure that is used clinically to screen for milder forms of cognitive impairment [72].

Following the AGPHA framework, we collected multifactorial data to create a comprehensive profile of the emotional, cognitive, and biological characteristics of the participants. Table 1 summarizes data that we collected in the study. A semistructured interview—to assess the challenge, excitement, enjoyment, goals, and likelihood to play and replay a game—was also performed, but those results are beyond the scope of this paper and will be presented separately.

The experimental design was a repeated measures crossover study (Figure 2). Participants were fully informed about the intention of the study, and no deception was used:

> *We would like to hear how you evaluate different games which are suggested to enhance cognitive function. We want to know how you appraise them in terms of fun, difficulty, or benefits. We will also collect physiological data using an arousal-sensing device that you will be wearing on your wrist and from saliva samples that let us know if the game stressed your body.*

Because this was a repeated measures study, we expected that increased familiarity with our experimental setting would reduce their overall stress. For this reason, we presented the games in increasing degrees of complexity and difficulty. Identical functional assessments (cognitive tests) were incorporated to control for learning effects. This design, accounting for habituation, allowed us to use the first (and presumably the simplest game) as a reference against which to compare gradual changes in game appraisal and familiarity with the game.

Table 1. Study variables.

Variable category and variable type	Screening	Baseline	Brain training	Car race	Dance
Characteristics					
Demographics	✓	N/A[a]	N/A	N/A	N/A
UCLA[b] Loneliness Index	✓	N/A	N/A	N/A	N/A
Perceived Stress Scale	✓	N/A	N/A	N/A	N/A
General Self-Efficacy	✓	N/A	N/A	N/A	N/A
Self-assessment of mental/physical health	✓	N/A	N/A	N/A	N/A
Prestudy appraisal of game (IF[c])	✓	N/A	N/A	N/A	N/A
Cognitive					
Montreal Cognitive Assessment (IF)	N/A	✓	N/A	N/A	N/A
Picture Encode/recall (DV[d])	N/A	N/A	✓	✓	✓
Stroop (DV)	N/A	N/A	✓	✓	✓
Biometrics					
Heart rate and heart rate variability (DV)	N/A	✓	✓	✓	✓
Electrodermal activity (DV)	N/A	✓	✓	✓	✓
Accelerometer (CV[e])	N/A	✓	✓	✓	✓
Saliva cortisol (DV)	N/A	✓	✓	✓	✓
Subjective					
Postgame appraisal survey (DV/IV[f])	N/A	N/A	✓	✓	✓
STAI-6[g] (DV)	N/A	N/A	✓	✓	✓

[a]N/A: not applicable.

[b]UCLA: University of California, Los Angeles.

[c]IF: independent factor.

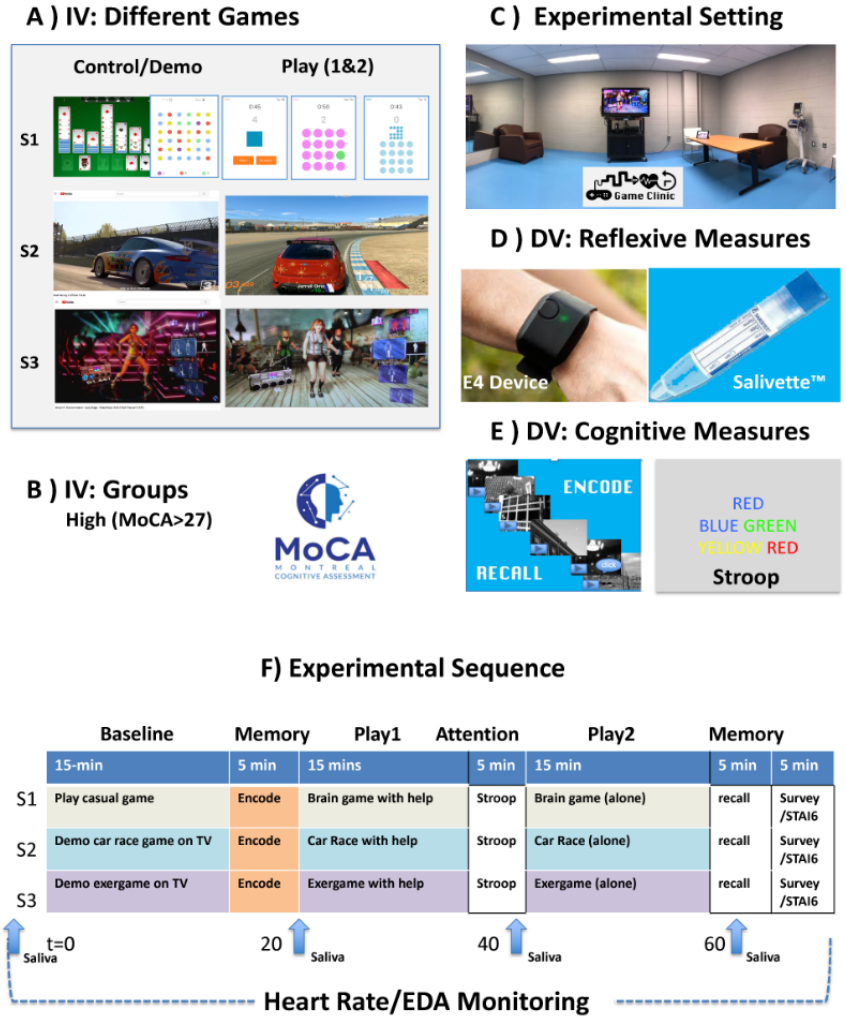
[d]DV: dependent variable.

[e]CV: control variable.

[f]IV: independent variable.

[g]STAI: Spielberger State-Trait Anxiety Inventory.

Figure 2. Experimental methods and procedure. (A) Different games that were used; (B) Montreal Cognitive Assessment tool was used as a predicting factor; (C) the experiment room, a small studio located at PERFORM Centre's Gym; (D) devices used for measurement. DV: dependent variable; EDA: electrodermal activity; IV: independent variable; MoCA: Montreal Cognitive Assessment.



Procedures

The study took place between 10 AM and 4 PM. Participants were asked to refrain from eating and drinking sweetened or caffeinated beverages or engaging in strenuous physical activity for at least 2 hours before their appointment at PERFORM. Each session was completed on separate days, with 3 to 7 days between visits. Each visit lasted about 2 hours. The details of the experimental procedure are presented in Multimedia Appendix 1. Briefly, *session 1* served as the baseline as we introduced players to cognitive training games played on iPAD (MindGame, by Tom Lake). In *session 2*, we introduced a visually and cognitively more complex game, using an iPad (Real Racing 3, v 5.4.0, Electronic Arts Inc), which allowed players to steer the car using the gyroscopic features of the iPad and thus required minimal efforts in learning the control buttons. In *session 3*, we introduced an exergame (Dance Central by Harmonix, MS Studios). In this game, players copy the moves of a virtual choreographer while the motion tracking Kinect evaluates them against the queued movement.

Outcome Measures

Postgame Appraisal

To study the relation between the participant's subjective appraisal of the gaming experience, we administered an exit survey at the end of each session, which was loosely based on the intrinsic motivation inventory and tapped into the question of enjoyment (*The experience was enjoyable, The experience was interesting*), competence (*The game was difficult*), tension (*The experience was stressful; I found this to be a frustrating experience. These games are visually intense*), choice (*I liked to play this game again; I will play this game again. I did not like this experiment*), and value (*This game help improve my mental wellness, I think this game is useless; These games are cognitively stimulating*). Instead of a 7-choice scale to measure degrees of satisfaction, we decided to implement a 4-choice response (definitely disagree, somewhat disagree, somewhat agree, and definitely agree), ranging from –2 to 2, but we allowed participants to add comments if they did not know the answer. We coded these responses to 0 or *I don't know*.

Saliva Cortisol

Saliva cortisol is often measured as a biomarker of a latent psychological modulation to the stress system [73]. Cortisol

production displays a typical diurnal rhythm with a peak in the morning hours (8-10 AM), followed by a periodic pattern consisting of ultradian oscillations (20-120 min periods) [74,75]. We therefore ensured to schedule the visits at the same time for each individual, and we timed the experiment to avoid measuring the sharp rise in the awakening cortisol. Free circulating cortisol was assessed from saliva, collected using the Salivette device (Figure 2). The samples were frozen at −80°C, centrifuged at 4°C for 10 min, and analyzed using luminescence-immunoassay (IBL International) using enzyme-linked immunosorbent assay (at PERFORM Centre). The intra- and interassay coefficient variability was less than 12% and 5%, respectively.

Electrodermal Activity and Heart Rate Variability

Since 1970s, the electrodermal activity (EDA) and the heart rate variability (HRV) have been used as proxy markers of sympathetic autonomic response to arousing or stressful stimuli, finding successful application in laboratory experiments involving human-computer interface and games [76-82]. We used the E4 device (Empatica, Inc), a light wrist-wearable device for continuous monitoring of the physiological signals. The E4 band (Figure 2) was properly fit on the wrist of the nondominant arm. This device is equipped with 4 sensors: (1) photoplethysmography sensor to measure cardiac activity, (2) EDA sensor to measure skin conductance as a marker of *arousal* and *stress*, (3) 3-axis accelerometer (ACC) to measure the amount of movement along the x-, y-, and z-axes, and (4) optical thermometer to measure skin temperature.

To facilitate the replicability of our study, we downloaded preprocessed data from the Empatica data portal. We used our in-house MATLAB software on these data to extract data for each activity (by averaging signals' amplitudes normalized to the duration of different activities). An *activity* denotes a specific interval measured from the onset of each experimental step. Activities were delimited using a *tag* button on the E4, which was pressed every time we administered a new task. A research assistant also kept track of detailed timing of the experiment. Because EDA is sensitive to the activity of sweat glands, the room temperature was maintained at 23°C. However, we also collected data from the temperature sensor and ACC on the E4 device to rule out confounding effects related to thermal or movement noise.

Stress-Sensitive Cognitive Tests

The triggering of physiological signals to stress serves the metabolic modulation of reward processing [83] and attention [84] systems that help individuals initiate an appropriate adaptive response to stress; thus, it can interfere with cognitive functions performed during or immediately after stress. We included a set of simple cognitive tasks to assess whether, despite the potential learning effect due to repeated nature of the design, increasing game difficulty would affect performance in cognitive tasks. The first set of cognitive tests used a picture encode/delayed recall memory test, which we have previously shown to be sensitive to stress modulations of the hippocampal function both under tasks [71] and under stress-inducing drug conditions [85]. In addition, we administered a simple Stroop word color test to assess an individual's cognitive processing speed and their selective attention accuracy. The Stroop test has been shown to be sensitive to physical exertion and cognitive challenge [86,87]. All cognitive tests were presented at a minimal level of difficulty (with 3-second delay between stimuli) to ensure these tasks did not introduce added stress.

The encode/recall test consisted of two parts. In the first part (the encode condition), the participant was presented with 50 black and white images of random scenes, places, people, and objects. Each image stayed on screen for 3 seconds; thus, the participant had time to commit it to memory. This set of 50 pictures included 14 unique pictures and 36 nonunique pictures that were shown more than once. The participant was asked to press *m* as soon as they saw a familiar picture. They were told to remember these pictures for a recall test at the end of the session. In the second part (delayed recall), 45 black and white images were shown. This set included 15 pictures from the encode session and 30 new pictures. Participants were asked to press *m* as soon as they detected a previously seen picture. In both sessions, each picture remained on the screen for 3 seconds. If no answer was provided, the screen would proceed to the next picture. This test was implemented in E-Prime, and we recorded the number of hits, misses, and false alarms, both for the encode and the recall conditions. We had designed 3 sets of unique encode/recall pairs. In other words, none of the pictures seen in session 1 were repeated in the pictures presented in sessions 2 or 3.

We also wanted to measure the reaction time (RT) to the Stroop effect, that is the time it takes a player to process the incongruency between the color of a word read, and the color represented by the word. At each trial of this test, a brief training session was held to ensure the players understood the test objectives. Following the training session (1 min), a randomly selected color word (red, yellow, blue, or green) was presented to the participants. The color of the word on the screen may or may not have been congruent with the word itself. The stimuli (50) were randomly selected from a stack of 320 cards (80 of which were incongruent). The participants were asked to press a colored key on the keyboard, which was associated with the color of letters of the word, as fast as they could. In our implementation, we provided immediate feedback on whether the participants provided the correct answer or not. The participants were told that their scores would depend on how fast they responded to each card, but the time interval between cards was set to 5 seconds. The test was implemented in E-Prime, and we recorded the number of correct responses and the RT to correct response.

Statistical Analysis

Our research questions were as follows:

- Can we detect within-subject game-related (ie, Session) differences in appraisal, physiological patterns over time (ie, ti: Activityi), and cognitive measures (immediate and delayed recall, and Stroop RT to correct)?
- Do differences related to cognitive abilities (measured by MoCA) predict differences in outcome measures for different sessions (S1: Brain training; S2: CarRace; and S3: Exergame) and activities (t1: Baseline; t2: Encode; t3: Play1; t4: Stroop; t5: Play2; t6: Recall)?

To examine the effect of *session×activity* in each outcome measure, we used generalized estimating equations (GEEs) with a robust estimator and an autoregression working correlations matrix. GEE is a special form of the general linear model that is recommended for longitudinal repeated measurements of within-subject data over time [88]. In all GEE models, S_1 and t_1 were used as within-subject references. For the group comparisons, all physiological factors were normalized to the within-subject, within-session baseline measures. For tests that included ambulatory measures as a dependent variable (EDA, HR, and HRV), we controlled for movement (measured from ACC) and duration of each activity. All results were plotted (mean and SEM), and post hoc comparisons were reported with least significant difference correction.

To explore differences in game appraisal between sessions, or between groups, we performed nonparametric tests (Spearman correlation and Kruskal-Wallis) on Likert scales. Results were plotted in terms of response frequency to each appraisal question to visually illustrate game- or group-related differences in the patterns of attitude toward games.

All statistical analyses were performed with SPSS (version 24 for Mac; IBM Corp). *MoCAGroup×Session×Activity* plots (mean, SEM) were generated with Prism (version 8 for Mac; GraphPad Inc).

Results

Who Wants to Play?

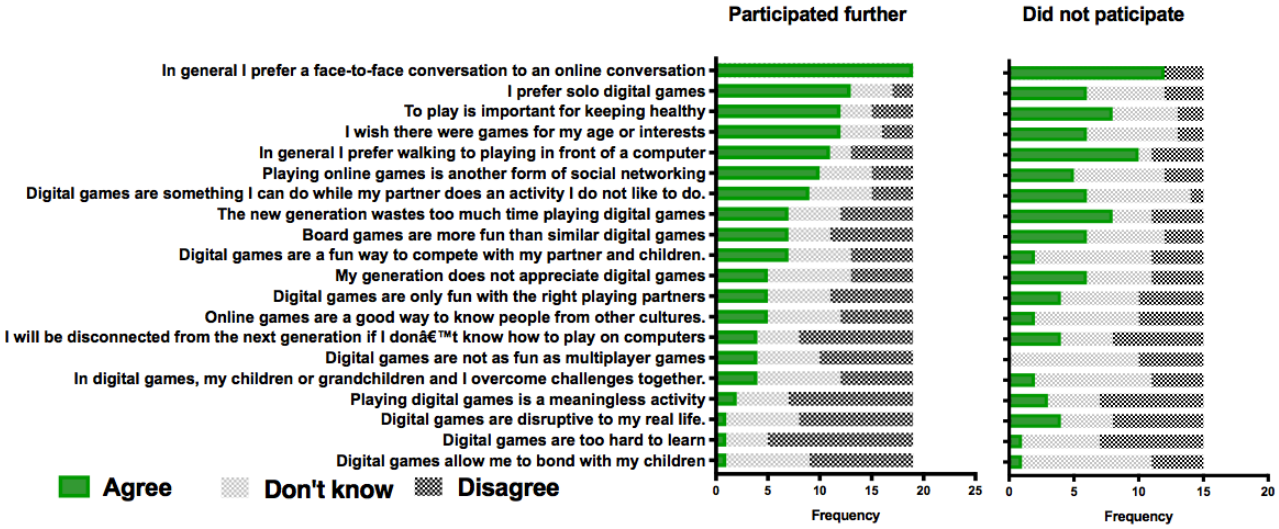
In total, 42 adults meeting the age criteria (>65 years) completed the survey, 19 of whom volunteered to enroll in the experimental study. Only 1 participant dropped out of the experimental phase after the first visit because of extreme physical discomfort that forced her to eat and drink (thus invalidating the cortisol sampling). Differences in participant characteristics are presented in Table 2. No significant group differences were observed (all $P>.5$).

Figure 3 summarizes the game attitude distribution in our sample. The response frequencies are ranked based on the largest number of favorable (*I agree*) responses to a given question in the sample who completed the study. Overall, those who completed the study and those who did not join the experiment after the screening had a positive attitude toward games; however, those who did not participate were not in disagreement but more frequently gave *I don't know* responses to various game-related questions. Kruskal-Wallis tests showed that those who participated in the experimental phase gave more positive responses to the following items: *In general, I prefer face-to-face conversations to an online conversation* (χ^2_1=6.7; P=.01); *I prefer solo digital games* (χ^2_1=4.1; P=.04); *I wish there were games for my age or interest* (χ^2_1=4.2; P=.04). The participants more frequently disagreed with the following items: *Digital Games are too hard to learn* (χ^2_1=5.3; P=.02) and *Digital games are disruptive to my real life* (χ^2_1=2.8; P=.09).

Table 2. Participant characteristics.

Characteristics	Participated in experiment	Did not participate further
Gender, n		
Male	6	10
Female	13	13
Other	0	0
Mental health, n		
Good	17	13
Could be better	2	2
Physical health, n		
Good	14	10
Could be better	5	5
Age (years), mean (SD)	70.47 (4.49)	69.70 (4.20)
Education (years), mean (SD)	16.26 (3.68)	16.22 (2.58)
Generalized Self-Efficacy, mean (SD), maximum n=40	33.79 (2.80)	32.42 (4.77)
Perceived Stress Scale, mean (SD), maximum n=40	17.78 (3.83)	18.46 (3.83)
Loneliness Index, mean (SD), maximum n=80	11.21 (11.36)	18.8 (15.54)

Figure 3. Participants' appraisal of gaming before enrollment in the study.



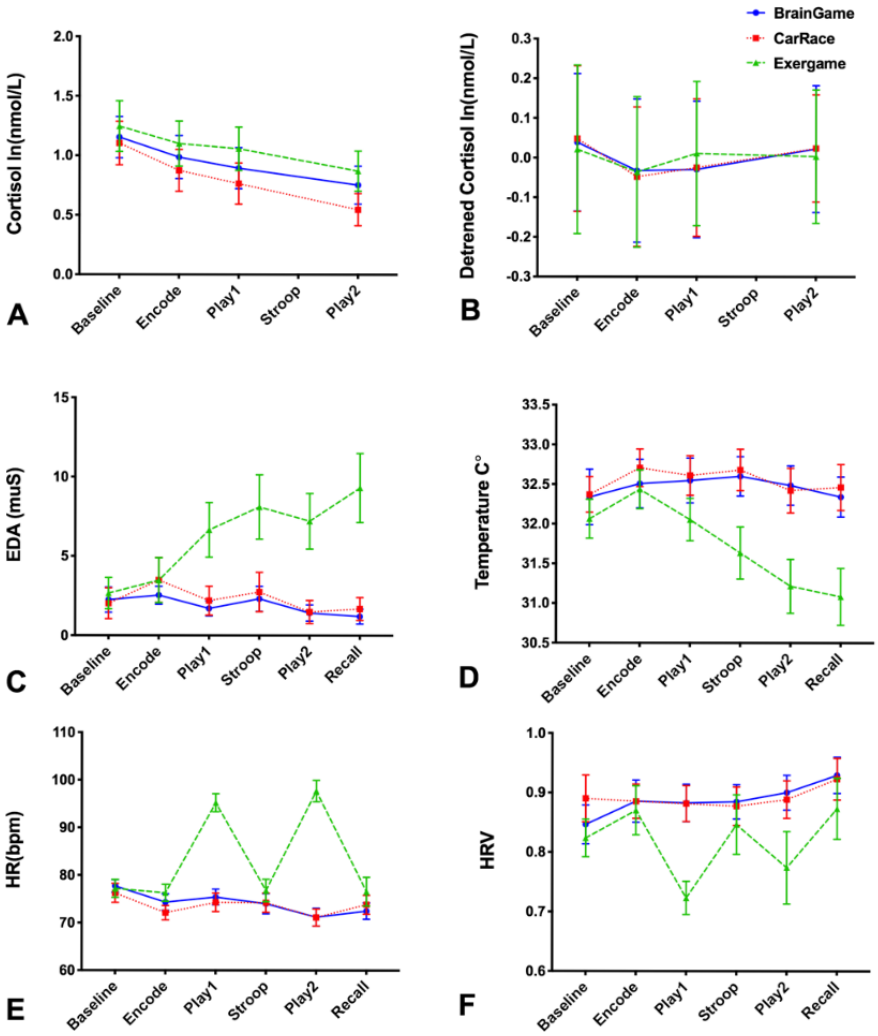
Effects of Game Type on Reflexive Outcomes

Physiological Response

Figure 4 illustrates the effects of games and activities on different signals measured during the experiment (mean, SEM). Session by activity interactions had a significant effect on EDA (χ^2_{10}=26; *P*=.004), HR (χ^2_{10}=24.5; *P*=.006), HRV (χ^2_{10}=96; *P*<.001) but not on Cortisol (χ^2_6=6.5; *P*=.37). In all sessions, we observed the highest levels of cortisol at the baseline, followed by an exponential decline in cortisol levels. Detrending the cortisol levels to remove this decline did not change the outcome of the statistical inference.

The main effect of *Session* was significant for EDA (χ^2_2=20.6; *P*<.001), HR (χ^2_2=23.4; *P*<.001), and HRV (χ^2_2=33.3; *P*<.001). The effects of control variables (acceleration and duration) were not significant on any of the outcome measures (albeit a trend was observed for a positive association between acceleration and HR (*P*=.08). There were no significant differences between S_1 and S_2, but EDA in S_3 was significantly higher than that in S_1 (mean difference 4.3 muS; *P*<.001; 95% CI 2.77 to 5.9) and S_2 (mean difference 3.97 muS; *P*<.001; 95% CI 2.4 to 5.5), expectedly as a result of physical activity. The HR in S_3 was higher than that in S_1 (mean difference 10.02 bpm; *P*<.001; 95% CI 7.5 to 12.2) and S_2 (mean difference 9.6 bpm; *P*<.001; 95% CI 7.2 to 12 bpm) and the previous two sessions, but the difference between S_1 and S_2 was not significant. The main effect of *Activity* was significant only for HR (χ^2_5=28.8; *P*<.001) and HRV (χ^2_5=79.3; *P*<.001).

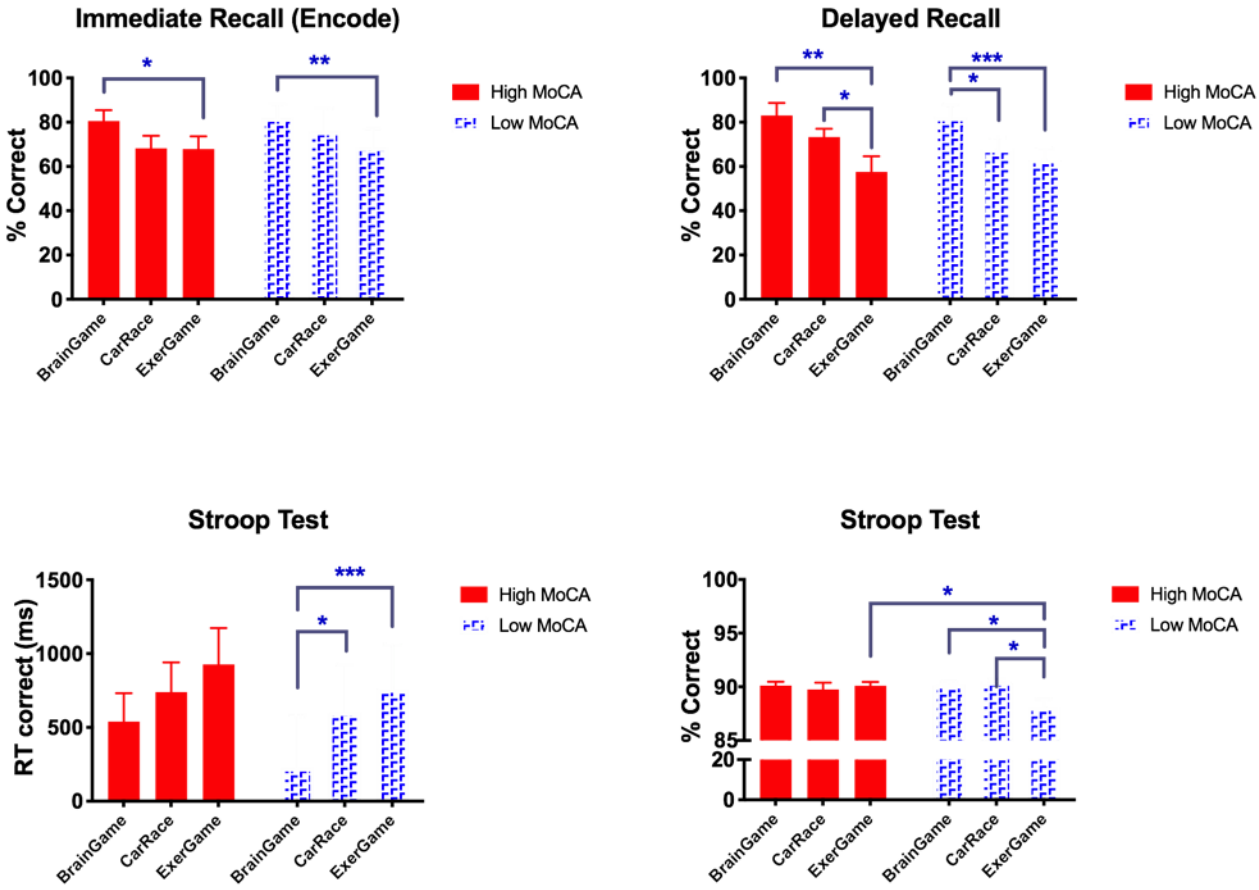
Figure 4. The profile of physiological signals changes over time. The only immediate significant game-related change was observed in heart rate and heart rate variability variables. HR: heart rate; HRV: heart rate variability.



Cognitive Performance

We had hypothesized that if a game was stressful, then it would interfere with cognitive processing. Indeed, we found that different game *sessions* affected the rate of correct immediate recall in the encode (χ^2_2=10.2; *P*=.006) and delayed recall (χ^2_2=24.6; *P*<.001), as well as on Stroop's RT to correct (χ^2_2=6.5; *P*<.05) but not on Stroop rate of correct response (χ^2_2=2.5; *P*=.29). Post hoc tests showed significant reduction of performance in the exergame session (S_3) compared with baseline (brain training, S_1) during encode (mean difference −12.6%; *P*=.02; 95% CI −23.5 to −1.68) and recall (mean difference −22.96; *P*<.001; 95% CI −35.6 to −10.2). A similar trend was observed in comparison of Car Race (S_2) vs S_1 (for encode, mean difference −10.9; *P*=.09; 95% CI −23.3 to 1.45; and for recall, mean difference −11.48; *P*=.06; 95% CI −23.4 to 0.47). No difference in encode rates was observed between S_3 and S_2, but there was a trend of reduced correct recalls (mean difference −11.48%; *P*=.08; 95% CI −24.0 to 1.06). Stroop RT was also slower in S_3 vs S_1 (mean difference 440 ms; *P*=.006; 95% CI 130 to 759) and S_2 vs S_1 (mean difference 269 ms; *P*=.03; 95% CI 20 to 510). Because encode and recall rates were correlated (*r=.631*; *P*<.001), we controlled for the effect of encode hit rates in the GEE model that estimated the effect of the session on recall hits. Regardless, the effects of *Session* on recall performance remained significant (χ^2_2=16.1; *P*<.001). These results suggest that even though the participants had become familiar with the tasks, their performance did not improve by the third session; it declined instead, suggesting that the exergame was the most challenging and potentially the most stressful game of the three. Figure 5 illustrates how this stress effect on performance was exacerbated in the group with lower MoCA scores.

Figure 5. Differences in cognitive performance between sessions and Montreal Cognitive Assessment groups (*P<.05; **P<.005; ***P<.001). MoCA: Montreal Cognitive Assessment.



Effects of Game Type on Reflective Outcomes

The experimental sessions did not cause changes in anxiety states as measured by the 6-item Spielberger State-Trait Anxiety Inventory Scale (χ^2_2=2.0; *P*=.36). However, participants did express an emotional response to the playing experience, as shown in Figure 6. Because our sample was small, we did not perform any factor analysis. Instead, we chose to illustrate the frequency of affirmative responses to each of the game appraisal questions at the end of the session. Most participants found all three games to be enjoyable, interesting, stimulating to cognition, and beneficial to mental wellness.

We evaluated game-related differences in appraisal of the session using a Kruskal-Wallis comparison of Likert-scale responses to each item. We did not find significant differences related to the experimental session in scoring items. The test statistics are presented in Multimedia Appendix 1. Although we did not perform any factor analysis, we explored the correlation among the variables. It is worth reporting that there was a significant positive correlation between expressing a will to play the game again (*I will play this game again*) and finding the game *Good for Mental Wellness* (Spearman =0.826, n=54; *P*<.001), *Cognitively Stimulating* (Spearman (N=54)=0.545; *P*<.001), and *Enjoyable* (Spearman =0.639, n=54; *P*<.001), confirming the link between meaningfulness and enjoyment. There was also a negative correlation between expressing a *Will to Play the Game again*, and finding it *Frustrating* (Spearman =−0.438, n=54; *P*<.001) and *Useless* (Spearman =−0.617, n=54; *P*<.001). A more detailed analysis of these results is beyond the scope of this report and will be presented separately, together with the qualitative data [89].

Figure 6. Frequency of responding positively to the postgame appraisal questionnaire at the end of each session.

Effects of Cognitive Ability on Outcome Measures

Characteristics of the Sample in Montreal Cognitive Assessment Groups

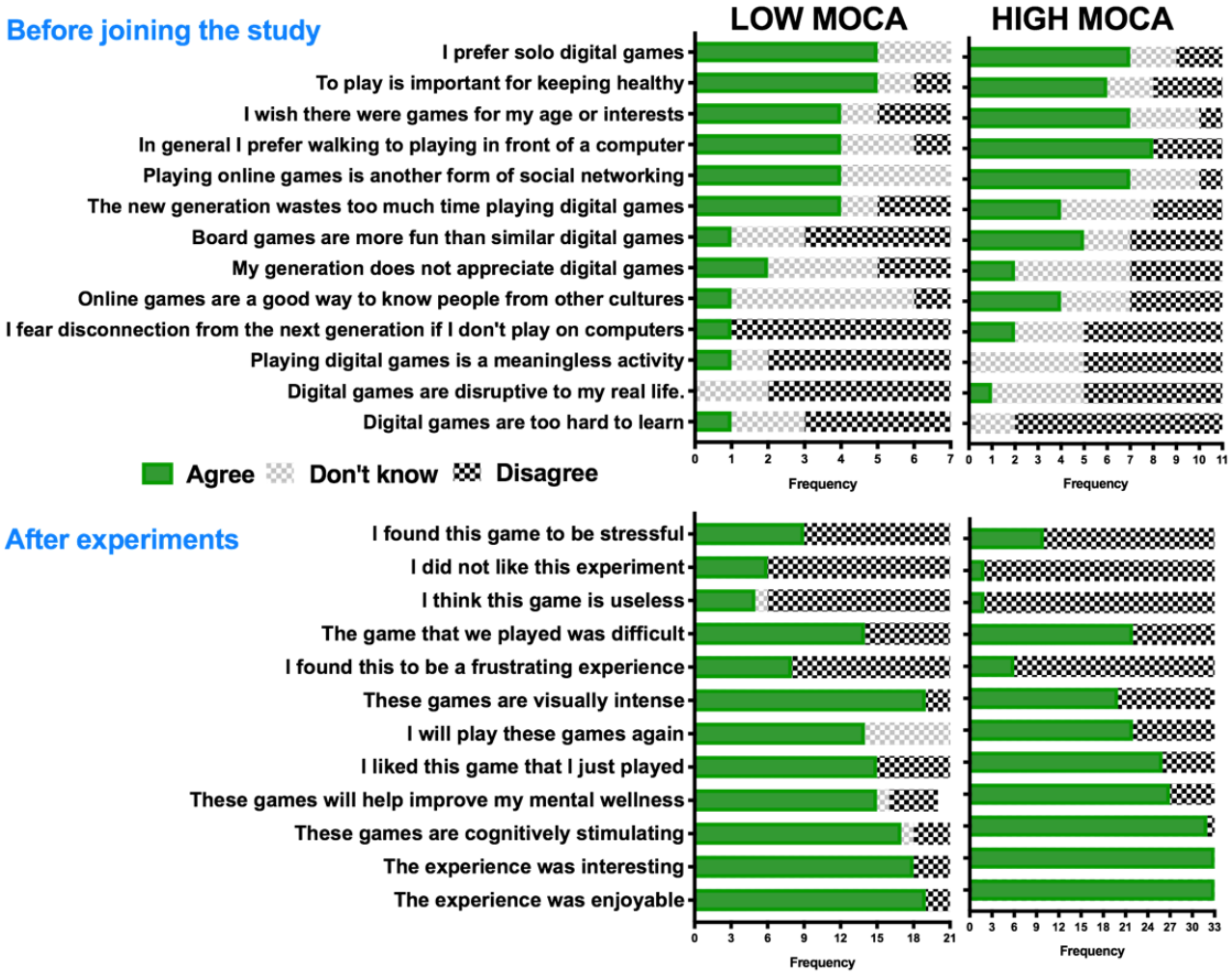
To examine whether cognitive reserve would predict the stressfulness of the gaming experience, the sample was split based on MoCA scores to low-MoCA (MoCA<27; n=8; mean 24.62, SD 1.41) and high-MoCA (MoCA ≥27; n=11; mean 28.27, SD 1.19) groups.

Independent *t* tests did not show significant differences in age (95% CI −3.8 to 2.3; *P*=.53), Perceived Stress Scale (95% CI −3.36 to 4.36; *P*=.73), General Self-Efficacy (95% CI −3.6 to 2; *P*=.53) or Loneliness scale (95% CI −19 to 2; *P*=.13)

Montreal Cognitive Assessment Group Differences in Game Appraisal

Figure 7 illustrates the patterns of game appraisal in the MoCA groups. In the screening questionnaires, the high-MoCA groups had a generally more positive attitude toward playful experience. The Kruskal-Wallis test demonstrated that in the pre-enrollment appraisal questionnaire, the low-MoCA group considered digital games *too hard to learn* (χ^2_1=4.05; *P*<.05), but other scores were not significantly different. In the postgame appraisal questionnaires, the low-MoCA group disliked the experience more (χ^2_1=5.1; *P*<.03) and found the game more useless (χ^2_1=4.92; *P*<.03), less interesting (χ^2_1=4.90; *P*<.03), and visually more intense (χ^2_1=5.6; *P*<.02); no other differences were statistically significant.

Figure 7. Response frequencies to the pre-enrollment and the postgame appraisal questionnaires.



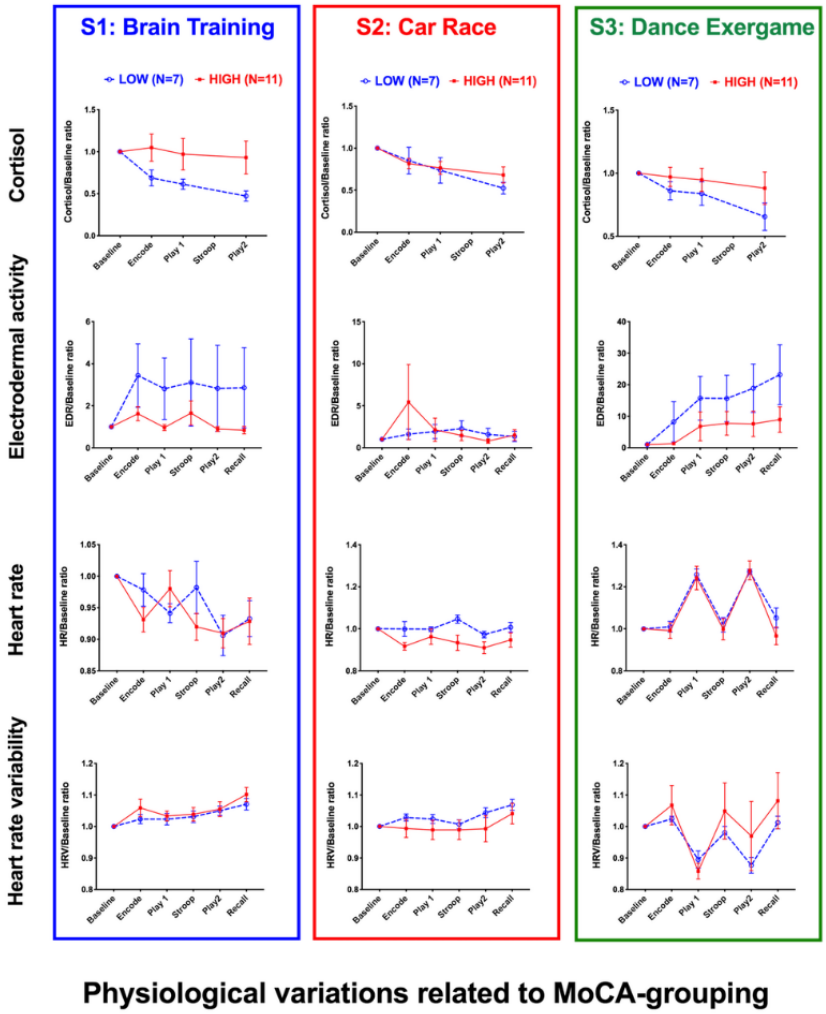
Montreal Cognitive Assessment Group Differences in Physiological Response

We expected individuals with lower MoCA scores to find the games more challenging and therefore be more stressed by it. To compare the groups, we first normalized all the physiological variables to the within-session and within-subject baseline. Figure 8 illustrates group differences in the pattern of physiological signals over time. Because the physiological profile was significantly different between sessions, we compared group differences separately for each session. A GEE model with independent variable MoCA was then tested for each physiological dependent variable. The results are summarized in Multimedia Appendix 1. The only significant differences in reflexive responses to the experiment were observed in the cortisol levels in the first session (S_1) and in the HR during the CareRace (S_2).

In S_1, cortisol in the low-MoCA group had a significantly larger drop from the baseline (mean difference −0.218; P=.046; 95% CI 0.004 to 0.432). This effect can reflect the fact that the low-MoCA group was more stressed about taking part in the study from the onset. Although not statistically significant, this group showed a steeper decline in cortisol level in the exergame session as well.

In S_2, the low-MoCA group increased their HR with respect to baseline and compared with the high-MoCA group. A trend for increased HR during cognitive tests during S_1 (Encode and Stroop) was also observed in the first session. These effects might suggest that irrespective of games, the low-MoCA group found the cognitive challenges in the experiment difficult and stressful.

Figure 8. Group×activity interaction effects. All results shown are normalized to the baseline (within-subject, and within-session) and plotted as mean+standard error of the mean. MoCA: Montreal Cognitive Assessment.



Montreal Cognitive Assessment Group Differences in Cognitive Tests

We expected that the performance of the low-MoCA group in cognitive tasks would be significantly reduced compared with that of the high-MoCA group. As Figure 5 illustrates, the interactions between *MoCA Group* and *Session* were mainly driven by session effects, which affected both groups similarly. The GEE test (*Session*$_i$×MoCA) revealed significant interaction effects on all cognitive variables (all $P<.005$), except Stroop Correct ($\chi^2_5=7.4$; $P=.19$). Post hoc analyses show that for both groups, performance in memory tasks was significantly lowered in S_3 vs S_1 (12% less hits in immediate recall, $P<.001$; and 22% less hits in delayed recall, $P<.001$). The Stroop RT was significantly increased in S_3 vs S_1 (mean difference 461 ms; $P=.001$). In the low-MoCA group, a small reduction in Stroop accuracy was observed between S_3 and S_1 (mean difference −2.1%; $P<.03$) and between S_3 and S_2 (mean difference −2.33%; $P=.008$). The Stroop RT to correct in S_3 was also the highest and significantly different from that of S_1 (mean difference 535 ms; $P<.001$). The only significant difference between the two groups was in percentage of correct Stroop in S_3 (mean difference 2.03%; $P<.03$). Although the game difficulty affected the Stroop performance in the low-MoCA group, it did not have any impact on the performance of the high-MoCA group.

Discussion

Summary

This study presents a prototype for AGPHA, which incorporates quantitative methods from stress research, to design serious games for use by older adults. The theoretical basis of AGPHA considers appraisal as the first criterion for the evaluation of gamified strategies for seniors' health care. We performed a mixed methods study to investigate whether playing unfamiliar digital games in the context of their cognitive benefits would be stressful for older adults. We measured stress both reflectively (using appraisal questionnaires before enrollment and after each game-play session), and reflexively (using a wearable device to measure electrodermal response, HR, and HRV; as well as from saliva cortisol). We found an overall positive attitude toward games and a significant link between general cognitive abilities (measured using MoCA, a clinical instrument that measures short-term memory, orientation, visuospatial and executive functions, language abilities, abstraction, and attention) and the degree to which different games (especially the more difficult one, exergame) affect the

game-related physiological and cognitive responses. In the following sections, we discuss the main findings, the questions that arise from this research, and the limitations to overcome in future work.

Principal Findings

What Are the Characteristics of Those Who Participated

Our snowball sampling survey was important in informing the results about the characteristics of those who found the topic of serious games interesting. Interindividual variations in game perception and motivation are important factors that engender the gameplaying experience [58,59]. The AGPHA framework [60] builds on the appraisal theory of stress and coping [90]. When confronted with a new challenging encounter, the primary appraisal process is to categorize it as irrelevant, benign-positive, or *stressful*, depending on what implications it would have for the individual's well-being. If the person has no investment in the outcome of the challenge, then they will have no need for it and will not commit to engaging with it. On the contrary, if they perceive immediate or potential benefits, they are willing to try it and enter the secondary appraisal stage. It is in the second stage that the individual focuses on evaluating the challenge: *Is it feasible and within my physical cognitive abilities?*

Our recruitment advertisement targeted a large mailing list of people interested in preventive health care and attracted 42 responses to the survey. Therefore, the number of individuals who entered the primary appraisal stage was not large. Of those, only 19 agreed to enter the secondary appraisal process. Those who did not participate were more likely to agree with the statement *Digital games are too hard to learn*, suggesting that from the onset, those with less confidence about their cognitive abilities excluded themselves from the experimental phase. Overall, the patterns of response (Figure 3) illustrated that the participating group had a generally more positive attitude toward gaming activities. The participating and nonparticipating groups did not differ in any other characteristics (eg, age, education, self-efficacy)

It must be emphasized that the participating sample had high self-efficacy and was well educated and socially and cognitively active. Thus, the following discussion hinges on the fact that the participants in the study were not representative of the aging population who are in need of cognitive or physical assistance. To address their needs by gamified digital interventions, we must repeat this experiment in a group with pronounced cognitive or physical disabilities (eg, in a nursing home or a rehabilitation center). Theoretically, any factors (such as accessibility or executive difficulty) that influence game appraisal will theoretically change the subsequent reflective and reflexive outcomes as well.

Are New Gaming Experiences Stressful for Seniors?

The second question we asked was whether playing a new digital game would cause stress. If this were the case, then we would expect to observe a significant increase in cortisol and ambulatory signals after the introduction of each game. As the patterns of signal in Figure 4 illustrate, this was not the case.

Cortisol is the hallmark of a latent psychosocial response to stress, but we did not see any significant cortisol effect after any of the gaming activities in the experiment. One explanation is that the highest levels of cortisol were measured at arrival time. This could have resulted from the participant's anticipation of the session, or from exertion of walking to our center. Because the hypothalamic pituitary adrenal stress system is regulated through a negative feedback mechanism, it is plausible that while the body was downregulating the high levels of basal cortisol, the system was not as responsive to the stress that may have been introduced during game play [91]. Detrending the cortisol signal to remove the sharp decay showed only a mild (and statistically insignificant) increase in cortisol post exergame.

While the cortisol response results from complex and relatively slow neuroendocrine processes, the EDA and HRV mark sympathetic autonomic response and have widely been used in human-computer interface studies [76-82]. The exergame was physiologically more demanding and higher physiological response was expected. Indeed, we observed significant differences in EDA, HR, and HRV, which significantly changed during the exergame (Figure 4) independent of the effect of movement and body temperature (measured on E4).

Interestingly, reflexive and reflective responses were not corresponding. Despite being more difficult, the exergame was not subjectively rated as more stressful (Figure 6). Nevertheless, the lowering of performance in cognitive tasks, which became statistically significant in the stress-sensitive recall task [71], indicates that it had a more pronounced interference with cognitive processing. This interpretation is consistent with previous reports that have shown a link between cognition and training with exergames [92-95]. In other words, the fact that exergame affects the cognitive performance immediately proves that it exercises the brain. Given that effects of stress on cognition are mediated through reward processing [83] and attention [84] systems, the challenge for game designers as well as gerontologists is to evaluate to what extent, for whom, and which exercises can become beneficial to the neurological health of aging individuals.

Effect of Cognitive Abilities on Stress Response to Games

Our third question was whether differences in cognitive ability (based on MoCA) predicted differences in reflective (Figure 7) and reflexive (Figure 8) response to games.

In terms of primary appraisal, the low-MoCA group found *digital games too hard to learn*. In the secondary appraisal (ie, after playing), the low-MoCA group was less likely to *enjoy* the game or find it *interesting*, less likely to find it *useful*, and more likely to find the game *visually more intense*. However, the groups did not differ in finding the games *difficult* or *stressful*. According to the appraisal theory, these anticipatory and perceptual differences should predict an increased stress response.

Indeed, physiological reactions to the games were stronger in the low-MoCA groups, although they were not statistically significant. The exception was in cortisol levels. The low-MoCA group had 21% more decrease in cortisol levels with respect to

baseline during the first session (brain training). This effect may have resulted from the anticipatory stress of the first session, or from the MoCA test itself, which was administered before the experiment began, and possibly caused a social evaluative stress.

Despite differences in perception and cortisol dynamics, cognitive performance in the first session was not significantly different between the two groups, and they both had high rates of correct responses to cognitive tests (>80%). However, in both groups, the performance in those tasks was lowered by increasing game difficulty and more pronounced in the low-MoCA group (Figure 5).

Van Reekum et al [80] have demonstrated the correlation between autonomic responses (cardiac and electrodermal signals) and performance in an action video game. It is plausible that the low-MoCA group experienced higher states of arousal as a result of adaptive coping to compensate for their initial discomfort with the game. This interpretation is consistent with the observation of Birks et al [58], who have argued that adding extrinsic motivation increases the efforts of those who do not have high levels of affinity with their game avatar. Thus, an increased stress response in the low-MoCA group could indicate the player's increased engagement with the game. Whether this engagement will lead to a desire to repeat play needs to be tested.

Comparison With Previous Studies

Intergenerational Considerations

To the best of our knowledge, this is the first quantitative crossover study to have compared the psychophysiological responses of older adults to different genres of marketplace games, with different levels of complexity in aesthetics, dynamics, and mechanics of games. Intergenerational differences in such studies must address differences in needs and values, as well as differences in physiology.

Poels et al [79] used a similar study design, but their participants were 19 young players. In the study by Poels et al, participants were monitored for hedonic and physiological reactions to four action games with different aesthetic features (two first-person shooters and two race games, with varying degrees of visual complexity). Their study indicated that initial physiological reactions predicted the likelihood of repeat playing in the long term.

Mandryk and Atkins [81] found that galvanic skin response, facial electromyograms, and cardiovascular responses can be used in machine learning algorithms to dynamically compute the degrees of valence and arousal during a gameplay session in 24 young gamers. Their study showed a high convergence between the subjective ratings of games and the machine-predicted levels of emotion and arousal.

In our study, postgame appraisal suggests that the desire to play the game again was highest in the brain training game (14 of 18 players indicated that they will play those games again), which was associated with lower levels of physiological response. In other words, it appears that younger players in the study by Poels et al [79] played games to induce a physiological response, whereas older players in our study preferred a game that did not induce strong reflexive responses.

Our findings are consistent with previous reports that in general, more seniors prefer the ease and pleasure of casual games (preferably with an intellectual component) over more cognitively demanding action games [3,56,57]. Our observations raise the following important questions that cannot be addressed in this study. What are the intergenerational differences in game appraisal? How are these differences in game appraisal correlated to age-related differences in physiological and cognitive reserves? Are physiological measures appropriate for evaluation of seniors desire to engage in the game challenge?

The Importance of Context

In a meta-analysis of 48 studies, involving uniplayer games (excluding exergames), Van der Vijgh et al [96] demonstrated and argued that although games can explain up to 57% of stress-related physiological variations (HR and blood pressure), it is not the game alone but the context of the experimental design and the study characteristics that moderate the stressful response to games.

In this study, we wanted to make the participants comfortable with games (eg, by sequencing the games from simple in the first session to hard in the last session). However, these games were presented in a *serious* context by the title of the study *An Objective Assessment of Interactions Between Appraisal, Arousal and Cognitive Benefits of Electronic Playing*. If the study characteristics (which we modified by altering the games in the different sessions) are important, then arguably, our complex experimental setting, and the inclusion of the memory and Stroop tests (even though simplified) could have altered the phenomenology of the experience and thus have hindered the physiological responses to the gameplay alone. Nevertheless, our complex experimental setup allows to illustrate the complexity arising from contextual factors that interact with psychophysiological adaptation. In real life, games are not experienced as isolated laboratory events, but in relation to other activities. The complexity of Group×Session×Activity interactions with physiological signals (Figure 8) provides evidence to concur with Van der Vijgh et al [96] that it is the context in which games are experienced that counts.

Stress and Performance

Acute stress is not necessarily a maladaptive response. Stress interacts with learning and cognitive function through myriad physiological and behavioral cascades [64,84]. The evolutionary function of an acute physiological stress response is to focus and consolidate the lessons to be learned from surviving new challenges [65,84,97,98].

Van Reekum et al [80] have demonstrated a correlation between autonomic responses (cardiac and electrodermal signals) and performance in an action video game. In our design, neither could we reliably record nor did we want to measure the player's performance in the commercial games that we presented. Instead, we used the simple version of a Stroop test in which RT is expected to be affected by acute stress [71,86], and which seems to acutely improve after casual exergaming in a younger sample [87]. We also used an encoding/recall task, which we

have previously shown to be sensitive to acute stress [71,85]. Although these measures were not chosen to be difficult (eg, the number of Stroop trials was very small) or to measure specific cognitive domains, they served as control variables to help us assess whether game difficulty could have an impact that exceeded the learning effect.

We found that the RT to a very simple Stroop (4 color, 75% incongruent stimuli) increased with game difficulty and that delayed recall accuracy decreased with game difficulty, especially in those with lower MoCA scores. Although we cannot infer about how games interacted with cognition, we demonstrate that such cognitive tests may offer a lower cost measure to trace effects of repeated play on neuropsychological factors that underlie cognition. As we have argued in introduction of the AGPHA framework [60], to document such data can potentially guide the decisions made in the design cycle, in terms of how to activate specific cognitive targets by modifying game aesthetics and dynamics.

Limitations

Sample Size

This study is limited primarily by the sample size, which was estimated with the expectation of 80% of power to detect a cortisol response to an explicit stress challenge [71]. In older adults, stress responses to the same task may be blunter than those in a younger sample [99]. Age-related variations in stress sensitivity may be connected to a myriad of endocrinological or psychological factors, all of which need to be carefully modeled using larger samples [100]. Adding multifactorial quantitative measurements (growing in availability and reducing in cost) to larger crowdsourced experiments such as the one conducted by Birks et al [101] could provide a finer grained picture of the physiological embodied qualities of a game experience. This would be of considerable importance for the clinical industries that are emerging around the utilization of game-based interventions in mental health care [32].

In addition, the complexity of our setup makes our ambulatory measurements more susceptible to instrumentation noise. Despite setting up the procedure to be identical and obtaining repeated measures of cortisol and ambulatory signals at baseline, we did not achieve interclass correlations above 70%. Endocrine measurements (eg, cortisol) are sensitive to factors such as time of the day (circadian rhythms), activity before sampling, and states of health and medications. Although we controlled and measured all of these factors, our small sample size does not allow including all of them in our statistical models. These factors must be controlled for in larger studies.

Experimental Complexity and Analytical Limits

The second limitation of this study is inherent to its experimental design. We wanted these experiments to be participatory and gave primacy to the participant's appraisal of games in relation to their cognitive benefits. We therefore avoided stressful elements such as keeping scores or time pressure. The main experimental variants were gradual increase in game complexity and MoCA categorization. Our repeated measures experimental design is advantageous in terms of statistical power but is not immune to habituation effects, which is a very important and confounding factor in stress studies.

The third limitation of our study is to have split the sample by MoCA scores. MoCA includes 30 questions, and a score of 1/0 per each question, to account for differences in short-term memory, orientation, visuospatial and executive functions, language abilities, abstraction, and attention. This categorization, especially in the context of evaluating a complex and interactive medium such as a game, is too reductionist. To use MoCA as a discriminating factor provided methodological simplicity to offer a proof-of-concept example of the application of AGPHA framework, but it did not account for the variations in behavioral strategies that compensate for decline in those specific cognitive domains. These issues must be further investigated.

Finally, our test studio (blue-floored and mirrored-walls) and the various assessment tools we used were quite burdensome and far from ecological. To repeat this experiment in a familiar setting and with a simpler design, such as in a living laboratory, a nursing home, or a senior's community center, will likely produce different results.

Conclusion and Future Work

The field of serious games needs methodological standards to evaluate the efficacy of games that are designed to benefit seniors [50]. Despite its limitations, this pilot study illustrates that the quantitative framework proposed in AGPHA is sensitive to uncovering the within-subject and between-group differences in reflexive and reflective reaction to games. We have used various instruments: surveys and appraisal inventories (which are available free of cost), multiple data from wearable physiological monitors (the device costs ~Can $2500 [~US $1871]), multiple saliva samples (~Can $15 [~US $11.22813] per each sample), and computerized neurocognitive tests (almost free). We found a complex pattern of associations between physiological factors and activities in each session, which suggests that variables such as cortisol and slow EDA signal changes are sensitive for detecting gross effects of experimental procedures. More simple measures—a delayed picture recall test and the RT to a correct response in a nonchallenging version of the Stroop test—were also sensitive enough to detect between-group and between-session variations in response to different games. Better defined cognitive tests can reveal more precise interactions between specific games and specific cognitive domains. The MoCA categorization in this study serves as a proof of concept for the AGPHA framework, but it does not represent the full scope of interindividual variations (eg, in sex, gender, personality, and health state). In larger and more heterogeneous samples, this multivariate approach can be explored from multiple facets to help us develop predictable models of health outcomes benefiting from different serious games.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplemental materials.
[DOCX File , 753 KB - mental_v7i3e12388_app1.docx]

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Abbreviations

ACC: accelerometer
AGPHA: Affective Game Planning for Health Applications
EDA: electrodermal activity
GEE: generalized estimating equation
HR: heart rate
HRV: heart rate variability
MoCA: Montreal Cognitive Assessment
RT: reaction time

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Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org