JMIR Mental Health

Journal Impact Factor (JIF) (2022): 5.2
Volume 6 (2019), Issue 1 ISSN 2368-7959 Editor in Chief: John Torous, MD, MBI

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Original Paper

Adoption of Mobile Apps for Depression and Anxiety: Cross-Sectional Survey Study on Patient Interest and Barriers to Engagement

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Abstract

Background: Emerging research suggests that mobile apps can be used to effectively treat common mental illnesses like depression and anxiety. Despite promising efficacy results and ease of access to these interventions, adoption of mobile health (mHealth; mobile device–delivered) interventions for mental illness has been limited. More insight into patients' perspectives on mHealth interventions is required to create effective implementation strategies and to adapt existing interventions to facilitate higher rates of adoption.

Objective: The aim of this study was to examine, from the patient perspective, current use and factors that may impact the use of mHealth interventions for mental illness.

Methods: This was a cross-sectional survey study of veterans who had attended an appointment at a single Veterans Health Administration facility in early 2016 that was associated with one of the following mental health concerns: unipolar depression, any anxiety disorder, or posttraumatic stress disorder. We used the Veteran Affairs Corporate Data Warehouse to create subsets of eligible participants demographically stratified by gender (male or female) and minority status (white or nonwhite). From each subset, 100 participants were selected at random and mailed a paper survey with items addressing the demographics, overall health, mental health, technology ownership or use, interest in mobile app interventions for mental illness, reasons for use or nonuse, and interest in specific features of mobile apps for mental illness.

Results: Of the 400 potential participants, 149 (37.3%, 149/400) completed and returned a survey. Most participants (79.9%, 119/149) reported that they owned a smart device and that they use apps in general (71.1%, 106/149). Most participants (73.1%, 87/149) reported interest in using an app for mental illness, but only 10.7% (16/149) had done so. Paired samples *t* tests indicated that ratings of interest in using an app recommended by a clinician were significantly greater than general interest ratings and even greater when the recommending clinician was a specialty mental health provider. The most frequent concerns related to using an app for mental illness were lacking proof of efficacy (71.8%, 107/149), concerns about data privacy (59.1%, 88/149), and not knowing where to find such an app (51.0%, 76/149). Participants expressed interest in a number of app features with particularly high-interest ratings for context-sensitive apps (85.2%, 127/149), and apps focused on the following areas: increasing

exercise (75.8%, 113/149), improving sleep (73.2%, 109/149), changing negative thinking (70.5%, 105/149), and increasing involvement in activities (67.1%, 100/149).

Conclusions: Most respondents had access to devices to use mobile apps for mental illness, already used apps for other purposes, and were interested in mobile apps for mental illness. Key factors that may improve adoption include provider endorsement, greater publicity of efficacious apps, and clear messaging about efficacy and privacy of information. Finally, multifaceted apps that address a range of concerns, from sleep to negative thought patterns, may be best received.

(JMIR Ment Health 2019;6(1):e11334) doi:10.2196/11334

KEYWORDS

mHealth; depression; anxiety; mobile apps; patient preference

Introduction

The majority of the US population owns smartphones (77% in 2016) [1], and the number of mobile apps for health has grown exponentially over the past decade. A study by the IMS Institute for Healthcare Informatics [2] found that the number of health and wellness apps available to consumers has more than doubled between 2013 and 2015 (from 43,000 to over 90,000). Although the content and quality of these apps vary widely, the potential public health impact of such tools is enormous. Research suggests that mobile health (mHealth) interventions can have a positive influence on a wide range of health conditions [3,4] and, while not a substitute for in-person treatment, these tools offer a treatment option that does not have as many access barriers as in-office treatment (eg, no transportation is required) and may allow for reduced cost of care (since marginal cost is negligible).

In mental illness—where stigma and self-reliance beliefs are additional barriers to treatment seeking and engagement [5]—mobile health (mHealth) offers even greater potential. Common mental health disorders such as depression and anxiety impact nearly a third of the US population, and most of those who need treatment do not receive it [6,7]. The sheer number of people affected makes providing adequate treatment in traditional clinical settings prohibitive in terms of availability of trained providers. Studies indicate that mHealth interventions can improve functioning and symptoms in those with depression and/or anxiety [8-11] and also that technology offers some advantages over in-person treatments. Specifically, mHealth interventions offer 24/7 support because mobile devices are often kept with users throughout the day. In addition, patients may be more likely to report severe symptoms on technology platforms than in person [12], and patients value the autonomy and empowerment that can be offered by such platforms [13].

Unfortunately, adoption of mHealth interventions for common mental illnesses such as depression and anxiety remains low. To date, mHealth is neither a routine part of mental health care offerings in the United States nor has any mHealth platform for mental illness been widely adopted by consumers in the United States. These patterns are particularly noteworthy in systems such as the Veterans Health Administration (VHA), which has invested substantially in building and evaluating several free behavioral health apps specifically designed for mental health concerns of veterans. Several theoretical models explaining technology adoption and continued use have been put forth in the literature [14-16]. Existing models have some conflicting and some overlapping components and have been found to explain as little as 17% and as much as 53% of the variance in adoption [15]. Newer unified models may explain more of the variance in adoption and use, but much of this literature has traditionally focused largely on adoption of technology in the workplace, a considerably different context than the treatment of mental illness. This multifaceted theoretical canvas underscores the complexity of understanding adoption and the potential importance of studying specific types of technology within the intended use population. At present, it is unclear what are the best approaches for encouraging patient adoption of mHealth interventions.

Research on patient adoption of technology in treatment of mental illness suggests that interest outpaces adoption. Specifically, studies of patients with depression, anxiety, and posttraumatic stress disorder (PTSD) suggest that interest varies widely based on the type of technology in question, but most patients are interested in using some kinds of technology in treatment [17,18]. With regard to mHealth specifically, Erbes et al [19] found that over half of a sample of patients with PTSD expressed interest in mHealth programs for PTSD, but less than 10% were currently using these platforms to help manage their symptoms.

Given high interest and low adoption, there is a need to build a stronger understanding of the factors that may affect adoption at the system level. Research on other patient-facing technologies suggests that how such technologies are integrated into the health care system may impact patient adoption. For example, findings from studies focused on adoption of one Web portal indicate that provider endorsement can improve rates of adoption [20]. It remains to be determined whether this is the case for mHealth interventions.

There is also a need to build a stronger understanding of factors that may affect adoption at the patient level. A large national survey of health app use in the general population indicated that lack of interest, cost, and concern about data privacy were key barriers to adoption [21]. These findings have been reinforced in other studies focused on mental health apps. Specifically, a study focused on mHealth interventions for depression found that cost, concerns about privacy, concerns over intervention efficacy, and misfit of intervention features to needs (ie, personalization) were key barriers to adoption of depression apps [22]. Another study focused on health and mental health apps found that efficacy and privacy are key barriers to adoption as well as not knowing where to find an app or knowing which

app to download [23]. However, these studies were conducted using only partially clinical samples, that is, presence of clinically significant symptoms (on self-report or via medical record diagnosis) was either not an eligibility criterion or not assessed.

Stronger understanding of patient perspectives on mHealth interventions in relevant clinical samples is required to support the development of targeted implementation strategies and platform modifications that will ultimately promote adoption. The aim of this study was to characterize mHealth interest, concerns, and preferences in a sample of patients with an active diagnosis of depression, anxiety, and/or PTSD. Specifically, we sought to (1) identify patients' degree of interest in mHealth interventions for mental health, (2) identify whether provider endorsement would impact degree of interest, (3) determine reasons for nonuse of mHealth interventions for mental health, and (4) identify what mHealth content or features are of most interest to patients.

Methods

Recruitment

We used the Veterans Affairs (VA) Corporate Data Warehouse (CDW) to identify individuals meeting eligibility criteria and to extract contact and diagnostic information for those individuals. Eligibility criteria were as follows: (1) US military veteran enrolled in care at the VA Boston Healthcare System; (2) receiving VA primary care, as indicated by having at least one encounter in the local primary care clinic between January 1, 2016, and July 1, 2016; (3) aged 18 years or older; and (4) attended a VA medical appointment between January 1, 2016, and July 1, 2016, in which an anxiety disorder (including obsessive-compulsive disorder), unipolar depressive disorder, or PTSD was documented as a condition treated in the appointment. Codes based on the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) were used to determine visits associated with unipolar depression (F32-F34) and anxiety and PTSD (F40-F43). The decision to include patients with any or all of these diagnoses in the sample was based on high comorbidity rates between these diagnoses and the similarity of pharmacological and psychotherapeutic treatments for these disorders [24-29].

A total of 2840 veterans in the CDW met the above criteria. Within this sample, we divided records into 4 strata (white men, nonwhite men, white women, and nonwhite women) and randomly sampled 100 records from each stratum to achieve a gender- and minority-balanced set of potential participants. These randomly selected 400 individuals were actively recruited for participation via mailed surveys and accompanying study information. Although electronic medical record diagnostic codes were used to define our CDW search parameters and establish a set of eligible participants, these codes were not extracted for use in our dataset. This decision was made to protect patients' privacy, especially those patients who chose not to participate. The only information extracted from patient's charts was name and mailing address.

We used a modified Dillman method for recruitment [30]. The 400 veterans identified as potential participants were sent a series of 3 mailings, each including a letter inviting the veteran to participate, a study fact sheet, the survey, a postage-marked opt-out postcard, and a postage-marked return envelope. In addition, the first mailing contained a $10 Patron coupon for use at the local VA facility cafeteria and general store. The study invitation letter informed veterans that they may keep this coupon regardless of their decision to participate in this research. Participants who returned either the survey or opt-out postcard were not included in successive mailings.

All recruitment and study procedures were approved by the VA Boston Healthcare System's institutional review board.

Survey

Survey items were a combination of validated measures and newly developed questions based on the literature on technology use and adoption [31-33]. As there was no precedent for items evaluating concerns related to mental health app use and/or interest after clinician endorsement, these items were developed based on existing literature and field tested among a diverse team of colleagues with expertise in survey development. Items on mental health app features of interest to participants were selected based on a review of the literature on common elements of depression and anxiety apps [34,35].

The final survey consisted of 38 questions focused on 6 domains: (1) sociodemographic characteristics; (2) physical and mental health symptoms assessed using the SF-1 (first item of the 36-item Short Form Health Survey) for overall health [31,36], the Patient Health Questionnaire-8 (PHQ-8) for depression symptom severity [32,37], and Generalized Anxiety Disorder-7 (GAD-7) for anxiety symptom severity [33,38,39]; (3) technology ownership and use; (4) interest in apps for mental illness; (5) reasons for not using apps for mental illness; and (6) interest in specific mental illness app features (see Multimedia Appendix 1 for a list of items in each domain).

Data Analysis

We aggregated descriptive data on the following: demographic and health characteristics, devices owned, current technology use, and ratings on interest in mHealth interventions.

We used paired sample *t* tests to evaluate the degree to which provider endorsement impacted participants' level of interest in use of mHealth interventions for mental illness. Specifically, *t* tests compared participants' general interest ratings with those provided when asked how interested they would be in using a mobile app for mental illness if their primary care provider (PCP) recommended it. A similar comparison was conducted between general interest ratings and those provided when asked how interested they would be in using a mobile app for mental illness if their mental health provider recommended the app. Finally, we used *t* tests to compare interest ratings associated with PCP recommendation with those associated with mental health provider recommendation.

We also compiled aggregate descriptive data on the following: reasons endorsed for using or not using mobile apps for mental health and interest in specific app features and content.

Results

Participants

A total of 149 surveys were returned (response rate of 37.3%, 149/400). The resulting sample was fairly balanced on demographic characteristics (see Table 1). For clarity and because no item or scale had missing data for more than 8.1% (12/149) of respondents, all results are reported as percentages of the full sample.

The mean PHQ-8 score was 11.25 (SD 6.62), and the majority of the sample (65.8%, 98/149) reported symptoms that met the PHQ-8 cutoff score of 8, indicating clinically significant depressive symptoms [40]. The mean GAD-7 score was 9.65 (SD 6.02), and more than half of the sample (56.4%, 84/149) reported symptoms that met the GAD-7 cutoff score of 8 for clinically significant anxiety symptoms [33,39]. Self-reported mental health conditions were collected and are detailed in Table 1.

Technology Ownership and Use

The majority of the participants reported owning a smartphone (75.8%, 113/149) and a smaller portion reported owning a tablet (45.6%, 68/149). Together, a total of 119 participants (79.9%, 119/149) reported owning a smart device that could be used to run a mental health app. Table 2 displays participant answers with regard to current app and smart device technology use.

Interest in Apps for Mental Illness

When asked how interested they would be in using an app for mental illness, 73.1% (87/149) reported some level of interest. Specifically, 12.8% (19/149) indicated that they would be completely interested, 22.1% (33/149) indicated that they would be very interested, 22.8% (34/149) indicated that they would be moderately interested, and 15.4% (23/149) indicated that they would be a little interested. When the sample was limited to only those who owned a smart device, the percentage of individuals with some level of interest in using an app for mental illness was slightly higher (77.3%, 92/149).

In addition, when asked about interest in apps that could deliver context-sensitive feedback (ie, utilizing passive sensors to respond to physical or behavioral changes), the majority of the sample (84.0%, 125/149) reported some interest. Specifically, 28.9% (43/149) reported that they would be completely interested, 26.2% (39/149) reported that they would be very interested, 16.1% (24/149) reported that they would be moderately interested, and 12.8% (19/149) reported that they would be a little interested. When the sample was limited to only those who owned a smart device, the percentage of individuals interested in an app that delivered context-sensitive feedback was only slightly higher (86.6%, 103/149).

Relationship Between Interest in Apps for Mental Illness and Provider Endorsement

Paired sample *t* tests were used to determine whether provider endorsement would impact interest levels. Starting with an alpha=.05 as the critical *P* value, the Bonferroni corrected *P* value for 3 t tests was .017. Participants rated global interest independent of provider endorsement (mean 2.81 [SD 1.38]) significantly lower than interest in the context of PCP endorsement (mean 3.13 [SD 1.38], $t_{147}=-5.65$, $P<.001$, $d=0.23$). Similarly, participants rated global interest independent of provider endorsement (mean 2.81 [SD 1.38]) significantly lower than interest in the context of mental health provider endorsement (mean 3.30 [SD 1.36], $t_{145}=-4.05$, $P<.001$, $d=0.36$). Finally, participants rated interest in the context of PCP endorsement (mean 3.13 [SD 1.38]) significantly lower than interest in the context of mental health provider endorsement (mean 3.30 [SD 1.36], $t_{145}=-3.37$, $P<.001$, $d=0.12$). When the sample was limited to only those who owned smart devices (n=119), these comparisons remained significant at the $P<.001$ level in the same directions.

Reasons for Not Using Apps for Mental Illness

Table 3 displays the frequency with which participants endorsed specific reasons for not using mental health apps. The most commonly endorsed reasons were not having proof that the app would work, concerns about privacy, and not knowing where to find such an app. These were the most commonly endorsed reasons both when the full sample was considered and when the sample was limited to only those participants who owned smart devices.

Interest in Specific Mental Illness App Features

Table 4 displays the frequency with which participants endorsed interest in features of mental health apps. The features with the highest interest ratings related to increasing exercise, getting better sleep, cognitive restructuring (changing negative or self-critical thinking), and behavioral activation (getting involved in more activities). These features were the most frequently endorsed both when the full sample was considered and when the sample was limited to only those participants who owned smart devices.

Table 1. Demographic characteristics of the sample (N=149).

Characteristics	Statistics
Age (years), mean (SD)	57.5 (13.9)
Gender, n (%)	
Male	77 (51.7)
Female	67 (45.0)
Not reported	5 (3.4)
Race or ethnicity, n (%)	
Caucasian or white	67 (45.0)
African American or black	44 (29.5)
Other	11 (7.4)
Hispanic or Latino	9 (6.0)
Not reported	7 (4.7)
Asian	6 (4.0)
American Indian, Alaskan Native	4 (2.7)
Pacific Islander	1 (0.7)
Education, n (%)	
Middle school (7th-8th)	1 (0.7)
High school (9th-12th)	24 (16.1)
Some college or vocational school	41 (27.5)
Associates degree (2-year college)	16 (10.7)
Bachelor’s degree (4-year college or university)	36 (24.2)
Graduate degree	27 (18.1)
Not reported	4 (2.7)
English as first language, n (%)	134 (89.9)
Marital status, n (%)	
Divorced or separated	49 (32.9)
Married	46 (30.9)
Single, never married	39 (26.2)
Widowed	11 (7.4)
Not reported	4 (2.7)
Annual household income, n (%)	
Less than US $20,000	36 (24.2)
US $20,000 to US $34,999	21 (14.1)
US $35,000 to US $49,999	35 (23.5)
US $50,000 to US $74,999	20 (13.4)
US $75,000 to US $99,999	15 (10.1)
US $100,000 to US $149,999	8 (5.4)
US $150,000 or more	2 (1.3)
Not reported	12 (8.1)
Self-reported health rating, n (%)	
Excellent	3 (2.0)
Very good	21 (14.1)
Good	56 (37.6)

Characteristics	Statistics
Fair	51 (34.2)
Poor	11 (7.4)
Not reported	6 (4.0)
Self-reported behavioral health conditions, n (%)	
Depression	107 (71.8)
Stress	97 (65.1)
Anxiety	96 (64.4)
Difficulty sleeping	93 (62.4)
Posttraumatic stress disorder	91 (61.1)
Chronic pain	88 (59.1)
Overweight	76 (51.0)
Smoking	32 (21.5)
Diabetes	26 (17.4)
Substance use disorder (not alcohol)	15 (10.1)
Alcohol use disorder	14 (9.4)

Table 2. Technology use characteristics of sample (N=149).

Type of technology use	Frequency endorsed, n (%)
Smartphone or tablet functions	
Texting	118 (79.2)
Taking pictures or camera	116 (77.9)
Apps	106 (71.1)
Searching the internet	104 (69.8)
Checking the weather forecast	103 (69.1)
Email	101 (67.8)
Driving or walking directions	95 (63.8)
Social media	83 (55.7)
Use of apps for other health-related goals	
Daily steps	42 (28.2)
Tracking calories	34 (22.8)
Mindfulness exercises	31 (20.8)
Weight management	30 (20.1)
Sleep	28 (18.8)
Mental illness	16 (10.7)

Table 3. Factors impacting use of mental health apps.

Reason	Smart device owners (n=119), n (%)	Full sample (N=149), n (%)
I might use an app for these problems if I saw proof that it worked.	92 (77.3)	107 (71.8)
I am concerned about protecting my privacy with having my information in an app like this.	73 (61.3)	88 (59.1)
I don't know how to find an app that would help.	61 (51.3)	76 (51.0)
I don't think an app can help me to get better.	44 (37.0)	55 (36.9)
I am already in treatment for stress, depression, anxiety or PTSD[a] and don't see the need for an app.	43 (36.1)	52 (34.9)
It would be embarrassing to have an app like this on my phone.	31 (26.1)	39 (26.2)
I don't use apps at all.	13 (10.9)	29 (19.5)
I tried an app like this before and did not like it because it was not personalized enough.	13 (10.9)	14 (9.4)
I don't think I have a problem with stress, depression, anxiety or PTSD.	12 (10.1)	21 (14.1)
I tried an app like this before and it did not help.	11 (9.2)	11 (7.4)
I tried an app like this before and did not like it because it was difficult to use.	10 (8.4)	12 (8.1)

[a]PTSD: posttraumatic stress disorder.

Table 4. Interest in specific features of mental health apps.

Item wording (intervention label)	Smart device owners (n=119), n (%)	Full sample (N=149), n (%)
Increase your physical activity or exercise (physical activity)	95 (79.8)	113 (75.8)
Help you learn to get better sleep (Cognitive Behavioral Therapy for Insomnia)	87 (73.1)	109 (73.2)
Learn how to change negative/self-critical thinking (cognitive restructuring)	86 (72.3)	105 (70.5)
Get involved in more activities (behavioral activation)	86 (72.3)	100 (67.1)
Track mood/stress/anxiety/PTSD[a] symptoms (progress monitoring)	80 (67.2)	95 (63.8)
Speak with a health coach when your symptoms are bad. (professional support)	79 (66.4)	98 (65.8)
Learn more about your mental health condition. (psychoeducation)	77 (64.7)	92 (61.7)
Help improve your social skills (social skills training)	75 (63.0)	92 (61.7)
Remind you to take your medications. (medication adherence)	73 (61.3)	91 (61.1)
Connect with a community of people with similar mental health problems (social support)	61 (51.3)	72 (48.3)

[a]PTSD: posttraumatic stress disorder.

Discussion

Principal Findings

Results from this study indicate that access and interest in mobile apps for mental illness outpace actual use. Specifically, we found that access to devices and use of apps, in general, was high: nearly 80% of our sample reported owning smart devices, and of those with smart devices, nearly 90% reported that they use apps. Interest in using mobile apps for mental illness was also high: over 70% of the sample indicated that they have some level of interest. Despite owning the requisite devices, having active and relevant diagnoses (as indicated by PHQ-8 and GAD-7 scores), and expressing interest, use of mobile apps for mental illness was low: only 1 in 10 participants used apps for mental illness. These findings could be interpreted as indicating that most participants wanted to use mHealth interventions for mental illness and had the device and technology knowledge to do so.

Findings also provide some guidance into factors that may impact adoption. First, the highest-rated reasons for not using apps for mental health were related to not having proof of efficacy, concerns about whether these apps could keep mental health information adequately private, and not knowing where to find such an app. These findings suggest that public dissemination of information on efficacy of apps for mental illness (eg, in doctors' offices or on public transportation) could improve adoption. Moreover, informing users how information within the app is protected (eg, in the introductory screens of the app) may increase adoption. Concerns related to efficacy and privacy are supported by earlier studies [21,22,41], but until recently [23], lack of information on where to find evidence-based apps has not been clearly articulated as a barrier to adoption. With regard to barriers to adoption, it is important to specifically note that this study did not evaluate cost as a barrier to adoption for 2 reasons. First, within VA, cost concerns of medical care are different than outside VA. Second, VA has developed a number of mobile apps for mental illness that are

freely available to the public and relevant for the veterans recruited in this study.

Provider endorsement also appears to be a promising avenue for increasing adoption of mHealth for mental illness. Participants provided significantly higher interest ratings in the context of provider endorsement than when asked more generally about interest in using such apps. These findings are consistent with existing literature on the impact of provider endorsement in patient adoption of other patient-facing technologies (eg, patient portals that offer messaging and other features) [20]. These findings go beyond the existing literature, however, by showing that the type of provider endorsing the intervention may matter because interest ratings were greater in the context of mental health provider endorsement than PCP endorsement. Provider recommendation is not currently the norm; recent research suggests that individuals are more likely to hear about mental health apps through social media, Web searches, or friends than through medical providers [23]. Findings from our study underscore that providers could potentially play a key role in increasing adoption. Findings also raise questions about who among providers should be endorsing mHealth interventions to maximize the chances of adoption.

Although this study did not seek to directly test existing models of technology adoption, some interesting parallels between these findings and existing models were observed. Specifically, the Unified Theory of Acceptance and Use of Technology [15] indicates that 2 key determinants of technology adoption and use are performance expectancy (a user's beliefs on whether the technology will be helpful) and social influence (how strongly an individual believes that important others think he or she should use the technology). Findings that both proof of efficacy and provider endorsement would encourage use are consistent with these 2 theoretical constructs. Considering the results from this research in relation to such constructs is particularly important to understanding how evolving theories of technology adoption can best be applied in different contexts, including patient adoption of technology and its integration into mental health treatment.

Findings also provide insight into what features and content of apps patients with depression, anxiety, and/or PTSD may find most useful. Over 70% of participants with smart devices reported interest in using apps that facilitate core functions of cognitive behavioral therapy such as cognitive restructuring and behavioral activation. Over 73% of participants with smart devices reported interest in features that would promote wellness in areas of behavioral health such as sleep difficulties and inactivity. These findings suggest that this population may be best served by individual apps or suites of apps that target depression and anxiety from multiple angles [10].

In addition, interest in context-sensing mobile app interventions was high; 85% of participants indicated some level of interest in this type of intervention. This finding contrasts with other research where participants endorsed skepticism and concern over context sensing [41]. Interest in context-sensing mobile app interventions may indicate an interest in personalization. Along these lines, Table 3 shows that the majority of those who reported having used an app for mental health also endorsed that they did not like it because it was not sufficiently personalized. This finding should be interpreted with caution because we do not know which apps these participants used, and it is difficult to draw conclusions based on such a small subsample (only 10.7% of the full sample had used apps for mental illness). However, other research corroborates that patient reports of insufficient personalization is a perceived barrier to using mobile treatment apps for depression [22].

It was also worth noting that although participants endorsed interest in apps that offered the option of speaking to a health coach, 5 other features were endorsed more frequently than this feature. There has been a lot of emphasis on the integration of health coaching into app platforms both as a way to enhance engagement and as a way to produce higher levels of change [42,43]. On the other side of this debate, some research indicates that integrating health coaching does not necessarily ensure engagement in technology-based interventions for depression as users can simply ignore calls from coaches [44]. Findings from this study contribute to this debate and indicate that health coaching capabilities may not be essential for user interest and/or engagement.

Strengths and Limitations

Key strengths of this study include engagement of a racially diverse, clinical sample and proactive recruitment methods. By mailing paper surveys to patients identified as eligible, we expect to have captured data from individuals who may not have responded to more passive recruitment approaches (eg, flyers in waiting rooms). However, our proactively mailed survey methodology also introduces some bias as it is also possible that those who were less interested in use of technology were less likely to respond to the survey. Nevertheless, it is our expectation that the clinical nature of our sample was appropriate for our research questions and that our recruitment method introduced less bias than studies recruiting online or via social media, which essentially make technology proficiency a condition for entry into the study.

The sample in this study consisted entirely of veterans receiving services at a single VA hospital in a metropolitan area in the northeastern United States. Generalizability of findings to nonveteran samples and samples collected in other geographical areas should be tested in future studies. In addition, given the scope and funding level of this study, the presence of diagnoses required for eligibility was based on patients' medical records and not verified by study staff independently through a structured clinical interview.

Finally, this study evaluated stated preferences and interests. A close-ended question format was used for this survey; however, the downside of survey items formatted in this manner is that they can produce less nuanced data when answer options do not fully capture patients' thoughts. Additional research that includes more nuanced data collection such as a mixed-methods study with qualitative interviews will be an important next step. Moreover, moving forward, it will be necessary to evaluate whether these self-reported findings hold up behaviorally. That is, future research will need to assess whether implementation strategies and platforms consistent with observed preferences

and interests are associated with positive impact on adoption and engagement.

Conclusions and Future Directions

Mobile apps are a new and promising adjunctive, and possibly even stand-alone, treatment option for patients with depression and anxiety disorders. They are technologies that can reach patients beyond the confines of traditional brick-and-mortar clinic visits and engage them directly, in the context of their daily lives. For these reasons, mobile apps are also a unique treatment option to implement, one that requires a thorough understanding of patient perspectives and preferences if effective implementation strategies are to be designed. As reinforced in this study, smart devices are ubiquitous and patients are interested in using this technology. Findings from this study offer several key takeaway points. First, in this sample of individuals with clinically significant mood and/or anxiety symptoms, most were interested in using mobile apps as part of treatment, but few were doing so. Second, participant interest ratings suggest that provider endorsement may positively influence adoption of these technologies. Third, integration of wearables and passive data to direct interventional content, interventions to improve self-care around sleep and inactivity, and common cognitive-behavioral therapy interventions such as cognitive restructuring and behavioral activation were all perceived as valuable by patients. Finally, messaging around these technologies should increase awareness of mobile apps available for this population, relay what is known around efficacy, and address privacy concerns. One way to disseminate these messages could be through patients' providers, but this would require that providers have easy access to up-to-date information on which apps are efficacious and safe.

Evaluating the generalizability of these findings in a nonveteran sample and determining whether preferences observed here translate to actual behaviors will be critical moving forward. It will also be important to evaluate whether patient interest and concerns are different across various demographic subgroups (eg, gender, race, age, and education) to determine how best to create systems that meet the needs of all segments of the population. Adjusting messaging and implementation strategies in ways that reflect these findings and evaluating patient adoption and engagement are essential next steps. In addition, evaluating whether preferences endorsed translate to preferential use of specific app features in real-world settings could direct attention of app developers toward the features that patients most value.

Acknowledgments

This study was partially supported by funds made available by the VA Office of Academic Affairs. In addition, Allen Labonte assisted with pulling recruitment data from the VA CDW. Finally, the authors acknowledge 1 key study author, JB, who passed away before the completion of this manuscript. He was an esteemed colleague and is sorely missed by the community.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey questions.
[PDF File (Adobe PDF File), 85 KB - mental_v6i1e11334_app1.pdf]

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Abbreviations

CDW: Corporate Data Warehouse
GAD-7: Generalized Anxiety Disorder-7
mHealth: mobile health
PTSD: posttraumatic stress disorder
PCP: primary care provider
PHQ-8: Patient Health Questionnaire-8
VA: Veteran Affairs
VHA: Veterans Health Administration

Edited by C Eichenberg; submitted 18.06.18; peer-reviewed by L Lim, C Fernández, H Baumeister; comments to author 14.07.18; revised version received 21.08.18; accepted 08.09.18; published 25.01.19.

Please cite as:
Lipschitz J, Miller CJ, Hogan TP, Burdick KE, Lippin-Foster R, Simon SR, Burgess J
Adoption of Mobile Apps for Depression and Anxiety: Cross-Sectional Survey Study on Patient Interest and Barriers to Engagement
JMIR Ment Health 2019;6(1):e11334
URL: http://mental.jmir.org/2019/1/e11334/
doi:10.2196/11334
PMID:30681968

Original Paper

Web-Based Measure of Life Events Using Computerized Life Events and Assessment Record (CLEAR): Preliminary Cross-Sectional Study of Reliability, Validity, and Association With Depression

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Abstract

Background: Given the criticisms of life event checklists and the costs associated with interviews, life event research requires a sophisticated but easy-to-use measure for research and clinical practice. Therefore, the Computerized Life Events and Assessment Record (CLEAR), based on the Life Events and Difficulties Schedule (LEDS), was developed.

Objective: The objective of our study was to test CLEAR's reliability, validity, and association with depression.

Methods: CLEAR, the General Health Questionnaire, and the List of Threatening Experiences Questionnaire (LTE-Q) were completed by 328 participants (126 students; 202 matched midlife sample: 127 unaffected controls, 75 recurrent depression cases). Test-retest reliability over 3-4 weeks was examined and validity determined by comparing CLEAR with LEDS and LTE-Q. Both CLEAR and LTE-Q were examined in relation to depression.

Results: CLEAR demonstrated good test-retest reliability for the overall number of life events (0.89) and severe life events (.60). Long-term problems showed similar findings. In terms of validity, CLEAR severe life events had moderate sensitivity (59.1%) and specificity (65.4%) when compared with LEDS. CLEAR demonstrated moderate sensitivity (43.1%) and specificity (78.6%) when compared with LTE-Q. CLEAR severe life events and long-term problems were significantly associated with depression (odds ratio, OR 3.50, 95% CI 2.10 to 5.85, $P<.001$; OR 3.38, 95% CI 2.02 to 5.67, $P<.001$, respectively), whereas LTE-Q events were not (OR 1.06, 95% CI 0.43 to 2.60, $P=.90$).

Conclusions: CLEAR has acceptable reliability and validity and predicts depression. It, therefore, has great potential for effective use in research and clinical practice identifying stress-related factors for the onset and maintenance of depression and related disorders.

(JMIR Ment Health 2019;6(1):e10675) doi:10.2196/10675

KEYWORDS

depression; life change events; life stress; health technology; internet; psychometrics; psychological tests

Introduction

Background

Severe life events and chronic long-term problems are significant factors in the onset and maintenance of depression and various clinical disorders [1-6] and an important focus of etiological research. However, life events research has become overreliant on quick-to-administer self-report checklists, resulting in a loss of specificity and power [7].

Life Event Checklists

Checklist approaches suffer from methodological limitations. The life events involved comprise predetermined event-types to endorse, without personal context, making them reliant on subjective interpretation, with potential for stress-response and stress-outcome confusion [7]. Event dating, severity, and independence are absent, despite being critical for determining their role as "provoking agents" prior to the onset of psychological disorders. Checklist life events lack information on focus and fall prey to "intracategory unreliability," having no definition or benchmark for guidance [8]. Additionally, checklist approaches condense linked events (eg, solely endorsing a birth event, which can include antenatal and postnatal experience).

Life Event Interviews

Life event interviews overcome these methodological constraints and are viewed as more reliable and accurate [9]. The Life Events and Difficulties Schedule (LEDS) [10], often considered the gold standard [11], is a widely used semistructured interview. It captures context and utilizes investigator-based ratings of severity according to precedents to reduce subjective bias [7]. The LEDS is better than self-report measures at capturing life events [12], and its severe life events (those with high negativity after 10-14 days and focused on the self) show superior effect sizes for depression [13]. Those prior to depression onset are given particular attention as provoking agents [14,15].

However, interviews are a high cost in both time and the need for expert administration and lack feasibility for large dispersed samples [16]. Furthermore, where research relies on checklists, in large-scale projects investigating gene-environment interactions, findings are mixed, for example, Culverhouse et al and Risch et al [17,18], with checklists identified as a key factor in nonreplication [19,20].

A New Life Events Measure

The need for a new reliable and valid life stress measure of life events that is less time- and cost-intensive than an interview but improves on checklists, is approached here through technological Web-based advances, which are increasingly popular in researching psychological concepts and disorders [21-23]. The Computerized Life Events and Assessment Record (CLEAR) is a Web-based measure of life events, including severe life events and long-term problems. The design was influenced by the LEDS to capitalize on the many benefits of the interview and improve existing self-report measures [16]. Advantages include using precoded algorithmic scoring [24], lower costs [25], project-personalized presentation [26], and personalized feedback [27]. To date, such digitalized methods have not been applied to the assessment of complex social risk factors such as life events.

This paper aims to assess the psychometric properties of CLEAR. Test-retest reliability was assessed over 4 weeks; concurrent validity was checked against parallel LEDS interviews and a self-report checklist, and predictive validity involved investigating associations between CLEAR severe life events and depression.

Methods

Participants

The sample consisted of 126 students (mean age 20.5 (SD 0.35) years; range 18-46 years) recruited from Middlesex University and 202 midlife adults (mean age 57.6 (SD 7.87) years; range 36-75 years) recruited from the Depression Case Control (DeCC) sample (75 recurrent depression cases and 127 controls). There were more females overall. Due to the prior genetic sampling, the DeCC participants were all white, while the students were more likely to be from ethnic minorities. Most of the DeCC sample had partners and children and were educated to at least a degree level. Few students had children, and over half had partners. The DeCC clinical group had the highest rate of current depression, which significantly differed from the control sample. The student rates proved to be more similar to the clinical group (Table 1).

Reliability Subsample (n=61)

Test-retest reliability of CLEAR was undertaken on a subset of the main sample (20 DeCC depression cases, 21 DeCC control group, and 20 students) measured 3-4 weeks apart.

Validity Subsample (n=30)

A subsample of 30 participants (10 DeCC depression cases, 10 DeCC controls, and 10 students) completed CLEAR and the LEDS interview, with half completing either CLEAR or LEDS first.

Procedure

The DeCC sample was drawn from a UK multicenter case-control genetic association study of unipolar depression in midlife white respondents [28,29]. Depressed patients were originally identified through psychiatric clinics, hospitals, general medical practitioner surgeries, and media advertisements, and had experienced at least 2 episodes of unipolar depression. Matched controls were recruited through general medical practices across the United Kingdom and were excluded if they had a personal or first-degree relative with a history of psychiatric disorder (Korszun et al) [29].

Table 1. Demographic characteristics by group (N=328).

Characteristics	Total DeCC[a] (n=202), n (%)	Controls (n=127), n (%)	Clinical (n=75), n (%)	DeCC comparison χ^2_1	*P* value	Students (n=126), n (%)	DeCC comparison χ^2_2	*P* value
Gender: female	122 (60.4)	70 (55.1)	52 (69.3)	4.0	.05	112 (88.9)	30.8	.001
Ethnicity: white	202 (100.0)	127 (100.0)	75 (100.0)	N/A[b]	N/A	47 (37.3)	162.8	.001
Degree-level education	103 (51.0)	66 (52.0)	37 (49.3)	0.1	.79	13 (10.3)	60.5	.001
In work	125 (61.9)	91 (71.7)	34 (45.3)	13.9	.001	61 (48.4)	5.7	.02
Partnered	167 (82.7)	113 (89.0)	54 (72.0)	9.5	.002	67 (53.2)	33.0	.001
Partner in work	104 (51.5)	68 (53.5)	36 (48.0)	1.2	.27	41 (32.5)	0.2	.70
Has children	164 (81.2)	110 (86.6)	54 (72.0)	6.6	.01	5 (4.0)	185.3	.001
General Health Questionnaire depression	43 (21.3)	10 (7.9)	33 (44.0)	37.5	.001	44 (34.9)	6.8	.01

[a]DeCC: Depression Case Control.

[b]N/A: not applicable.

Participants who gave permission to be recontacted during the original DeCC study were considered eligible for this study. Electoral rolls and social media were searched to obtain participants' current contact details, and death records were checked to remove those deceased.

Invitation letters were sent to 511 depression cases and 587 controls whose addresses were known. The letters, with log-ons and the website address, were sent out in waves of approximately 200 with a follow-up letter or email a week later during February-December 2016. There were 142 returned as not known at that address, and 127 controls and 75 recurrent depression cases were successfully recruited. Assistance with Web-based completion of CLEAR was offered to 4 respondents who needed aid, from a researcher who visited the respondents with a Wi-Fi-enabled laptop. There was no notable difference in the responses from these participants.

The transition to university is associated with a large amount of life change [30], and students have high rates of depression [31]. Therefore, Middlesex University students were also recruited, mainly from first-year undergraduate psychology. The students were sent an email containing a log-on and the website address; 31.0% (126/406) responded from February-October 2016. A further 7 participants were recruited from the psychology department by convenience sampling.

There were 54 participants who started CLEAR but did not complete it. However, this was not considered problematic, as the timing suggests it was owing to difficulties with site loading, which occurred soon after 1 wave of letters was dispatched. This is supported by the fact that noncompleters were equally distributed between the case and control groups. None of the students failed to complete CLEAR, and recruitment procedures were halted during this time.

Ethical approval was granted from Middlesex Psychology Department's Ethics Committee and Integrated Research Application System National Health Service ethics.

Ethical Standards

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

Measures

Computerized Life Events Assessment Record Web-Based System

CLEAR mainly identifies life events and difficulties from the original LEDS interview [10], with updates to include a few new technological events (eg, cyber-fraud) and geopolitical circumstances (eg, asylum experience). It collects quantitative and qualitative data regarding demographics (eg, date of birth, partner status, and employment), information about close others (eg, relationship and frequency of contact), life events, and long-term problems. Additional questionnaires included the List of Threatening Experiences Questionnaire (LTE-Q) and General Health Questionnaire.

Life events and long-term problems are subsumed under 3 overarching groups, each of which is organized into several categories based on the LEDS domains: Lifestyle (education, work, housing, money, crime, and geopolitical events), Health (illness, pregnancy and bereavement), and Relationships (partner, children, and close others). Within each of these 12

categories, a list of potential events are presented, and if selected, the participant can use menus to further refine and add associated contextual information (Spence et al) [16]. The event type and context options are based on the precedent examples outlined in the LEDS manual. Participants are provided with guidance on rating 12-month life events and long-term problems consistent with the LEDS through written and video instruction, examples, and benchmarking. Throughout CLEAR, text fields for open responses and pull-down menus and checkboxes for closed responses are used. Life event short-term and long-term severity are rated from 1: "Extremely: life-changing, catastrophic, traumatic" to 5: "Not at all: no negative implications experienced or expected." Focus describes who or what the event is focused on and is categorized as 1: "Self", 2: "Joint", 3: "Other," or 4: "Possession." Severe events are those rated ≥3 and are focused on the respondent either jointly (respondent and someone close) or alone (ie, rated 1 or 2). For all events, characteristics such as loss and danger are rated. A personalized feedback report is provided on life events and symptoms on completion.

The List of Threatening Experiences Questionnaire

The LTE-Q [32] is a self-report questionnaire comprising a list of 21 potentially significant life events to self or those they consider close (eg, family members) . This has been validated against the LEDS and used extensively, including with the DeCC sample previously [33]. It yields a score of the number of severe life events in the past 12 months.

The Life Events and Difficulties Interview

The LEDS [10] is an investigator-led semistructured interview of life events and difficulties. It includes extensive demographic information and covers 10 life event domains: education, work, fertility, crime, housing, money, health, other relationships, partner, and miscellaneous (including death, geopolitical events, etc). Information is collected on the event timing, surrounding context, the focus of the event (ie, who the event mainly affected), and other factors. Life event severity is rated on a 5-point scale (1 "marked"' to 5 "not at all") with higher points (1-3) required for a severe life event definition. The original scale was 4-point but supplemented by an additional scale of "a=upper" or "b=lower" for those rated "moderate" severity. These were subsumed into the adapted scale. Severe life events also require the *focus* of the event to include the "self," either solely or "jointly" with another close person.

Difficulties (renamed Long-term Problems on CLEAR) were chronic stressors identified in main categories (eg, health, education) and rated on a 1-4 scale with severe difficulty (1=high marked, 2=low marked, and 3=upper moderate) and nonsevere (4=lower moderate). The interviews were conducted by RS or LK, and all LEDS interview ratings were checked by 1 of the original authors of the LEDS manuals (AB) blind to the study group and depression status, with queries reconciled at a consensus meeting of the 3 trained raters.

The General Health Questionnaire

The 12-item General Health Questionnaire [34] is a self-report symptoms questionnaire for depression that includes 6 positively worded and 6 negatively worded items rated along a 4-point Likert scale. Each question is dichotomized, with items denoting a greater frequency of symptoms (eg, "more so than usual" scored 1, and lower frequency ratings, eg, "much less than usual" scored "0"). A score of 5 or more was taken to indicate a likely clinical case of depression [35]. The date of onset and peak symptoms was ascertained.

Data Analysis

CLEAR data were downloaded from MySQL and transformed into derived variables using Python programming language. The data were transferred into SPSS for statistical analyses. Group differences were assessed using chi-square analysis. Mann-Whitney U tests were used when the data were skewed.

Guidelines for reporting reliability and agreement studies [36] were followed. Cohen's kappa (K) for dichotomous variables or intraclass correlation coefficients (ICCs) were used to assess the association over repeat testing and interview-CLEAR association, with the interpretation of the level of association guided by Cohen's accepted levels [37]. Analyses focused on severe life events and long-term problems, as these are most pertinent to clinical and research use.

The sensitivity (true positive) and specificity (true negative) of CLEAR in comparison with LEDS was calculated for severe life events. Sensitivity reflects the ability of a test to correctly classify when the property of interest is present (true positive), whereas specificity indicates the ability of a test to correctly classify when it is absent (true negative). Logistic regression was used to examine severe life events in relation to depression.

Results

Prevalence of Life Events

In the sample as a whole, the average rate of CLEAR life events was 2.28 (SD 2.37, range 0-8), with 41.5% (136/328) of the sample having at least 1 severe life event (Table 2). For long-term problems, the average was 1.28 (SD 1.99, range 0-19), with 49.7% (163/328) of the sample having at least 1 long-term problem, and 32.0% (105/328) having at least 1 severe long-term problem. Table 2 shows comparisons between the subgroups. The clinical group had significantly more severe life events, long-term problems, and severe long-term problems. The students had significantly fewer life events, long-term problems, and severe long-term problems than the DeCC group. The 2 DeCC groups did not have significantly different LTE-Q scores, but students reported significantly more LTE-Q events.

Test-Retest Reliability

In total, 173 life events were reported; 53 events were rated as severe at either 1 or both time-points, and 15% (9/61) individuals reported no events at either time-point. There was good test-retest agreement for severe life events (85.4%, K=.60, 95% CI 0.40 to 0.81; P<.001). The reliability of severe life event characteristics reported using CLEAR is shown in Table 3.

The association between the overall number of events at both time-points was good for CLEAR (ICC=.89, 95% CI 0.82 to 0.94); however, this did vary by domain, ranging from.93 (partner) to.28 (money). The association was moderate at retest for the LTE-Q (ICC=.75, 95% CI 0.56 to 0.86) with ICCs

ranging from.85 (separated from partner) to.17 (Burglary or mugged).

There were 94 long-term problems reported, and 22/61 (36%) participants reported no long-term problem at either time-point.

The agreement for severe long-term problems was modest (K=.38, 95% CI 0.21 to 0.55; *P*<.001). Table 3 shows associations for characteristics of severe long-term problems at both time-points.

Table 2. Life event and long-term problem frequency by group (N=328).

Life events and long-term problem	Total DeCC[a] (n=202), mean (SD); range	Controls (n=127), mean (SD); range	Clinical (n=75), mean (SD); range	Mann-Whitney U Test	*P* value	Students (n=126), mean (SD); range	Mann-Whitney U Test	*P* value
Life events	2.41 (2.28); 0-11	2.11 (1.88); 0-10	2.91 (2.77); 0-11	1.70	.09	2.08 (2.50); 0-12	1.97	.049
Severe life events	0.78 (1.28); 0-8	0.50 (0.82); 0-3	1.25 (1.73); 0-8	3.38	.001	0.75 (1.14); 0-6	−0.01	.99
Long-term problems	1.57 (2.24); 0-19	1.01 (1.43); 0-7	2.53 (2.94); 0-19	4.82	.001	0.80 (1.40); 0-7	3.89	.001
Severe long-term problems	0.75 (1.31); 0-7	0.37 (0.70); 0-3	1.39 (1.79); 0-7	4.82	.001	0.42 (0.96); 0-5	2.76	.01
List of Threatening Experiences Questionnaire events	3.83 (3.18); 0-15	3.38 (2.67); 0-13	4.59 (3.80); 0-15	1.88	.06	5.07 (3.01); 0-16	−4.17	.001

[a]DeCC: Depression Case Control.

Table 3. Test-retest reliability of severe life events and long-term problems' attributes.

Attributes	Intraclass correlation coefficient	*P* value
Severe life event attribute		
Category	.91	.001
Focus (1-4)[a]	.64	.01
Short-term threat (1-5)	.42	.09
Long-term threat (1-5)	.63	.01
Long-term problem attribute		
Category	.97	.001
Who involved	.65	.002
Severity now (1-4)	.70	.001
Severity worst (1-4)	.62	.01

[a]Focus describes who or what the event is focused on and is categorized as 1: "Self", 2: "Joint", 3: "Other," or 4: "Possession."

Concurrent Validity of Computerized Life Events and Assessment Record and Life Events and Difficulties Schedule

Across CLEAR and LEDS, 184 life events were reported, of which 72 were rated severe on 1 or both measures. Owing to missing data, analyses could only be conducted for the events recorded by both measures (48/184, 26.1% of all events). The level of agreement for severe life events was fair but not significant (K=.25, 95% CI −0.02 to 0.52, *P*=.09). Both specificity and sensitivity for severe events were moderate (65.4%, 95% CI 44.3 to 82.8 and 59.1%, 95% CI 36.4 to 79.3, respectively). The characteristics of events were examined across LEDS and CLEAR (Table 4).

There were 88 long-term problems recorded, 47 severe ratings were given, and 4/30 (13%) respondents reported no long-term problems on either measure. As with the events, only the minority of long-term problems were captured by both methods (21/88, 24%), and therefore, owing to missing data, analyses could only be performed on these. The agreement for severe long-term problems was moderate (K=.43, 95% CI 0.05 to 0.81, *P*=.04), but the sensitivity (66.7%, 95% CI 34.9 to 90.1) and specificity (77.8%, 95% CI 40.0 to 97.2) were good.

Concurrent Validity of List of Threatening Experiences Questionnaire and Computerized Life Events and Assessment Record

Severe life events on CLEAR and LTE-Q were compared for the total sample of 328. There was poor agreement (K=.06, 95% CI 0.01 to 0.11, *P*=.03) owing to many more events being identified only by the LTE-Q (n=170, 52%). Sensitivity was 43.1% (95% CI 37.5 to 48.9) and specificity was 78.6% (95% CI 59.1 to 91.7).

Relationship Between Computerized Life Events and Assessment Record, Severe Life Events, and Depression

The presence of at least 1 severe life event in CLEAR related to depression: 41.4% (55/133) of those with a severe life event were depressed versus 16.8% (32/191) of those with no severe life events (odds ratio, OR 3.50, 95% CI 2.10 to 5.85; *P*<.001). This held in the DeCC clinical group (OR 3.45, 95% CI 1.30 to 9.15, *P*=.01) and the student group (OR 3.62, 95% CI 1.68 to 7.80; *P*<.001) but not the DeCC control group (OR 2.11, 95% CI 0.58 to 7.73, *P*=.26), where both severe life events and depression were at a low rate. The majority of domains with 10 or more severe life events also significantly predicted depression (Table 5).

Table 4. Concurrent validity; Life Events and Difficulties Schedule Interview versus Computerized Life Events and Assessment Record characteristics of events (N=48).

Variable	Intraclass correlation coefficient	*P* value
Category	.85	.001
Focus	.91	.001
Short-term severity (1-5)[a]	.52	.01
Long-term severity (1-5)[a]	.49	.01

[a]Life event short-term and long-term severity are rated from 1: "Extremely: life-changing, catastrophic, traumatic" to 5: "Not at all: no negative implications experienced or expected."

Table 5. Computerized Life Events and Assessment Record Severe Life Events by category and General Health Questionnaire depression.

Computerized Life Events and Assessment Record event category	Severe life event, n/N (%) depressed	No severe life event, n/N (%) depressed	Odds ratio (95% CI)	*P* value
Education	19/33 (57.5)	68/291 (23.4)	4.45 (2.12-9.35)	.001
Work	17/36 (47.2)	70/288 (24.3)	2.79 (1.37-5.65)	.01
Housing	6/10 (60.0)	81/314 (25.8)	4.32 (1.19-15.68)	.03
Money	8/17 (47.1)	79/307 (25.7)	2.57 (0.96-6.88)	.06
Health or death	27/66 (40.9)	60/258 (23.3)	2.29 (1.29-4.04)	.004
Partner	7/16 (43.7)	80/308 (26.0)	2.22 (0.80-6.15)	.13
Other relative	9/16 (56.2)	78/308 (25.3)	3.79 (1.37-10.52)	.01

The presence of a provoking agent was examined in relation to the onset of depression. This required the selection of the severe life event immediately prior to the onset of disorder or severe life event closest to the point of CLEAR completion for those not depressed. This excluded severe events during or after the depression. This showed that 36.1% (44/122) of those with a provoking agent had depression vs 21.3% (43/202) with no provoking agent (OR 2.09, 95% CI 1.27 to 3.44, *P*=.004).

The presence of a severe long-term problem was similarly related to depression, with 44.1% (45/102) with a severe long-term problem reporting depression versus 18.9% (42/222) without a severe long-term problem (OR 3.38, 95% CI 2.02 to 5.67; *P*<.001). This relationship held in the DeCC clinical group (OR 4.0, 95% CI 1.48 to 10.80, *P*=.01) and the student group (OR 3.67, 95% CI 1.55 to 8.70, *P*=.003) but was nonsignificant in the DeCC control group (OR 1.98, 95% CI 0.52 to 7.5, *P*=.32).

When LTE-Q events were grouped by category, none were statistically related to depression (Health OR 1.39, *P*=.29; Work OR 1.35, *P*=.29; Crime OR 1.26, *P*=.40; Fertility OR 1.62, *P*=.09; Housing OR 1.42, *P*=.17). The presence of any 1 severe life event similarly did not relate to depression: 27.0% (80/296) of participants with an LTE-Q event versus 25.9% (7/27) without an LTE-Q event were depressed (OR 1.06, 95% CI 0.43 to 2.60, *P*=.90). However, there was a modest association between LTE-Q score and General Health Questionnaire symptom score (r=0.19; *P*<.001).

Discussion

Summary of Results

The results demonstrated that CLEAR significantly predicted depression and was superior to a commonly used checklist approach. The test-retest reliability was good for severe life events and their characteristics, although agreement missed the significance for short-term threat ratings. Reliability was fair for severe long-term problems and good for their characteristics. In comparisons with the LTE-Q, CLEAR performed better.

Although the average rate of life events found by CLEAR was similar to previously reported interview [10] and self-report [12] rates, CLEAR missed the majority of life events and long-term problems rated by LEDS. However, it is likely this is because the LEDS records many more nonsevere events; in the validity sample, 26.9% of LEDS events were severe, compared with 46.2% of CLEAR events. Additionally, the LEDS events could often be trivial in nature (eg, "*husband started TEFL course*," "*end of moduleexams*"). Furthermore, each LEDS event was rated separately, for example, "*job*

interview" and "*starts new job"* would be recorded as 2 events, whereas in CLEAR, these were likely collapsed into 1. Perhaps discrepancies could be reduced by having more active rather than passive prompts for events throughout CLEAR.

Nevertheless, for the events that were captured, the results were promising. The specificity and sensitivity for severe events were moderate, and the event characteristics had fair to very good associations. Severe long-term problems also had a moderate agreement, sensitivity, and specificity. Crucially, predictive validity showed a high association between CLEAR severe life events and depression, including those prior to onset, consistent with prior research [4,38] and superior to the checklist findings.

Implications

The issue of a lower event and long-term problem identification in CLEAR when compared with LEDS needs to be considered in relation to its potential usefulness. Where event totals are the key element, the method would miss many potential events, although still have more potential coverage than checklist approaches. However, for clinical purposes, CLEAR's more robust inclusion of severe events and the significant associations with depression indicate greater utility than self-report checklists. The tool could aid with the routine assessment of stressors where these relate to disorder or treatment outcomes. For instance, identifying key provoking agents in emotional or trauma-related disorders to be linked with cognitive behavioral therapy treatment or identifying the number and range of severe stressors relevant for lifestyle risks in health settings such as antenatal care or diabetes treatment. Indeed, CLEAR can be personalized with different outcome measures and respondent feedback, making it a flexible measurement tool.

Limitations

Nonetheless, there are limitations to this study. The sample was skewed by age and gender and is not representative. The actual response rate was not calculated owing to the lack of information on the accuracy of the DeCC sample contact details, and a proportion did not complete CLEAR. The self-report symptom scale is only a proxy measure of clinical depression. Finally, the validity subsample was rather small and proved insufficient for comprehensive validation of long-term problems.

Strengths

Despite this, CLEAR is a promising tool for assessing life stress in large, nationally distributed samples including gene-environment research, which requires large numbers. Here self-report measures have been found to be less effective [13] and face-to-face interviews impractical. CLEAR is quick and cheap to administer, and the reliability and validity were shown to be good for depression-related events (those severe and focused on the individual). Moreover, the automated coding to provide prederived SPSS variables enables future ease of data analysis. The measure is likely to be effective for the large-scale study of depression and other disorders involving severe life events.

Conclusions

The study indicates success in producing a more sophisticated measure of socioenvironmental stressors with the use of new technologies. CLEAR is a viable option for clinical or research services wanting to provide more exact predictions of risk to help prevent and treat disorders.

Acknowledgments

This project was funded by the Economic and Social Research Council (grant number ES/K00638X/1). HLF was supported by an MQ: Transforming Mental Health Fellows award (MQ14F40).

Conflicts of Interest

None declared.

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Abbreviations

CLEAR: Computerized Life Events and Assessment Record
DeCC: Depression Case Control
ICC: intraclass correlation coefficient
LEDS: Life Events and Difficulties Schedule
LTE-Q: List of Threatening Experiences Questionnaire
OR: odds ratio

Edited by J Torous; submitted 03.04.18; peer-reviewed by S Monroe, M Cernvall, E Toki; comments to author 01.06.18; revised version received 11.07.18; accepted 26.07.18; published 08.01.19.

Please cite as:
Bifulco A, Spence R, Nunn S, Kagan L, Bailey-Rodriguez D, Hosang GM, Taylor M, Fisher HL
Web-Based Measure of Life Events Using Computerized Life Events and Assessment Record (CLEAR): Preliminary Cross-Sectional Study of Reliability, Validity, and Association With Depression
JMIR Ment Health 2019;6(1):e10675
URL: https://mental.jmir.org/2019/1/e10675/
doi:10.2196/10675
PMID:30622088

Review

Internet-Based Interventions for Problem Gambling: Scoping Review

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Abstract

Background: This study seeks to give an overview of academic research on internet-based interventions that are used to address problem gambling. The rate of treatment seeking has been demonstrated to be low across several research environments. This is in part because of the systemic barriers that treatment seekers face to accessing traditional face-to-face treatment. Making treatment resources for problem gambling available through the internet is one way to reduce the impact of those systemic barriers. The use of internet-based resources to address problem gambling has been growing, and a field of research evaluating it has developed as well. However, little has been done to summarize this collection of research.

Objective: This study aimed to provide a scoping review of the use of internet-based interventions for problem gambling treatment and prevention to provide an understanding of the current state of the field.

Methods: A scoping review was performed for 6 peer-reviewed research databases (Web of Science, PsycINFO, Cumulative Index to Nursing and Allied Health Literature, MEDLINE, Social Science Abstracts, and Scopus) and 3 gray literature databases (MedEdPortal, Proquest: Dissertations, and OpenGrey). Article inclusion criteria were as follows: published over the 10-year period of 2007 to 2017, including an intervention for problem gambling, and involving the use of internet to deliver that intervention.

Results: A total of 27 articles were found that met the review criteria. Studies were found from several different areas, with particularly strong representation for Australia, New Zealand, and Scandinavia. Cognitive behavioral therapy was the most common form of internet-based intervention. Internet-based interventions were generally shown to be effective in reducing problem gambling scores and gambling behaviors. A wide range of interventions that made use of internet resources included text-based interactions with counselors and peers, automated personalized and normative feedback on gambling behaviors, and interactive cognitive behavioral therapies. A lack of diversity in samples, little comparison with face-to-face interventions, and issues of changes in the treatment dynamic are identified as areas that require further investigation.

Conclusions: Internet-based interventions are a promising direction for treatment and prevention of problem gambling, particularly in reducing barriers to accessing professional help. The state of the current literature is sparse, and more research is needed for directly comparing internet-based interventions and their traditional counterparts.

(JMIR Ment Health 2019;6(1):e65) doi:10.2196/mental.9419

KEYWORDS

problem gambling; treatment; intervention

Introduction

Background

Problem gambling can lead to serious consequences at the individual and societal levels. To limit the negative impact of problem gambling, a wide range of problem gambling interventions have been developed, although the uptake of problem gambling treatment lags behind those for substance use problems such as tobacco cessation programs [1]. Only a small proportion of those experiencing problem gambling seek professional help [2]. For example, a representative survey of Ontario residents found that only 6% of those identified as having a possible gambling problem at some point in their lives sought some kind of treatment [3]. A possible explanation for the low rates of treatment seeking is that there are several barriers that discourage those experiencing gambling-related harm from seeking professional help. In a review of the literature on treatment seeking among problem gamblers, Suurvali et al [2] found that such barriers included gamblers' desires to handle their problems on their own, wanting to avoid the stress or stigma of being identified as a problem gambler, and practical issues surrounding treatment such as accessing treatment facilities.

One solution that has been offered to address these barriers is to increase the availability of gambling treatment options using new information technologies, interventions delivered over the internet in particular [1]. Offering treatment options over the internet can reduce barriers that potential treatment seekers may face in several ways. First, treatment options over the internet offer greater anonymity, which can help reduce the barriers associated with the stigma of treatment seeking [4]. In addition to encouraging treatment seeking, anonymity may also encourage more openness and honesty through the treatment process [5]. Treatment options delivered over the internet can also help treatment seekers overcome practical barriers associated with more traditional methods of treatment. Such barriers include, but are not limited to, distance to treatment facilities, conflicts between treatment availability and other constraints on time such as child care or paid work, cost of transportation to treatment facilities, and treatment relevant to cultural or language needs [2].

There have been several reviews of the current evidence of using internet-based resources to offer interventions in addressing problem gambling [6]. Giroux et al [7] conducted a review of the efficacy of interventions for problem alcohol use, problem substance use, and problem gambling delivered entirely through online environments. Their review found that for alcohol- and substance-focused interventions, online environments offered a great opportunity to deliver interventions that were largely similar in content and theory to those delivered through more traditional means, with the added benefit of increasing access for those that might not otherwise seek treatment. The current efficacy research shows good short-term benefits for internet-delivered interventions, although more research on long-term outcomes is needed. However, the exclusion criteria used meant no studies on gambling were included largely because of inconsistent evaluation of intervention efficacy, a focus on prevention measures and nonproblem gambling samples, and a mix of online and in-person treatment programs [7]. The paucity of research on online interventions on gambling was also identified in a review of tobacco smoking, alcohol, and gambling interventions performed by Danielsson et al [8]. However, these reviews were not focused solely on gambling and included a narrow range of study designs such as structured therapeutic interventions [6,7] or control trials [8] or failed to find gambling studies that met inclusion criteria [7]. There have also been reviews of such evidence related to other problem behaviors [9,10]. As found in a review by Barak et al, internet-based psychotherapeutic interventions show similar effect sizes (weighted mean 0.53) compared with face-to-face therapies. Their review also showed that across 14 studies, the weighted effect sizes of internet-based therapies versus face-to-face therapies were not statistically significant.

Objective

Although delivering interventions for problem gambling over the internet has been suggested to address some of the barriers to seeking treatment for problem gambling, and several studies have shown that internet-based interventions have been shown to be effective, there is still relatively little research on the topic. The purpose of this scoping review is to provide an overview of research on problem gambling interventions that are made available through internet (hereafter referred to as internet-based interventions). Such interventions include one-on-one counseling with a mental health professional (video or voice-only conferencing, live chat, and email contact), self-help tools, peer-to-peer support, and educational tools. This scoping review was conducted to inform the development of a provincial online problem gambling treatment resource. In particular, the information provided by this review will help direct the range of interventions to implement and identify gaps in the literature for the program to contribute to the growing knowledge base surrounding the use of internet-based interventions for problem gambling. To inform this project, it is necessary to map the current literature to identify the range of interventions being offered through internet-based resources and to identify gaps in our knowledge surrounding these types of interventions. The research question was, "How are internet-based resources being used to deliver problem gambling interventions?" This review provides information on the different types of interventions that are available, the types of populations that have been exposed to these interventions, and identifies the gaps in the knowledge surrounding internet-based interventions. This review contributes to the dissemination of current knowledge on internet-based interventions and identifies possible areas for future research, given our current understandings of the potential of such intervention strategies.

Methods

Definitions

The structure of this scoping review is based on the methodology laid out by Arksey and O'Malley [11]. Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines for reporting results of literature reviews were also consulted [12]. When conceptualizing internet-based interventions, we defined such interventions as *any prevention or treatment program designed to reduce the harm of problem gambling that makes use of internet resources to deliver content or resources*. Interventions using mobile apps or mobile devices were excluded in this review.

Search Strategy

Peer-reviewed journal articles were collected primarily through a search of 6 research databases: Web of Science, PsycINFO, Cumulative Index to Nursing and Allied Health Literature, MEDLINE, Social Science Abstracts, and Scopus. The gray literature was searched through the following databases: MedEdPortal, Proquest: dissertations, and OpenGrey. The following search string (modified to reflect the search logic of each database) was used to locate studies relevant to the research question: (problem* OR Patholog* OR Compuls* OR addict* OR disorder*) (adjacent within 3 words of gambl*) AND (online OR web OR internet OR internet-based OR app OR apps OR application* OR tablet* OR ipad) (adjacent within 3 words of) (therap* OR intervention* OR psychiatr* OR counsel* OR treatment*) OR (e-therap* OR etherap* OR ecounsel* OR e-counsel* OR cybercounsel* OR cyber-counsel* OR cybertherap* OR cyber-therap* OR teletherap* OR telecounsel* OR telepsychiatr*). Individual search outputs can be found in Multimedia Appendix 1. Studies were to be published between 2007 and 2017. The search strategy was designed in consultation with a team of experts in the fields of problem gambling research and treatment and with consultation with library services at the Centre for Addiction and Mental Health. Hand searches of journals especially those relevant to the field were performed. Finally, consultation with a team of experts on the research and treatment of problem gambling was performed to add articles that may have been missed using the above methods. The initial search strategy produced 610 articles. Overall, 211 articles remained after removing duplicates. The remaining article abstracts were reviewed for relevancy to the topic and to remove any publications that did not contain original research including reviews and protocol papers, leaving 41 publications. A final review of the full texts of the publications removed another 14 articles based on a lack of original research or irrelevancy to the topic, leaving a final collection of 27 articles. The process is displayed below in Figure 1.

Study Selection, Inclusion, and Exclusion Criteria

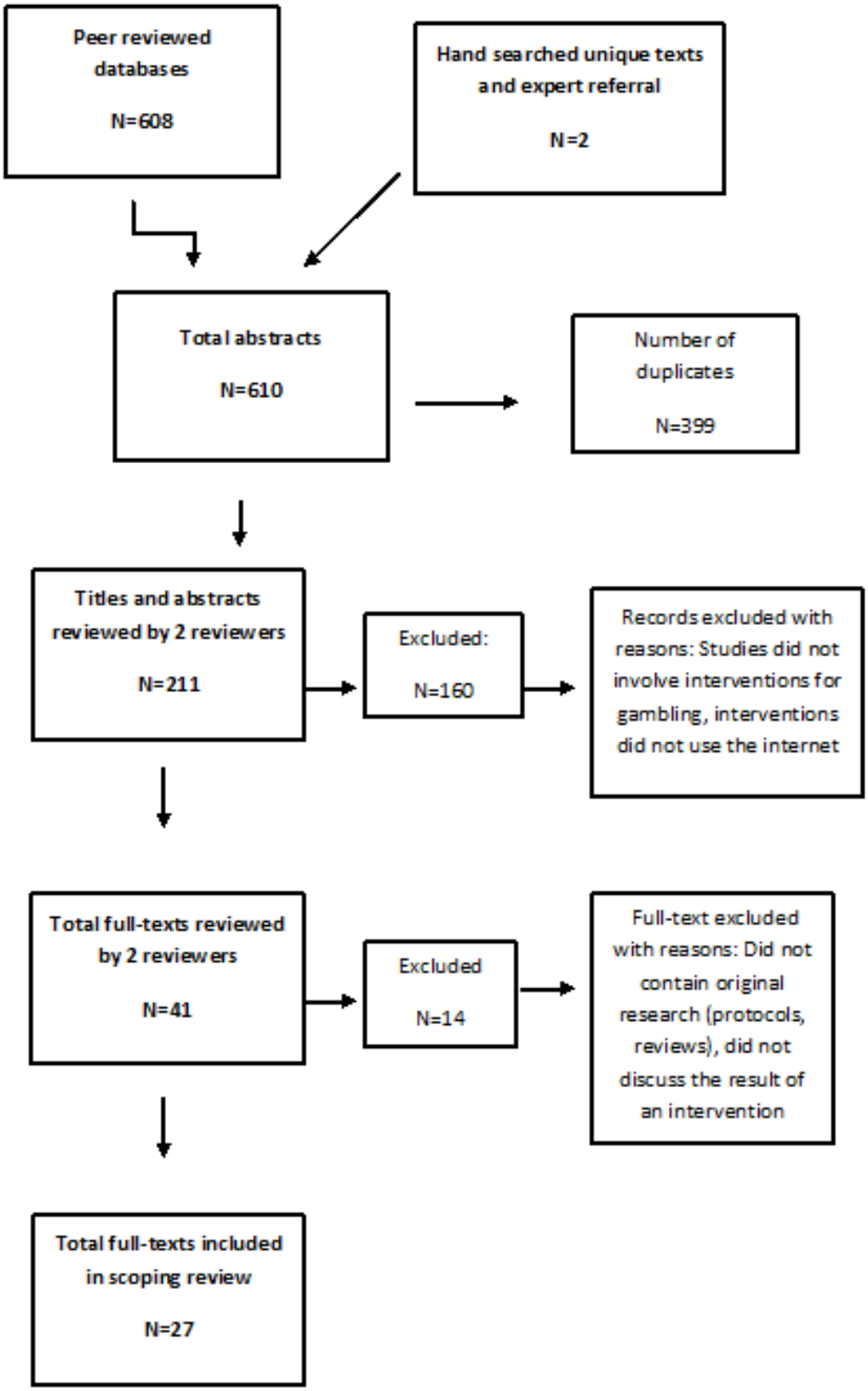
Studies were selected for the review if they involved a primary analysis of any type of problem gambling intervention through internet or in online environments. Articles were included in this review if they involved problem gambling interventions or if they involved interventions for other substances or problem behaviors in addition to problem gambling. Such interventions included treatment, prevention, education, and early intervention. Likewise, studies were included if they involved interventions delivered solely in an online environment or if they were delivered through other media in addition to the internet.

Studies were excluded if they did not involve original research (eg, literature reviews, systematic reviews, and study protocols) and did not include information on internet-based interventions. Overall, 2 independent reviewers (1 postdoctoral fellow and 1 graduate student) reviewed all abstracts selected by the database queries. The inter-rater reliability for abstract screening was 82.5%. In cases of disagreement, a third reviewer with expertise in the field was consulted and made the final decision on inclusion. The second stage involved a review of the full-text versions of the selected articles by both reviewers. The inter-rater reliability for full-text screening was 100%.

Data Extraction

The information from the final articles was extracted into a table that included the study aims, study sample, study and intervention design, and the central results of the study. The results of this extraction process were then synthesized and interpreted in consultation with a team of experts in the field of problem gambling treatment in Canada.

Figure 1. Study selection process.



Results

Location

Multimedia Appendix 2 provides descriptions of the selected articles. Many of the studies involved gambling help websites that were available over the internet and as such could have been accessed by anyone with an internet connection. Due to this lack of a physical geographical location, each study will be defined as the country from which the internet-based interventions were delivered. There was a strong representation of research from Australia and New Zealand, with 7 articles examining online-delivered problem gambling interventions [13-20]. The majority of these studies were analyses of the interventions offered through *Gambling Help Online* [15-19,21]. This site has been in operation since 2009 and provides 24-hour chat and email counseling and support services, access to professional counselors, access to face-to-face or telephone counseling, and a variety of self-help resources. Several studies were also based in Europe, the majority in Scandinavian countries (namely Norway [22], Finland [23,24], and Sweden [25,26]), although there were also studies conducted in France [27], Italy [28], Germany [29], and the United Kingdom [30]. Several studies have been conducted in Canada and the United States. Ontario was the sole province included in the results [31-33], 2 American studies involved college counseling websites across America [34,35], 1 study involved participants from Nevada and Massachusetts [36], and 1 study involved undergraduate students in Oklahoma [36]. Overall, 1 study involved an international comparison of problem gambling resources available on college and university counseling websites in the United Kingdom and the United States [34].

Sample Populations

There was relatively little range in the sample characteristics found in the studies. Many of the studies drew their samples from clients of existing gambling help websites [13-19,20-24,37]. For these studies, participants accessed the internet-based inventions voluntarily and gave consent for their information to be used for research purposes. Media advertising was also used by several studies [20,25,26,31], and 1 study surveyed grade 9 students from a single high school in Italy [28].

Most of the studies had samples with more males than females ranging from 50.6% [19] to 90.4% [30]. Overall, 2 studies used exclusively female samples [24,31]. There was also a single case study involving a woman aged 31 years [13]. Studies tended to focus on adult samples (>18 years), ranging in mean ages of 31.9 [26] to 56 [31]. Overall, 1 study included minors in its sample of grade 9 high school students [28]. The majority of studies did not explore differences in terms of cultural backgrounds. However, 1 study did explore Asian self-identification as a factor impacting concerned significant others of problem gamblers [14].

Samples of help seekers were common in the selected studies being the focus of 12 of the included studies [13,15-19,20-24,37]. As a result of recruiting participants directly from those seeking information or help problem gambling, the studies tended to have high proportions of problem or pathological gamblers ranging from 60.6% [32] to 100% [16,20] in those studies where a gambling screen was applied.

Use of Technology

Several types of internet-based technologies were employed in the selected studies. The most common form of technology used was email contact. This was found in 10 of the selected studies [18,25-28,32,33,36-38]. Email was commonly used for feedback that did not need to be communicated in real time. This included feedback on work completed through a therapy program [25,26,28], normative or personalized feedback on gambling behaviors [32,33,36,38], and therapist contact [18,37]. Text communication was also common in real-time chat apps [14,15,18,19,21,24,31,37] and moderated discussion boards [22,23,24,26,31]. Electronic versions of digital workbooks for therapy programs were common, particularly in studies that used cognitive behavioral therapy (CBT) or Motivational Interviewing (MI) [20,22,23,25,26,27,28,31]. Other uses of internet-based resources included voice and video chat [13,31,37], pop-up messages [29], monitoring and screening services [16,38], and Web-based educational resources [34,35].

Study Design

The goal of 2 studies was to give a profile of the consumers accessing internet-based interventions for problem gambling. Statistical analyses of those accessing online problem gambling websites were common for these studies. These studies provided descriptive profiles of users [32] and gender comparisons in the types of online resources accessed [18].

Several studies involved longitudinal designs that compared pre-and postintervention score on a variety of measures. Overall, 6 studies employed a randomized controlled trial (RCT) to test the effectiveness of internet-based interventions [20,26-28]. In each case, the comparison was made between the use of internet-based interventions versus no intervention in the control group. Overall, 1 study included another comparison treatment group including internet delivered CBT, internet delivered Monitoring Feedback and Support therapy, and a waiting list control [20]. Overall, 5 other studies employed pre/postintervention designs but without control groups [33]. Follow-up points for all studies involving pre-and postintervention assessments ranged from 1 week to 4 years with 3 to 6 months being the most common.

Overall, 8 studies employed qualitative analysis to explore the use of online resources [13,15-17,19,21,24,37]. Overall, 2 studies conducted analyses of online chat sessions or discussion boards on gambling help websites [15,24]. Other qualitative studies included typed responses to open-ended surveys delivered online, [19] and a case report of a 31-year-old woman's experience with internet-based exposure therapy [13].

In terms of assessment and data collection, most studies used only online resources to collect information. Overall, 3 studies had some degree of face-to-face contact in addition to online resources. In addition, 1 study [13] used face-to-face assessment of gambling problems, whereas 2 studies [31,37] made at least some portion of their assessment of problem gambling over phone. For all other studies, problem gambling was assessed

using online resources. Moreover, 1 study compared results from an open-label parallel-group trial with random assignment with the results of an earlier study with parallel therapy design delivered through face-to-face contact [20].

Numerous screens were employed to identify problem gambling. Specific problem gambling screens included the Problem Gambling Severity Index (PGSI) [16,17,21,27,31-33], Gambling Attitudes Scale [28], South Oakes Gambling Screen (SOGS) [13,20], SOGS-R (revised) [22], and SOGS-RA (revised adolescent) [28], and the National Opinion Research Center DSM Screen for Gambling Problems (NODS) [23,25,26]. Scales related to gambling behavior included Problem Gambling Significant Other Impact Scale (PG-SOIS) [14], Gambling Urges Scale [20], Gambling Refusal Self-Efficacy Scale [20], Gambling Symptom Assessment Scale [20], and the Diagnostic and Statistical Manual for Mental Disorders criteria for pathological gambling (DSM IV [31] and DSM V [20]). Of these scales, PGSI and NODS were the most commonly used scales. There were also other gambling-related assessments made including time and money spent on gambling, faulty cognitions, and types of gambling.

Several studies also included measures of mental health issues that are often found to be comorbid with problem gambling. These included the following: Work and Social Adjustment [13]; Beck Depression Inventory [13]; Beck Anxiety Inventory [13]; Perceived Stress Scale [31]; Depression, Anxiety and Stress Scale [20,31]; Alcohol Use Disorders Identification Test [20,23,25,26]; Montgomery-Åsberg Depression Rating Scale [23,25,26]; Hospital Anxiety and Depression Scale [23,25,26]; Quality of Life Inventory [11,20,22-26]; Satisfaction with Life Questionnaire [20]; and The Positive and Negative Affect Schedule [17].

Types of Interventions

Several types of interventions were delivered through online resources. The most common form of intervention found was one-on-one counseling with a trained therapist [13,14,15,16,17,18,26]. These sessions were performed using a variety of methods including videoconferencing, telephone, email, and chat. Typed communications were also used in the included studies. Several studies analyzed the transcripts from chat sessions between consumers and mental health professionals on gambling help websites [14,15,17,18]. These single chat sessions were often on a nonappointment basis, and were frequently accessed by first time help seekers. For example, 1 study [15] found that 62.4% of chat session users were new to counseling. In addition to counseling targeting potential problem gamblers, 1 study focused on internet-delivered counseling for concerned significant others and explored the use of a new assessment scale for the concerned significant others of problem gamblers (PG-SOIS) [14].

CBT and other work assignment based therapies were commonly used in the included studies [20,23,26-28,31,39]. CBT programs ranged from 3 weeks [28] to 3 months [22,31]. Weekly feedback was provided to clients and took the form of either telephone or voice-only contact with a counselor or therapist or in the form of weekly email contact. Assignments and workbooks were made available through online communication.

Several studies explored the use of the internet to host a group discussion with multiple clients and mental health professionals [24,25,31,40]. The group discussion either took place in online chat spaces with simultaneous use by several clients, by mental health professional–moderated discussion boards [24], or by the use of webinars with a mental health professional facilitator [31]. These group discussions were often used in conjunction with CBT.

Although the majority of studies focused on treatment-based interventions, there were several studies that focused on prevention and early intervention strategies. These included pop-up messages [29], online responsible gambling tools [30,32,36,37,38], and problem gambling education materials [34,35].

Some forms of interventions were less common among the included studies. Overall, 1 study tested the effectiveness of a normative feedback generated based on a short survey of gambling-related activities and demographic information [29,32,33]. The goal of this intervention is to compare the participants' gambling activities with those of similar backgrounds to motivate treatment seeking or re-education about gambling involvement. Another research team looked at the availability of gambling relevant information on college counseling websites rather than the effectiveness of interventions [22,35] and a single study used exposure therapy [13].

Several studies examined the use of the internet to deliver information-based interventions to gambling participants through the use of personalized or personalized normative feedback [27,28,29,32,33,36]. For these interventions, the data tracking possibilities offered through online gambling website allows the flagging of problem behaviors and/or delivery of targeted information related to one's own gambling in comparison with others. This is a more efficient manner of identifying possible problem behavior than relying on help seeking or identification of problem behaviors by gambling venue staff.

Central Findings

The majority of studies with treatment designs noted significant improvements in problem gambling over time using a variety of measures. Of the 7 RCT design studies, 5 found significant improvement from the internet-based intervention group over controls (no treatment in all cases) [20,24,26,28]. In addition to problem gambling improvement (based on problem gambling scores), these studies also found improvements in gambling behaviors, anxiety, and depression [26]. Significant improvements in problem gambling, gambling frequency [23,25], faulty cognitions surrounding gambling [22], alcohol consumption [23], and distress [17,22] were also noted in intervention studies that did not include a control group.

One study with an RCT design found that those receiving an internet-based CBT intervention did not show significant improvement in problem gambling scores compared with a control group. The authors note that this may have been because of recruiting players from an online casino website and that these participants were not seeking help [27]. Another RCT design study found that normative feedback did not offer significantly different reductions in gambling behaviors

compared with controls [36]. For those studies that included treatment programs, high rates of attrition were identified. For those studies that reported them [20,22,23,27,31], attrition rates ranged from 38% [22] to 83% [27].

Several of the studies in the review identified important diversity in the ways that clients use internet-based interventions ([16,17, [38]). Use of online resources to address problem gambling was shown to be related to perceived ability and desire to change ([16,21]; greater problem gambling website usage being related to greater experience of gambling-related harm [38]).

Discussion

Principal Findings

The purpose of this review was to provide an overview of how internet-based resources were used in interventions for the treatment and prevention of problem gambling. The selected studies showed a wide range in the types of interventions that were being offered through internet-based resources. Most commonly, information technologies were used to modify or extend existing, popular forms of treatment for problem gambling. The most common therapy type was CBT, which was used in 6 of the 27 included studies. Other therapies included MI, Monitoring Feedback and Support, and exposure therapy. By and large, these interventions showed significant reductions in problem gambling scores and indicators of gambling involvement including time and money spent. The majority of the selected interventions (15/27) involved using the internet in some way to connect clients to mental health professionals for some kind of counseling, typically through typed chat or video sessions. This increase in access was identified as one of the key features that the internet can offer to the treatment of problem gambling [14,15,18].

Another common way that internet-based resources were used in the selected studies was using large amounts of collected data to improve the detection of potential problems or to allow potential participants to contextualize their own gambling behaviors. The ability to collect and use data from online gambling or treatment environments allows gambling providers and responsible gambling site operators to improve their harm prevention strategies efficiently [30,33].

There was a relatively small range of samples found in the review given the relatively few studies selected. Help-seeking samples were the most common. This is a result of many studies drawing their samples from clientele of problem gambling help websites. As help seeking is relatively rare among problem gamblers, it is difficult to say how representative the results are of the existing literature of the experiences of the problem gambling population. Those studies that targeted females using internet-based interventions and found that females were highly receptive to them [13,24,31]. Internet-facilitated treatment makes it possible to create single gender discussion and treatment groups. This can be especially important for females who may feel more comfortable in female-only groups but are too spread out geographically for in-person discussion groups [31]. Single-gender groups may also be important to females and males as gendered interpretations of stigma associated with problem gambling have been shown to have different effects in discouraging treatment-seeking [41].

In the selected studies, little consideration was given to the impact of age in the use of internet-based technologies in the treatment or prevention of problem gambling. Only 1 study [28] focused analysis on a sample of adolescents, whereas all other studies included adult samples with little consideration for variation in experience by age. This is unfortunately as younger clients and online gamblers were also identified as groups that were especially receptive to internet-based interventions [18]. The 1 study that used a sample of adolescents also suggested that internet-based interventions would be an effective tool in preventing problem gambling in younger cohorts. This is encouraging considering rates of problem gambling are disproportionately higher in younger cohorts and that adolescents are generally unaware of how to recognize problem gambling or how to access help [42]. However, problem gambling information available to younger cohorts is sparse [35], demonstrating that although internet-based interventions may be effective for targeting this priority population, they are currently underutilized.

Gaps and Challenges

The included studies also show numerous challenges in using internet-based interventions. The authors of the selected studies identified a wide range of challenges and concerns associated with using internet-based technologies in the treatment and prevention of problem gambling. One of the most important challenges was a high rate of attrition as noted in several studies. However, although attrition rates were found to be high, these studies noted that they were similar to those found in studies of face-to-face interventions [1,23,31]. As noted in a review of internet-based treatments for psychological conditions, it is difficult to compare dropout rates of in-person and internet-based interventions because of inconsistent definitions and tracking of dropouts [43]. It has also been suggested that attrition rates for studies of gambling help websites may be inflated because consumers may register for gambling help sites to simply see what kinds of services are available but are not ready to use those services [1]. The convenience of internet-based interventions may also contribute to the lack of program completion and online counseling or self-help programs may only be engaged in for as long as the consumer feels they are necessary [26]. Overall, 1 study compared the results of an internet-based CBT program and found a substantially higher dropout rate (47.7%) compared with a similarly structured face-to-face program (18.6%) [20].

Another gap regarding internet-based interventions is determining whether there is deficit in rapport when compared with face-to-face interactions with mental health professionals. Rapport is an important component of effective treatment from both the perspective of the health professional and the client. For example, in a study of stated preferences and the acceptability of internet-based treatment of anxiety and depression, 71.1% of health professionals and 58.0% of lay respondents stated that they would prefer in-person treatment compared with therapy over the internet (3.9% and 9.1%, respectively) [44]. Aspects of interpersonal communication

such as facial expressions and body language can be important tools for counselors in detecting distress in their clients [45,46]. Similarly, several studies that screened for problem gambling used online self-reported versions of problem gambling screeners; however, this increases the chances of diagnostic inaccuracies relative to face-to-face screening [26,32]. Although the greater anonymity offered by online resources can increase accessibility for some consumers, it can also present difficulties in tracking the progress of clients. It is possible for clients to have multiple concurrent accounts, delete old accounts, and create new accounts in the case of relapse, creating confusion in the data produced by their participation. This potential issue points to the importance of clear instructions regarding research integrity to prevent this from happening.

Internet-based interventions for problem gambling are relatively new; therefore, several studies identified a need to replicate their findings or extend their studies to new groups and therapies. In particular, there is a lack of comparison between in-person interventions and internet-based interventions. Although multiple RCT studies confirmed internet-based interventions led to significantly better improvements than no intervention (with 2 exceptions), no peer-reviewed studies examined the comparative effectiveness between online and in-person delivered treatment. The experience of treatment using online resources may be substantially different from more traditional intervention. For example, Rodda et al [19] found that the flexibility, anonymity, and style of communication (written) were important motivating factors in consumers choosing internet-based interventions over traditional face-to-face therapy. They note that although the goal of traditional helpline interventions is to ultimately direct potential consumers to face-to-face counseling, the convenience and range of intervention options available through gambling help websites makes it more likely to be the first and last source of support that they might access. Although no study directly compared the effectiveness of internet-based interventions with face-to-face interventions, 1 study did compare effect size of their internet-based intervention with the results of a previous, similarly structured study on face-to-face intervention. The results suggested that internet-based CBT delivered comparable reductions in gambling amount, gambling frequency, and improved gambling refusal efficacy. However, lower dropout rates (18.6% vs 47.7%) and lower faulty gambling cognitions were observed in the face-to-face program [20].

Limitations

There are several limitations of this study. First, the scoping nature of this review was intended for the purpose of mapping the current literature regarding internet-based interventions for problem gambling. This means that the search strategy was not as exhaustive as may be included in a systematic review and thus was likely to miss a number of relevant articles on the subject. As noted by Arksey and O'Malley [11], the scoping nature of this review brings with it limitations. Specifically, this review is not able to assess the quality of evidence or provide an analytical synthesis of the evidence. Another limitation is the lack of inclusion of mobile device–delivered interventions (often referred to as mHealth interventions). Although many of the technologies and challenges involved in these forms of interventions may be similar, we regarded these technologies as being outside of the scope of this study. Although non-English language studies were not excluded purposefully from this review, all searches were performed in English and as such were likely to miss studies in other languages. This biases the current results to reflect predominately English language research. The search strategy was also limited as a result of focusing on search terms related to problem gambling specifically and not on more general language of gambling-related harm. As a result, the current selection strategy may be biased toward including studies focused on treatment rather than harm reduction and prevention studies. It should be noted that in some cases, several of the articles included in this review were based on data from a single program of work. Overall, 7 studies were based on data collected from *Gambling Help Online*, an Australian online counseling and support website [14-19]. This commonality between these studies should be kept in mind by the reader as it can potentially bias the findings of this study.

Conclusions

This scoping review sought answers to 1 central question surrounding internet-based interventions: "How are internet-based resources being used to deliver problem gambling interventions?" The selected studies show that internet-based resources are primarily used to modify existing popular therapies for problem gambling, largely to increase access and flexibility. The existing body of knowledge suggests that internet-based interventions show potential but that their effectiveness compared with in-person treatment is unknown, and possible unintended side effects are largely unexplored. Researchers have found evidence that a variety of forms of internet-based interventions show positive results in treating problem gambling. However, this scoping review found a lack of replication of study or intervention designs as well as a lack of research on marginalized groups for whom barriers to access traditional treatment are the greatest. In short, although the initial research on internet-based interventions is supportive of greater deployment, there are still many unanswered questions regarding the positive and negative aspects of internet-based interventions relative to face-to-face treatment for problem gambling.

Acknowledgments

This study was completed with much-appreciated support from the Ministry of Health and Long Term Care (grant #425).

Conflicts of Interest

None declared.

Multimedia Appendix 1

Search strings.

[PDF File (Adobe PDF File), 27KB - mental_v6i1e65_app1.pdf]

Multimedia Appendix 2

Included studies.

[PDF File (Adobe PDF File), 69KB - mental_v6i1e65_app2.pdf]

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Abbreviations

CBT: cognitive behavioral therapy
DSM: Diagnostic and Statistical Manual for Mental Disorders
MI: Motivational Interviewing
NODS: National Opinion Research Center DSM Screen for Gambling Problems
PGSI: Problem Gambling Severity Index
PG-SOIS: Problem Gambling Significant Other Impact Scale
RCT: randomized controlled trial
SOGS: South Oakes Gambling Screen

Edited by G Eysenbach; submitted 14.11.17; peer-reviewed by S Rodda, M Boffo, M Boffo; comments to author 19.02.18; revised version received 31.07.18; accepted 23.10.18; published 07.01.19.

Please cite as:
van der Maas M, Shi J, Elton-Marshall T, Hodgins DC, Sanchez S, Lobo DSS, Hagopian S, Turner NE
Internet-Based Interventions for Problem Gambling: Scoping Review
JMIR Ment Health 2019;6(1):e65
URL: https://mental.jmir.org/2019/1/e65/
doi:10.2196/mental.9419
PMID:30617046

Viewpoint

Recommendations for Methodology of Virtual Reality Clinical Trials in Health Care by an International Working Group: Iterative Study

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Abstract

Background: Therapeutic virtual reality (VR) has emerged as an efficacious treatment modality for a wide range of health conditions. However, despite encouraging outcomes from early stage research, a consensus for the best way to develop and evaluate VR treatments within a scientific framework is needed.

Objective: We aimed to develop a methodological framework with input from an international working group in order to guide the design, implementation, analysis, interpretation, and communication of trials that develop and test VR treatments.

Methods: A group of 21 international experts was recruited based on their contributions to the VR literature. The resulting Virtual Reality Clinical Outcomes Research Experts held iterative meetings to seek consensus on best practices for the development and testing of VR treatments.

Results: The interactions were transcribed, and key themes were identified to develop a scientific framework in order to support best practices in methodology of clinical VR trials. Using the Food and Drug Administration Phase I-III pharmacotherapy model as guidance, a framework emerged to support three phases of VR clinical study designs—VR1, VR2, and VR3. VR1 studies focus on content development by working with patients and providers through the principles of human-centered design. VR2 trials conduct early testing with a focus on feasibility, acceptability, tolerability, and initial clinical efficacy. VR3 trials are randomized, controlled studies that evaluate efficacy against a control condition. Best practice recommendations for each trial were provided.

Conclusions: Patients, providers, payers, and regulators should consider this best practice framework when assessing the validity of VR treatments.

(JMIR Ment Health 2019;6(1):e11973) doi:10.2196/11973

KEYWORDS

clinical trials; consensus; virtual reality

Introduction

Therapeutic virtual reality (VR) is an innovative treatment modality to manage a broad range of health conditions and is gaining considerable attention [1-19]. Users of VR wear a head-mounted display (HMD) with a close-proximity screen that creates a sense of being transported into life-like, three-dimensional worlds. VR has been used to assess and treat a wide variety of medical, surgical, psychiatric, and neurocognitive conditions including pain [1,2,4,9,13,18], addiction [20-25], anxiety disorders [3,6,7,14-15,26-34], schizophrenia [10,11,19,35-38], eating disorders [1,8,39-45], stroke rehabilitation [5,12,16-17,45-47], vestibular disorders [48], and movement disorders [49]. One of the first published uses of HMD-based therapy was the treatment of acrophobia in 1995 [50]. There have also been functional magnetic resonance imaging studies demonstrating the effect of VR on the brain during receipt of a painful stimuli [51,52]. VR is thought to work through a combination of distraction, extinction learning, cognitive-behavioral principles, mindful meditation, stress reduction, gate-control theory, and the spotlight theory of attention [53,54]. Importantly, VR has become increasingly portable, immersive, and vivid, which has enabled the technology to be used in a broad range of inpatient and outpatient applications.

As the use of therapeutic VR expands, it is essential that guidelines are established to ensure scientific rigor in the development and evaluation of VR applications, similar to established standards for pharmacotherapies [30,55]. VR developers would benefit from systematic guidance on best practices for designing and conducting VR clinical trials. To fulfil this unmet need, we garnered input from an international working group, called the Virtual Reality Clinical Outcomes Research Experts (VR-CORE) committee. This paper presents the resulting best practice framework informed by expert input, along with specific recommendations on ways to conduct high-quality VR treatment trials. Although the focus of this paper is VR, the framework also applies to other emerging "XR" technologies, including augmented reality and mixed reality, as the methodologic considerations for clinical trials are largely similar across XR platforms.

Methods

Identifying Virtual Reality Clinical Outcomes Research Experts

We performed a systematic review of randomized controlled trials (RCTs) using therapeutic VR to help identify eligible VR-CORE committee members through review of author lists. To cover the largest breadth of studies, the literature search focused on existing meta-analyses of therapeutic VR RCTs identified through search of PubMed, Google Scholar, and the Cochrane Database of Systematic Reviews using a combination of keywords: ("virtual reality" OR "VR") AND ("review [pt]" OR "systematic review [pt]" OR "meta-anal*" OR "metaanaly*"). Based on our literature search, and supplemented by recommendations from established experts, we developed a multidisciplinary group for the VR-CORE, including experts in fields relevant to developing and testing VR treatments such as user-centered design principles, software design, epidemiology, statistics, and clinical trial methodology. The committee was formulated to balance expertise across clinical disciplines (medicine, pediatrics, surgery, psychology, psychiatry, neuroscience, anesthesia, nursing, and rehabilitation) and reflect multinational perspectives.

Collecting Input From the Virtual Reality Clinical Outcomes Research Experts

To obtain systematic feedback from the committee, a series of electronic meetings were held to collect and synthesize structured input. An iterative approach was modeled after similar processes were employed by our previous working groups in other fields of health care [56,57]. Using an online meeting platform that allows users to view and react to each other's comments [58], committee members initially responded to open-ended "think aloud" prompts [59] (eg, "When you think about the current state of the clinical VR research, what comes to your mind?"), followed by increasingly specific probes prepared by the moderators (eg, "What should be the role of human centered design principles in developing VR treatments?"). The full set of questions and responses is listed in Multimedia Appendix 1. The active members of the VR-CORE at the time of this discussion are listed in the Acknowledgments section. Emergent themes and proposed methodologic best practices were culled from the online dialogue, and the resulting recommendations were distributed to the members for synthesis and iterative rephrasing.

Results

Emergent Themes from Virtual Reality Clinical Outcomes Research Experts Meetings

Multimedia Appendix 1 provides excerpted transcripts of the VR-CORE responses to discussion topics. Key themes drawn from the online dialogue are summarized in the following sections.

Perceptions Regarding the Current State of Clinical Virtual Reality Research

Committee members described the current state of clinical VR research as the "Wild West" with a "lack of clear guidelines and standards." The state of current VR research was described as "heterogeneous," often focused "more on the tech rather than the theories behind it." Committee members expressed concern that much of the current research is "merely descriptive" in nature, often insufficiently powered, focused on small case reports and retrospective analyses, and often does not employ experimental designs.

Perceptions About Ways to Improve Virtual Reality Literature

The committee believed it is vital to "include the patients' voice early and often in the development of VR treatments" and that developers must "carefully, systematically, and meticulously seek the patients' feedback" through participatory research and design thinking that involves multidisciplinary collaboration. The committee acknowledged the importance of including the

voice of providers as well. The committee also called for better definitions and standardization of therapeutic VR study designs.

Most Important Considerations for Designing and Standardizing Clinical Virtual Reality Trials

The committee described various stages for developing and validating VR treatments, beginning with content development in partnership with end-users, progressing through initial clinical testing and safety evaluation, and ending with properly powered RCTs. The committee outlined a wide range of considerations for each stage (Multimedia Appendix 1), including the importance of standardizing control groups, selecting clinically relevant outcome measures, reporting which equipment was used in the trial, accounting for dropouts and disqualified participants, and allowing for pragmatic features of each study design.

Clinical Trial Framework of the Virtual Reality Clinical Outcomes Research Experts

The Framework

Although there are fundamental best practices in study design that apply to all biomedical intervention trials, the committee identified VR-specific attributes that are unique considerations for VR trials. Using the Food and Drug Administration Phase I-III pharmacotherapy model as guidance [55] and combining the results of literature synthesis with VR-CORE input, a framework emerged to support three phases of VR clinical study designs, named VR1, VR2, and VR3.

VR1 studies focus on content development by working with patient and provider end-users through principles of human-centered design. VR2 trials conduct early testing with a focus on feasibility, acceptability, tolerability, and initial clinical efficacy. VR3 trials are RCTs that compare clinically important outcomes between intervention groups and a control condition. Each study should undergo ethical review before initiation. Figure 1 summarizes each phase of the VR-CORE model. Best practice recommendations for each trial design are described below.

VR1 Studies

The committee strongly believes that therapeutic VR applications should be designed with direct input from patient and provider end-users. Lack of patient involvement, poor requirement definitions, and nonadaptation to user feedback are some of the common factors that explain failures of digital interventions [60]. Incorporating patients into the design process enables developers to increase the relevance and effectiveness of VR treatments. The committee stresses that VR treatments should be created with acknowledgment of patients' knowledge, attitudes, beliefs, preferences, and expectations of therapeutic VR. VR-CORE refers to a VR1 study as one that results in the development of VR treatment in partnership with patient and provider end-users and follows best practices for patient-centered design.

After their review of the literature on human-centered design both generally [61,62] and in relation to digital [60] and VR interventions [63], the committee identified three key principles that are fundamental for developing "desirable, feasible and viable" VR treatments [61]. These principles promote empathy, team collaboration, and continuous user feedback (Table 1). The committee believes that the use of these principles allows development teams to better identify users' needs, incorporate user feedback, and institute rapid cycle improvements that generate more relevant products at lower cost [64]. The key principles for VR1 studies are outlined in Table 1.

Figure 1. Summary of VR1, VR2, VR3. VR: virtual reality.

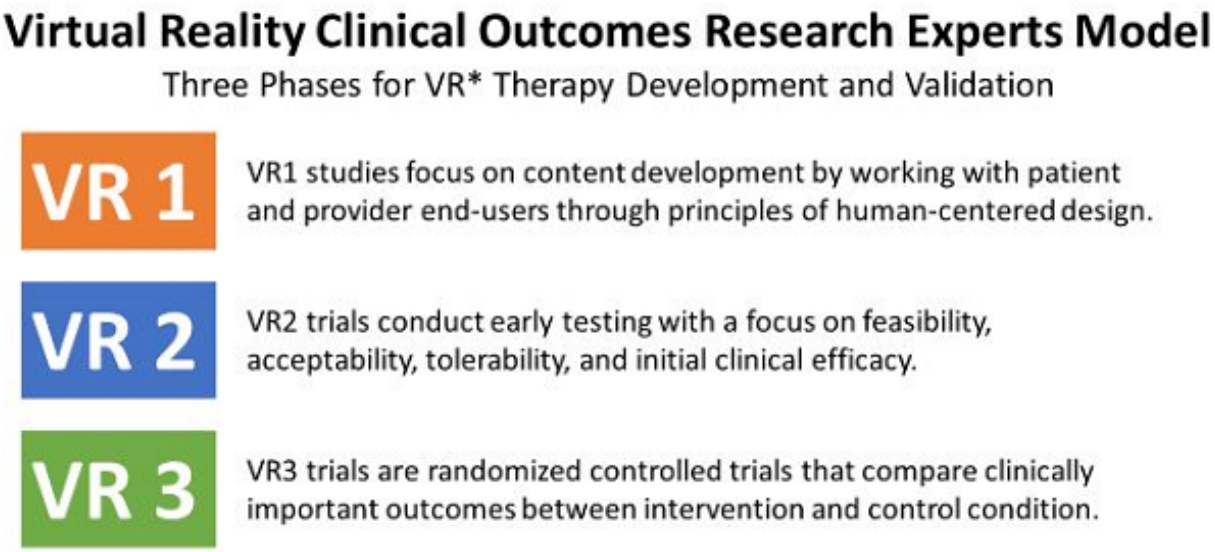

Table 1. Summary of design principles, strategies, and recommended best practices for VR1 studies.

Design principles and strategies	Best practices
Inspiration through empathizing	
Recruitment	• Determine the population of interest (who do we need to hear from?). • Think about a variety of factors (age, gender, ethnicity, health conditions, and social position).
Observation	• Learn about patients and their behavior by observing them in a clinically relevant context. • Observe what patients do in a specific context and what they see and say.
Patient interviews	• Perform individual cognitive interviews and focus groups with patients to learn about their relevant needs, struggles, experiences, fears, aspirations, and expectations. • Document a diverse set of opinions from a variety of patient profiles across ages (eg, above vs below "digital divide"), comorbidities, and experience and comfort with technology (eg, technophiles vs technophobes).
Expert interviews	• Perform cognitive interviews and focus groups with relevant experts representing different points of view such as treating providers and other staff members.
Journey mapping and personas	• Define the patient user and describe the sequence of events in which the patient will experience the virtual reality treatment within the context of their illness experience.
Ideation through team collaboration	
Sharing stories and notes	• Collect stories, pictures, impressions, and notes about patients' experiences and behavior. • Share information among team members to generate many ideas through techniques such as story-boarding, storytelling, and mind mapping.
Generating ideas	• Encourage team members to generate ambitious ideas without being judged. The committee believes that idea generation should be distinguished from idea evaluation. • After generating ideas, the team evaluates each idea and culls out the most feasible and appropriate idea for prototyping within technical and budgetary constraints.
Prototyping through continuous user feedback	
Building prototype	• Convert ideas into tangible figures through drawings or mock-ups and obtain initial user feedback prior to advanced prototyping. • Iteratively improve designs with user feedback.
Continuously testing prototype	• Test quickly and iterate on the design of the prototype by collecting both positive and negative user feedback. Document all stages of user feedback in the resulting VR1 study paper.

The Design Process of Virtual Reality Treatments Should Promote Empathy

The committee believes that the more attuned a development team is to the specific perspective and needs of patients, the more likely they are to design meaningful VR treatments. Promoting empathy toward the design process involves carefully listening to and elucidating patients' social environment, needs, fears, desires, habits, hopes, aspirations, and expectations. The committee recommends initiating the design process with an *inspiration step, or exercise focused on culling* patients' voice and understanding their needs, struggles, and experiences. Table 1 describes best practices for sparking inspiration within the framework of empathy. Different patient profiles and scenarios should be included in this first step. Many techniques can be used to develop empathy and inspiration of the design team. These include qualitative assessments, observations, spending time with users, and conducting interviews and user experiments. In addition, a patient journey map can be used to illustrate the interpretation of a story from a patient's perspective. The working group also recommends seeking input from relevant nonpatient end-users, including health care providers who may prescribe the VR treatment or interact with patient users.

The Design Process of Virtual Reality Treatments Should Promote Team Collaboration

The committee believes that team collaboration is fundamental for collectively designing a VR treatment and synthesizing data collected during the inspiration step. *Brainstorming* helps generate ideas from the initial corpus of data and findings. Table 1 describes best practices for ideation within the framework of team collaboration. The process of ideation allows team members to think expansively and divergently. As a range of ideas is generated, some ideas will be extreme or ambitious, whereas others will be achievable. Depending on the time and the available budget, the team decides what ideas should be prototyped further.

The Design Process of Virtual Reality Treatments Should Promote Continuous User Feedback

An effective VR treatment should be developed through continuous user feedback and *iterative prototyping*, thereby enabling the team to rapidly test their ideas during real-time

assessment from end-users. Table 1 describes best practices for VR treatment prototyping within the framework of user feedback. Prototypes should be refined with continuous testing by patient end-users, and failures are viewed as a way to learn and improve the prototype to better meet users' needs. Hence, the number of defects will tend to be lower and less costly in the future. To help facilitate the learning process for patients, it is recommended, when feasible, that the research team use a "mirroring" program [65] to allow the research staff to see what the patient is viewing through the VR headset and help them learn the user interface.

Briefly, the committee believes that the VR1 treatment design process should start with end-users. VR-CORE recommends specifying who the real users are and what they say, see, feel, and do. Hence, implementation of a patient-design approach is an important way to place users at the center of the VR design process. For researchers who are developing an open-source VR intervention that they would like to share with the academic community for collaborative V1 development process, the use of a software-development platform such as GitHub.com [66] and citation of the latest version of the program within the methods section of VR1 research papers are recommended. The committee also recommends use of the Integrate, Design, Assess, and Share checklist developed by Mummah and colleagues [60] as a supplemental, structured guide for conducting a VR1 study.

VR2 Trials

Once the research team has developed a VR treatment in partnership with end-users, the resulting product should undergo initial assessment in the target patient population within a representative clinical setting, herein termed a VR2 trial. Modeled after the work of Mosadeghi and colleagues [67], the purpose of VR2 trials is to conduct early testing with a focus on *acceptability*, *feasibility*, *tolerability*, and *initial clinical efficacy* prior to initiating a more definitive VR3 clinical trial. Although developers may opt to bypass a VR2 trial in lieu of a VR3 trial, there is a risk of subjecting an incompletely tested intervention to a larger and costlier RCT, and best practices in digital intervention development suggest an intermediary stage between initial VR design and definitive testing [60]. The following sections describe the features of a VR2 trial.

Clinical Setting

In contrast to a VR1 study, which is focused on collaborative content development in a design environment, the VR2 trial evaluates what happens when the VR treatment is placed in the hands of target patients within the intended clinical setting. For example, a VR treatment focused on management of inpatient pain should be tested in an inpatient environment. A VR treatment targeting outpatient stroke rehabilitation should be evaluated in locations where patients receive rehabilitation, such as in a physical therapy center or, if intended, at home. In short, a comprehensive VR2 trial evaluates the VR treatment in the natural setting(s) where the product is intended to be used. Table 2 summarizes the best practices for VR2.

Acceptability

In the context of a VR2 trial, *acceptability* refers to a patient's willingness to use the VR treatment. Previous research on therapeutic VR reveals a drop off in the relation between patient eligibility to receive VR and patient willingness to try VR [67]. The disconnect emphasizes that many patients are uninterested in using novel health technologies such as VR, particularly when hospitalized or under duress. Among those who are eligible for a VR trial, some choose not to participate for a wide variety of reasons. Patients may express varying degrees of skepticism, fear, vulnerability, and concern regarding psychological consequences or simply not want to be bothered by the equipment [67]. In a VR2 trial, investigators collect data regarding patient willingness to try the VR treatment, including reasons why they did or did not find the intervention to be acceptable for use. Researchers should collect and report acceptability data using techniques such as focus groups, cognitive interviews, or structured questionnaires.

Feasibility

In the context of a VR2 trial, *feasibility* is the degree to which the VR treatment can be successfully integrated within the flow of usual care. The committee noted that even the best designed VR treatments can face implementation challenges when applied on the front lines of health care delivery [67]. It is wise for developers to understand potential barriers early and often, identify workarounds and solutions to these barriers, and only then consider testing their interventions in VR3 RCT trials. For example, patients and providers often seek information regarding the frequency and "dosing" of a VR treatment; these details could be manually collected in the context of a VR2 trial. Similarly, treatments deployed in a clinical environment may be unfamiliar to doctors, nurses, and other health care providers, giving researchers an opportunity to study the interaction among staff and proactively identify areas of confusion or misuse. The committee recommends including a table that enumerates patient, provider, technical, and operational barriers to use; identifies root causes; and offers solutions to enhance effectiveness in future clinical applications.

Tolerability

The VR2 trial offers an early opportunity to evaluate patient *tolerability* of the VR treatment, including both hardware and software components. Researchers should measure and report the prevalence of patient-reported physical (eg, vertigo, nausea, and "cybersickness") and emotional (eg, fear and anxiety) adverse effects of the VR treatment, along with any discomfort or inconvenience related to the VR equipment (eg, ill-fitting headset, facial or nasal pain, inability to explore the three-dimensional environment fully due to limited mobility).

Cybersickness (or VR sickness) is a unique side effect of VR. There a several different terms used interchangeably within the literature, such as simulator sickness or "sim sickness," although some believe they are different types of motion sickness [68]. When the vestibular system and oculomotor system notice a discrepancy between reality and the virtual environment, one or more of following symptoms ensue: eyestrain, nausea, fatigue, headache, blurred vision, and postural instability [69]. The specific mechanism of cybersickness is still unknown.

Table 2. Summary of best practice recommendations for VR2 trials.

Trial attribute	Best practice
Patient population	• Study a representative population for whom the VR[a] treatment is intended. • Recruit a large enough sample to represent the breadth and depth of target patients and provide statistically stable estimates in descriptive analytics.
Clinical setting	• Select a clinical setting that represents the intended environment for the VR treatment to be used (eg, inpatient vs outpatient, clinic vs home based)
Assessment of acceptability	• Collect data regarding patient willingness to try the VR treatment, including reasons why they did, or did not, find the intervention to be acceptable for use. Researchers should collect and report acceptability data using techniques such as focus groups, cognitive interviews, or structured questionnaires.
Assessment of feasibility	• Conduct patient and provider interviews to identify potential barriers and facilitators to using the VR treatment in the intended clinical environment. • Collect information regarding the optimal frequency and "dosing" of a VR treatment; consider manualizing these details, where possible. • Study interactions among staff and proactively identify areas of confusion or misuse. • Consider including a table that enumerates patient, provider, technical, and operational barriers to use; identifies root causes; and offers solutions to enhance effectiveness in future clinical applications.
Assessment of tolerability	• Measure and report the prevalence of patient-reported physical and emotional adverse effects of the VR treatment, along with any discomfort or inconvenience related to the VR equipment.
Assessment of initial clinical efficacy	• Identify and justify selection of a clinically relevant and validated PRO[b] to evaluate the evidence of efficacy. • Measure the PRO before and after receipt of the VR treatment; consider comparing results against nonrandomized concurrent or retrospective control groups, where available.

[a]VR: virtual reality.

[b]PRO: patient-reported outcome.

Recommendations for developers already exist [70,71]: appropriately accelerate within the program [71,72], anticipate changes in direction [73], affect changes in the field of view [73], establish realistic virtual avatar movements, reduce drops in the frame rate below 60 fps [71], blur the display with movement [74], and provide other solutions at the level of program design.

There are also several strategies for medical staff and researchers including habituation [75], assessment of the risk of side effects before the intervention [76], use of oculomotor exercises before the intervention [77], and diaphragmatic breathing during the intervention [78]. One of the most useful strategies is to limit the total duration of each treatment session, particularly early in the process [70].

The VR-CORE recommends assessing for side effects at every phase (VR1, VR2, and VR3). Regarding assessment scales, the Simulator Sickness Questionnaire is the most commonly used scale in the literature [70,72,75,76].

Initial Clinical Efficacy

Although the VR2 trial is not designed to definitively test whether a VR treatment is efficacious or effective, it offers an early opportunity to measure efficacy within the context of a small clinical trial. There is no requirement in a VR2 trial to include a control group, although uncontrolled case series carry a higher risk of bias than controlled studies; even studies with nonrandomized concurrent controls, "wait list" controls, or retrospective controls may reduce the risk of bias as compared to an uncontrolled series.

Regardless of the inclusion of a control group, investigators should identify a clinically relevant and validated patient-reported outcome (PRO) to evaluate the evidence of efficacy. For example, a study evaluating pain might include a standard 11-point numeric rating scale [79] before and after exposure to the VR treatment. A study evaluating stroke rehabilitation might measure physical function with the National Institutes of Health Patient Reported Outcomes Measurement Information System [80]. Selection of the most appropriate PRO is at the discretion of the research team, but should be carefully justified and capture the most salient features of patient-reported health that might improve with the VR treatment.

VR3 Trials

The most definitive clinical validation of a VR treatment is the VR3 trial, which is a prospective, adequately powered, methodologically rigorous RCT evaluating clinical outcomes and safety in target patients receiving the VR treatment as compared to a control condition. Although the therapeutic mechanism of action may be studied as a secondary goal in a VR3 trial (eg, through neuroimaging, blood biomarkers, and physiologic testing), the principal goal is to evaluate the treatment's impact on a clinically meaningful patient outcome rather than surrogate markers.

Although the committee acknowledged understandable costs and resource barriers involved in conducting VR3 trials, there was broad agreement that RCTs are of equal scientific importance in therapeutic VR as any other form of treatment and should be prioritized whenever possible. Multicenter collaborations may facilitate VR3 trials by combining patients and resources through shared protocols. The features of a VR3 trials are described below and summarized in Table 3.

Standardization of Intervention and Patient Population

Having been developed in a VR1 study and initially tested in a VR2 trial, the study intervention should be clearly described in preparation for a VR3 trial. Researchers should provide details regarding the equipment used; visualizations employed (with representative screenshots or videos); and frequency, duration, and timing of use. Optimally, the intervention should be manualized, and at the very least, enough details should be provided to allow other investigators to repeat the trial, if desired. The Template for Intervention Description and Replication checklist provides a useful framework for describing study interventions [81] and should be applied to VR treatments. The target patient population should be clearly described, including explicit inclusion and exclusion criteria employed. Certain exclusion criteria may be standardized among VR trials, such as a history of significant motion sickness, active nausea, and vomiting or epilepsy.

Selection of Control Condition

The committee acknowledged that there is no perfect or standardized control condition for all VR treatment trials; the optimal control depends on the patient population, proposed mechanism of action of the intervention, and clinical setting, among other considerations. Selection of the control is at the discretion of the research team but should be justified and explained. The committee described a hierarchy of control conditions, ranging from "usual care" without any active intervention to passive visualizations on a two-dimensional screen and nonimmersive visualizations within a headset, immersive but passive experiences within a headset, and immersive and active experiences within a headset. Selection of the optimal control may be guided by considering the hypothesized target of engagement and the proposed mechanism of action.

Randomization

Randomization should be described and ideally achieved using an appropriate computer program (eg, MS Excel Random Number Generator) [81] or random number tables without involvement of the investigators who enrolled the patients.

Blinding and Concealment of Allocation

The committee acknowledged that blinding and concealment can be challenging, but they identified techniques to incorporate these RCT principles within the constraints of VR research. For example, Spiegel and colleagues (2017) achieved concealment of allocation in an RCT comparing a library of VR content to a "health and wellness" television channel in hospitalized patients experiencing pain [83]. At the time of consent, the researchers explained to patients that the study compared "two different audiovisual experiences designed to reduce pain," but did not describe the details of the competing interventions. Patients randomized to the television intervention did not know that VR was the other condition and vice versa. This approach may reduce the "novelty effect" of receiving VR rather than a familiar experience like television. Equipoise may also be achieved by exposing patients in both arms to headsets, but varying the content viewed within the headset (eg, immersive vs nonimmersive, active vs passive). At a minimum, study analysts should be blinded to patient group allocation, allowing for unbiased evaluation of the data without the knowledge of the study group. Patients should be asked not to reveal details of the program they experienced to decrease the chance of unblinding the study analysts. The measurement of perceived group assignment at the end of the study can help assess the success of blinding within the study. This should be done at the discretion of the research team.

Endpoints

Like the VR2 trial, VR3 trials must prespecify a clinically relevant and validated PRO as the primary endpoint. The study must be appropriately powered to demonstrate a minimally clinically important difference (MCID) [84] in that endpoint between the VR treatment and control arms. The psychometrics of PRO measurement are beyond the scope of this document, but existing references may assist investigators in protocol development [84,85]. Secondary endpoints may include a variety of clinical, imaging, biometric, and physiologic surrogate markers, as deemed appropriate by the study team. Like VR2 trials, potential adverse events must be prospectively measured and reported.

Study Duration

VR3 studies should monitor patients for a sufficient period to determine whether the VR treatment meaningfully impacts clinically important outcomes. One-time, short-term evaluations may be insufficient to evaluate the true clinical value of an intervention. Follow-up over several days may be appropriate if the study only focuses on hospital stay, but measurement over weeks, or even months, may be necessary to assess the impact on long-term clinical benefits.

Presentation and Analysis of Results

VR-CORE recommends that the primary outcome be reported as the before and after *difference in difference* between study arms, with accompanying 95% CIs. For example, the change in the mean PRO score before and after the VR intervention should be compared against the change in the mean PRO score before and after the control intervention. In addition, the panel recommends predefining a binary response criterion, guided by the MCID of the primary endpoint. The proportion achieving the MCID should be reported and compared between groups, and the resulting number needed to treat should be calculated.

Table 3. Summary of best practice recommendations for VR3 Trials.

Trial attribute	Best practices
Patient population	• Study a representative population for whom the VR[a] treatment is intended. • The target patient population should be clearly described, including explicit inclusion and exclusion criteria employed.
Clinical setting	• Select a clinical setting that represents the intended environment for the VR treatment to be used (eg, inpatient vs outpatient, clinic vs home based).
Standardizing intervention	• Provide details regarding the equipment used; visualizations employed; and frequency, duration, and timing of use for VR treatment. • Consider following the TIDIER[b] checklist [81] as a useful framework for describing features of the VR treatment.
Selecting control condition	• Select and justify the control condition(s) by considering the hypothesized target of engagement and the proposed mechanism of action.
Randomization	• Randomization should be achieved using an appropriate computer program (eg, MS Excel Random Number Generator) [82] or random number tables without involvement of the investigators who enrolled the patients.
Blinding and concealment of allocation	• Describe efforts to conceal allocation of the study intervention to the participants. • Describe efforts to blind patient, providers, and analysts, wherever possible. • Measure perceived group assignment to assess success of blinding.
Endpoints	• Prespecify a clinically relevant and validated PRO[c] as the primary endpoint. The psychometric properties of available PRO measures may need to be modified in the context of immersive therapy and then revalidated as needed. • Trials must be appropriately powered to demonstrate an MCID[d] [83] in the primary endpoint between the VR treatment and control arms. • Secondary endpoints may include a variety of clinical, imaging, biometric, and physiologic surrogate markers, as deemed appropriate by the study team. • Potential adverse events must be prospectively measured and reported.
Study duration	• Select and justify the follow-up period that is sufficient to determine whether the VR treatment meaningfully impacts clinically important outcomes.
Presentation and analysis of results	• Report the before and after *difference in difference* in the primary outcome measure between study arms, with accompanying 95% CIs. • Predefine a binary response criterion, guided by the MCID of the primary endpoint. The proportion achieving the MCID should be reported and compared between groups, and the resulting number needed to treat should be calculated. • Use intention-to-treat analysis for primary outcome assessment. • Per-protocol analysis may be reported if prespecified, as relevant. • To perform a multivariable analysis, it is optimal to have at least 10 (preferably, 20) observations for each independent variable included in the multivariable model.
Reporting the trial	• Trial must be registered on a publicly accessible registry (eg, clinicaltrials.gov). • All completed trials should be published, whether positive or negative. • The CONSORT[e] guidelines provide the framework for reporting RCTs [86] and should be followed in VR3 trials. • Include a CONSORT diagram demonstrating the flow of patients through each stage of the trial, including the number screened to the number randomized into each study group and the number analyzed.

[a]VR: virtual reality.

[b]TIDIER: Template for Intervention Description and Replication.

[c]PRO: patient-reported outcome.

[d]MCID: minimally clinically important difference.

[e]CONSORT: Consolidated Standards for Reporting Trials

The primary analyses should use the intention-to-treat population, including all patients randomized regardless of follow-up or receipt of study interventions. However, per-protocol analysis may be appropriate in certain situation,

such as if patients refuse the VR treatment after randomization; in this instance, reporting the rate of refusal would be important, but investigators might also seek to compare therapeutic responses only among those receiving the intervention.

Multivariable analysis may be useful in adjusting for prespecified confounding factors (especially if not equally distributed in the study groups) and exploring independent predictors of outcomes. To perform a multivariable analysis, it is optimal to have at least 10 (preferably, 20) observations for each independent variable included in the multivariable model.

Trial Reporting

VR3 trials must be registered in a publicly accessible registry (eg, such as ClinicalTrials.gov). All completed trials should be published, regardless of whether they are positive or negative. The Consolidated Standards for Reporting Trials (CONSORT) guidelines provide the framework for reporting RCTs [86] and should be followed in VR3 trials. VR3 trials must include a CONSORT diagram to demonstrate the flow of patients through each stage of the trial, including the number screened to the number randomized into each study group and the number analyzed.

Conclusions

To improve methodological quality in the therapeutic VR literature, the VR-CORE international working group presents a three-part framework for best practices in developing and testing VR treatments. This framework may be used to facilitate development of high-quality, effective, and safe VR treatments that meaningfully improve patient outcomes. Patients, providers, payers, and regulators should consider this framework when assessing the validity of VR treatments.

Acknowledgments

BS is supported by the Marc and Sheri Rapaport Fund for Digital Health Sciences and Precision Health. In addition to the authorship team, the following committee members actively participated in the online discussion forums and contributed to this paper: Tom Caruso, MD, MEd - Stanford University School of Medicine, Stanford, CA; Ali Fardinpour, PhD - Wise Realities, Perth, Australia; Diane Gromala, PhD - Simon Fraser University, Surrey, BC; Rafael Grossmann, MD - Eastern Maine Healthcare System, Bangor, ME; Kate Hardy, Clin PsychD - Stanford University School of Medicine, Stanford, CA; Constance Johnson, PhD - The University of Texas Health Science Center, Houston, TX; Ted Jones, PhD - Pain Consultants of East Tennessee, Knoxville, TN; Kate Laver, PhD - Flinders University, Adelaide, Australia; Sheila Parinas, BSN, RN - University of Illinois, Champaign, IL; Les Posen, FAPS, Clin Psych - Flightwise, Melbourne, Australia; Barbara Rothbaum, PhD, ABPP - Emory School of Medicine, Atlanta, GA; David Thomas, PhD - National Institute of Drug Abuse (NIDA), Bethesda, MD; Stefan Van Rooijen, MD PhD - Maastricht University, Maastricht, Netherlands; Herve Rosay, MD - Centre Leon Berard, Lyon, France; Earl Scott, MD - HCA Midwest Physician, Kansas City, MO; Andrea Stevenson Won, PhD - Cornell University, Ithaca, NY.

Conflicts of Interest

BS was the Principal Investigator of a 2016 Virtual Reality (VR) research grant (#CSR211835), administered by his academic institution, from AppliedVR (Los Angeles, California). He is currently the Principal Investigator of a VR research grant (#CSR212943), administered by his academic institution, from Traveler's Insurance (New York City, NY) and Samsung Electronics (Suwon, South Korea). AR's research relating to this paper has been funded by the National Institutes of Health (NIH), National Science Foundation, US Army Research Office, Telemedicine and Advanced Technology Research Center, US Army Medical Research Acquisition Activity, Department of Veterans Affairs, and Kesseler Foundation. All other authors (BB, CK, XL, SC, ID, and KB) have no conflicts of interest. Regarding the other Virtual Reality Clinical Outcomes Research Experts members, Dr Rothbaum owns equity in Virtual Better, Inc, which is developing products related to virtual reality research related to this paper. The terms of this arrangement have been approved by Emory University in accordance with its conflict of interest policies. Dr Johnson receives funding through the NIH to study virtual environments. Some of Dr van Rooijen's VR research has been funded by Phillips, Inc (Amsterdam, Netherlands). All other members of the committee (Tom Caruso, Ali Fardinpour, Diane Gromala, Rafael Grossmann, Kate Hardy, Ted Jones, Kate Laver, Sheila Parinas, Les Posen, David Thomas, Herve Rosay, Earl Scott, and Andrea Stevenson Won) have no conflicts of interest.

Multimedia Appendix 1
Excerpted transcripts of Virtual Reality Committee of Outcomes Research Experts responses to selected discussion topics. Key themes and phraseology included in the manuscript are highlighted. Note that not all committee members responded to all questions.
[PDF File (Adobe PDF File), 76 KB - mental_v6i1e11973_app1.pdf]

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Abbreviations

CONSORT: Consolidated Standards for Reporting Trials
HMD: head-mounted display
MCID: minimally clinically important difference
PRO: patient-reported outcome
RCT: randomized controlled trial
TIDIER: Template for Intervention Description and Replication
VR: virtual reality
VR-CORE: Virtual Reality Clinical Outcomes Research Experts

Edited by W Greenleaf; submitted 19.08.18; peer-reviewed by C Fowler, J Torous; comments to author 01.10.18; revised version received 23.10.18; accepted 23.10.18; published 31.01.19.

Please cite as:
Birckhead B, Khalil C, Liu X, Conovitz S, Rizzo A, Danovitch I, Bullock K, Spiegel B
Recommendations for Methodology of Virtual Reality Clinical Trials in Health Care by an International Working Group: Iterative Study
JMIR Ment Health 2019;6(1):e11973
URL: https://mental.jmir.org/2019/1/e11973/
doi:10.2196/11973
PMID:30702436

Original Paper

Effects of a Mindfulness Meditation App on Subjective Well-Being: Active Randomized Controlled Trial and Experience Sampling Study

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Abstract

Background: Mindfulness training (MT) includes a variety of contemplative practices aimed at promoting intentional awareness of experience, coupled with attitudes of nonjudgment and curiosity. Following the success of 8-week, manualized group interventions, MT has been implemented in a variety of modalities, including smartphone apps that seek to replicate the success of group interventions. However, although smartphone apps are scalable and accessible to a wider swath of population, their benefits remain largely untested.

Objective: This study aimed to investigate a newly developed MT app called Wildflowers, which was codeveloped with the laboratory for use in mindfulness research. It was hypothesized that 3 weeks of MT through this app would improve subjective well-being, attentional control, and interoceptive integration, albeit with weaker effects than those published in the 8 week, manualized group intervention literature.

Methods: Undergraduate students completed 3 weeks of MT with Wildflowers (n=45) or 3 weeks of cognitive training with a game called 2048 (n=41). State training effects were assessed through pre- and postsession ratings of current mood, stress level, and heart rate. Trait training effects were assessed through pre- and postintervention questionnaires canvassing subjective well-being and behavioral task measures of attentional control and interoceptive integration. State and trait training data were analyzed in a multilevel model using emergent latent factors (acceptance, awareness, and openness) to summarize the trait questionnaire battery.

Results: Analyses revealed both state and trait effects specific to MT; participants engaging in MT demonstrated improved mood (r=.14) and a reduction of stress (r=−.13) immediately after each training session compared with before the training session and decreased postsession stress over 3 weeks (r=−.08). In addition, MT relative to cognitive training resulted in greater improvements in attentional control (r=−.24). Interestingly, both groups demonstrated increased subjective ratings of awareness (r=.28) and acceptance (r=.23) from pre- to postintervention, with greater changes in acceptance for the MT group trending (r=.21).

Conclusions: MT, using a smartphone app, may provide immediate effects on mood and stress while also providing long-term benefits for attentional control. Although further investigation is warranted, there is evidence that with continued usage, MT via a smartphone app may provide long-term benefits in changing how one relates to their inner and outer experiences.

Trial Registration: ClinicalTrials.gov NCT03783793; https://clinicaltrials.gov/ct2/show/NCT03783793 (Archived by WebCite at http://www.webcitation.org/75EF2ehst)

(JMIR Ment Health 2019;6(1):e10844) doi:10.2196/10844

KEYWORDS

mindfulness; attention; mobile health; interoception; mood; stress, psychological

Introduction

Background

Mindfulness training (MT) is a collection of meditation, introspection, and yoga practices aimed at the cultivation of psychological resilience and the alleviation of mental health symptoms [1]. In its modern secular form, MT was originally developed as an instructor-facilitated clinical group intervention for chronic pain and mood disorders [2,3], and much of its scientific efficacy stems from the study of these clinical interventions [4]. However, MT has recently been offered through a growing variety of novel and largely unvalidated delivery vehicles, including a growing number of smartphone apps. To date, there are no actively controlled experience sampling studies investigating whether such apps can replicate the therapeutic efficacy associated with validated group interventions.

Mindfulness has been defined as "the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment by moment" [5]. Accordingly, MT aims to cultivate this adaptive form of awareness, primarily through guided meditation practices, suggesting that mindful awareness is a regulatory skill that can be developed over time [6]. To promote mindful regulation, mindfulness meditation has been integrated into a variety of MT interventions such as mindfulness-based cognitive therapy (MBCT) and mindfulness-based stress reduction (MBSR) [4]. Meta-analyses focusing on clinical populations have found moderate effects of mindfulness-based interventions on reducing symptom burden in chronic pain, anxiety, and depression [4,5,7]. In nonclinical populations, mindfulness-based interventions have been found to have strong effects on psychological well-being, including the reduction of stress, negative emotions, and anxiety [8]. Moreover, in both clinical and nonclinical populations, mindfulness-based interventions have been found to increase self-reported mindfulness [9,10]. Mindfulness meditation, both guided and self-guided, without the broader context of an MT intervention, has also been associated with improvements in well-being, including increases in self-reported mindfulness, improvements in attention, decreases in anxiety, decreases in stress, and reductions in negative personality traits [8,11].

Some of the proposed mechanisms for the effectiveness of MT include increases in metacognitive awareness, acceptance, and attentional control [12,13]. Metacognitive awareness involves being able to step back from one's internal experiences and observe them from a third person perspective [14]. Acceptance involves a willingness to allow difficult internal experiences to happen while taking a nonjudgmental stance toward them; it has been suggested that greater acceptance reflects decreased experiential avoidance, which is attempting to change or control difficult internal experiences [15-17]. Attentional control may involve different subcomponents of attention, including the ability to direct attention toward stimuli (orienting), the ability to remain receptive to stimuli (alerting), and the ability to prioritize attention (conflict monitoring) [13]. These proposed mechanisms reflect key components of mindfulness, as defined by Bishop and colleagues, which includes self-regulation of attention and adopting an open and accepting attitude toward internal experiences [6].

Despite well-established benefits of mindfulness-based interventions, and some understanding of the mechanisms involved, MT dissemination can be difficult. For example, MBCT and MBSR require a commitment of weekly meetings and at-home practice of learned mindfulness skills for 8 weeks [3,18,19]. Moreover, these interventions are costly and not easily accessible because of the requirement of therapists to implement these interventions [20,21]. These limitations have prompted research on the minimum dose required for efficacious MT, and there is now some evidence that brief MT as short as 3 days to 4 weeks may have positive effects on anxiety, negative mood, mindfulness, perceived stress, and attention [22-24]. Moreover, a systematic review found no relationship between hours spent in MT sessions and changes in psychological distress [25], suggesting that formal meditation time is not the most important factor in efficacious MT. Indeed, a recent dismantling study of internet-based MT found no effect of formal meditation practice, although both formal and nonformal practice arms of the study outperformed a no-intervention control group [26].

Growing awareness of MT-related benefits, coupled with uncertainty around the necessary components leading to these benefits, has allowed for a rapid expansion of MT delivery modalities, including implementation through technological platforms. Technology-delivered mindfulness-based interventions have proven to be successful in improving well-being [27-29], including reductions in anxiety, depression, and stress [20,30-36]. Moreover, a variety of mindfulness-based smartphone apps have been developed that seek to replicate the success of group interventions [37]. However, although smartphone apps are scalable and accessible to a wider swath of population, their benefits remain largely untested [38].

Perhaps the fastest growing market for MT lies in smartphone apps for MT; the most popular current MT app, Headspace, boasted over 6 million users in 2016 [28]. However, despite a booming user base, only 4 randomized controlled trials have investigated the efficacy of smartphone apps for MT, and only half of these trials used an active control group. Van Emmerik and colleagues investigated the beneficial effects of a mindfulness app called VGZ Mindfulness Coach. After 8 weeks of using this app, participants demonstrated increases in

mindfulness, improvements in psychiatric symptoms, and improvements in quality of life, relative to a waitlist control condition [21]. Similar findings were observed with the Headspace meditation app with regard to psychiatric symptoms; after using the Headspace app for 10 days, participants demonstrated reduced depressive symptoms and increases in positive affect, relative to an active control condition (participants had to make a list of what they did on that day the previous week). However, there were no changes in satisfaction with life or in negative affect. The authors reasoned that these findings may be a result of the short period that this app was used and that the changes in positive affect may have eventually led to changes in these other domains [39]. Two more recent randomized controlled trials have also investigated Headspace; the first trial found that after 10 sessions with Headspace, participants in the MT group demonstrated reductions in irritability and improvements in affective balance, relative to a psychoeducation control condition [40]. The second recent trial found that compared with a waitlist control, participants who completed 8 weeks of MT with Headspace demonstrated improvements in well-being and reductions in workplace stress [41].

Although these studies found some benefits from using these MT apps, they relied solely on subjective self-reports, which may be confounded with participant expectancy. For example, participants may believe that MT improves attention regulation [13], but such regulation can and should be assessed through behavioral performance rather than self-report alone. Moreover, these studies investigated the effects of MT while only comparing longitudinal *trait* outcomes, without evaluating the local or *state* effects of meditation sessions. Exploring state effects may be useful in demonstrating the immediate benefits of MT by limiting retrospective bias [42].

Goal and Hypotheses

With few investigations of the effectiveness of MT apps on well-being, further research is warranted. The goal of this study was to better evaluate the local and longitudinal effects of app-delivered MT, relative to a randomized active-control group. For this purpose, we employed a newly developed MT app that was designed to collect user's ratings of current mood and stress level as well as heart rate before and after each guided meditation session. In the active control condition, a popular cognitive game was adapted to allow for the same collection of mood, stress, and heart rate data. To investigate subtle changes across domains related to optimal psychological experience and functioning, a broad definition of well-being was measured, including both hedonic (ie, pleasure vs pain) and eudemonic aspects (ie, realizing one's true nature) [43], and a data-driven approach was used to efficiently report on these domains.

As outcome variables, we attempted to provide several longitudinal and local MT targets. For longitudinal targets, we modeled 3 commonly cited MT benefits: improved subjective well-being, attentional control [8-11,13], and interoceptive integration [44-47]. For local targets, we tested for improvements in mood, physiological arousal [24,48,49], and stress [11,22,26,50].

It was hypothesized that MT via a smartphone app would improve trait subjective well-being, attentional control, and interoceptive integration, albeit with weaker effects for a brief 3 weeks of MT with the app than those published in the 8-week manualized group intervention MT literature. In addition, it was expected that beneficial state MT effects would be observed in mood, heart rate, and perceived stress, suggesting the immediate benefits of brief mindfulness meditation.

Methods

Recruitment and Design

Undergraduate students were recruited from the University of Toronto Mississauga and randomly assigned to train with 1 of 2 smartphone apps: Wildflowers, an MT app or 2048, a cognitive training app, which was used as an active control condition to control for expectancy and daily engagement. Both apps were described to participants as a cognitive training app that might promote well-being. This description was given to foster positive expectancy in the active control condition, without introducing any real stressor or emotion regulation training.

To be eligible to participate in this study, participants were expected to (1) have normal or corrected-to-normal vision and hearing, (2) be 18 years or older, (3) be fluent in English, and (4) own an iPhone, iPad, or iPod with access to the internet.

Upon recruitment, each participant was asked to come in to the laboratory to complete self-report questionnaires of well-being through a Web-based survey platform called Qualtrics and complete behavioral measures of attentional control and interoceptive integration on a computer in the laboratory. After completing the questionnaires and tasks, participants downloaded their assigned app and made sure it was working on their phone and they knew how to use it. Participants did not know their condition assignment until after completing the pretraining measures. Ratings of current mood, stress level, and heart rate were recorded within each app before and after each training session. Heart rate was sampled with the camera on the participants' smartphone using a well-established algorithm. This technique included an internal reliability check where if reliability was low, heart rate data were not provided to the user or researchers [51-53]. After 3 weeks of training, using their assigned app for at least 10 min per day, each participant returned to the laboratory to retake the self-report questionnaires and behavioral measures of attentional control and interoceptive integration.

Before participating in the study, undergraduate students gave written informed consent. Participants were aware that their usage data (date and usage time, mood, stress, and heart rate) from each of the apps was sent anonymously via email to the researchers. Students recruited through the university's undergraduate recruitment site received course credit for their participation. Students recruited via flyers posted throughout the university received Can $10 for every hour spent in the laboratory and for using their assigned app, to a maximum of Can $90 in compensation for their participation. The research protocol was approved by the University of Toronto Social

Sciences, Humanities, and Education Research Ethics Board (REB). This study was retrospectively registered on ClinicalTrials.gov; ID: NCT03783793.

Training Conditions

Mindfulness Training App

Mindfulness training in the study was performed using a new app called Wildflowers (Mobio Interactive Inc, Toronto), which was developed in collaboration with our laboratory. This smartphone app incorporates features that have been deemed to be important to include in smartphone MT, as suggested by Mani and colleagues [37]. For example, Wildflowers includes guided meditations such as breathing, body scans, and open monitoring practices and also provides didactic content in the form of lessons and information about the benefits of MT. In addition, the app was designed to collect user's ratings of current mood and stress level as well as heart rate, before and after each guided meditation session. This feedback is aggregated and provided to the user and might be useful in providing the user with helpful insights into the physiological and psychological benefits of MT.

Using the Wildflowers app (Multimedia Appendix 1), participants were able to choose and complete a variety of guided meditations. Participants could decide on a certain mindfulness meditation through different avenues. First, they could complete a lesson on a certain type of meditation (eg, mindfulness of breath or mindfulness of body). Each lesson included (1) a fact about the particular meditation; (2) teaching the user about *snapshots* to record current mood, stress level, and heart rate; (3) a minute of flow where the participant was asked to connect with the present moment; (4) the meditation; (5) a fact on how to increase resilience such as practicing being nonjudgmental; and (6) ending with another snapshot. Instead of a lesson, participants could also choose from a library of guided meditations that are each unlocked after completing a certain number of meditations. Finally, participants could also have a guided meditation suggested to them based on their current mood and stress level.

The Wildflowers MT app is freely available in the Apple App Store and on Google Play, with additional content and features available to subscribing customers. The training experience described in this study is available through the free features on the app.

Cognitive Training With 2048

The training app for the control condition was based on an open source code for a popular cognitive training app called 2048, which is marketed by Ketchapp in the Apple app store as a "fun and relaxing puzzle game" (Multimedia Appendix 2). Within 2048, participants slide numbered tiles around a grid, matching tiles of the same value. Instead of tiles disappearing, as in *Candy Crush* or other similar grid-sliding games, matching 2 numbered tiles in 2048 combines them into 1 new tile displaying the sum of the previous 2 numbers. For example, two 2-tiles linked side-by-side become a 4-tile, whereas 2 matched 4-tiles become an 8-tile, and so on. The goal is to match tiles until the sum of 2048 is reached on a single tile. There is no time limit. Importantly, the identical in-app psychobiometric features for ratings of mood, stress, and heart rate before and after each training session were built into the control condition app to provide parity in measurement of state effects between the 2 training conditions.

Measures of Subjective Well-Being

Perceived Stress Scale

The Perceived Stress Scale (PSS) [54] is a 10-item scale that measures the global perception of stress. However, because of a question that was inadvertently missing when the 10-item PSS questionnaire was loaded onto the survey platform, Qualtrics, participants from both groups did not see or respond to this missing question during data collection. Therefore, results from the short 4-item version of the PSS were alternatively used in subsequent analyses. The 4-item PSS has demonstrated satisfactory evidence of internal consistency and convergent validity [55].

Big Five Inventory

The Big Five Inventory (BFI) [56,57] is a 44-item scale that measures the 5 dimensions of personality: extraversion, agreeableness, conscientiousness, neuroticism, and openness. Extraversion includes sociability, assertiveness, and positive emotionality. The BFI has demonstrated excellent evidence of internal consistency, test-retest reliability, and convergent validity [57,58].

Psychological Well-Being Scale

The Psychological Well-Being Scale (PWBS) [59] is an 84-item questionnaire that measures psychological well-being. This measure includes 6 subscales measuring autonomy, self-acceptance, positive relations with others, environmental mastery, purpose in life, and personal growth. The PWBS has demonstrated satisfactory evidence of internal consistency [59] and convergent validity and excellent evidence of test-retest reliability [60].

Acceptance and Action Questionnaire-II

The Acceptance and Action Questionnaire-II (AAQ-II) [17] is a 7-item scale that measures psychological inflexibility and experiential avoidance. The AAQ-II has demonstrated satisfactory evidence of internal consistency and excellent evidence of test-retest reliability and convergent validity [17].

Philadelphia Mindfulness Scale

The Philadelphia Mindfulness Scale (PHLMS) [61] is a 20-item scale that measures 2 components of mindfulness: awareness and acceptance. The PHLMS has demonstrated satisfactory evidence of internal consistency and convergent validity [61]. However, test-retest reliability has not been reported [62].

Multidimensional Assessment of Interoceptive Awareness

The Multidimensional Assessment of Interoceptive Awareness (MAIA) [63] is a 32-item scale that measures the multidimensional construct of interoceptive body awareness. This scale is made up of 8 subscales: noticing, not distracting, not worrying, attention regulation, emotional awareness, self-regulation, body listening, and trusting. The MAIA has

demonstrated satisfactory evidence of convergent validity, internal consistency [63], and test-retest reliability [44].

Spiritual Experience Index-Revised

The Spiritual Experience Index-Revised (SEI-R) [64] is a 23-item scale that measures a person's faith and spiritual journey. This scale consists of 2 subscales: the spiritual support subscale and the spiritual openness subscale. The SEI-R has demonstrated satisfactory evidence of convergent validity and excellent evidence of internal consistency [64]. However, test-retest reliability has not been reported.

Meaning in Life Questionnaire

The Meaning in Life Questionnaire (MLQ) [65] is a 10-item scale that measures 2 dimensions of the meaning in life and as such includes 2 subscales: presence of meaning and search for meaning. The MLQ has demonstrated satisfactory evidence of internal consistency, convergent validity, and test-retest reliability [65].

Mood Board Circumplex

The mood board is a visual representation of negative and positive emotions on a spectrum, ranging from intense emotions to mild emotions. This mood board provides a maximum of 32 emotions that a participant can select and yields 4 scores: degree of intense negative emotions, degree of intense positive emotions, degree of mild negative emotions, and degree of mild positive emotions. This questionnaire is currently under validation; however, the words chosen for the mood board are commonly used in other measures of mood [66,67]. In addition, previous research has demonstrated the efficacy in taking these emotion-specific measures of mood and converting them to a visual analog scale with 4 dimensions [68].

For additional details and psychometric properties for each of the questionnaires used in this study, please see Multimedia Appendix 3.

Measure of Attentional Control

Centre for Research on Safe Driving-Attention Network Test

The Centre for Research on Safe Driving-Attention Network Test (CRSD-ANT) is a 10-min version of the Attention Network Test (ANT) that measures 3 different functions of attention: alerting, orienting, and conflict monitoring [69]. Alerting involves achieving and maintaining attention to incoming stimuli, orienting involves directing attention to sensory input, and conflict monitoring involves resolving conflict among responses [70]. This behavioral task requires participants to determine whether a directional object (car) is pointing left or right, and the network scores (alerting effect, orienting effect, and conflict effect) are calculated as the difference between median response times [69,70].

Measure of Interoceptive Integration

Respiration Integration Task

The Respiration Integration Task (RIT) is a newly developed behavioral task created in our laboratory to assess interoceptive attention (see Multimedia Appendix 4 for rationale and validity evidence). In the RIT, participants view a circle on a computer screen that expands and contracts rhythmically. In each trial, participants will view 2 cycles of expansion and contraction, the reference and the target. The reference circle always expands and contracts at a fixed rate, whereas the target varies in its frequency. Participants are to report on whether the target is faster or slower than the reference. The change in the frequency of cycling begins with a large change (about 2000 ms) and employs a psychophysics staircase to determine the *just noticeable difference* of change detection. The staircase uses a *3 up/1 down* algorithm in which 3 consecutive correct responses reduce the frequency change in the subsequent trial, making it more difficult, whereas 1 incorrect response increases the frequency difference, making it easier.

The RIT has 3 phases, a vision only baseline, a respiration entraining practice period, and the respiration integration period. During the baseline, participants use vision alone to detect changes in circle frequency. Once this threshold is established, participants spend 60 seconds entraining their breath, that is, practicing matching respiration to the movement of the circle as it pulses at the reference frequency. Afterwards, in the integration period, participants repeat the task while matching their breathing to the expansion and contraction of the sphere. The visual and breath scores are calculated by taking the mean frequency across the final 6 trials from each of these conditions.

Statistical Analysis

Power

An *a priori* power analysis for the group-specific training effects was modeled as the interaction of the within-subjects factor of time (pre vs post) and the between-subjects factor of group (MT vs control). The power analysis was conducted using the G*Power software app to determine how much power would be needed to find weak-to-moderate interaction effects in this study. A moderate effect, eta-squared of 0.06 or Cohen *F* of 0.25, was assumed. It was also assumed that repeated measures scores had a moderate-to-strong correlation of .5. The analysis suggested a total N=34 for 80% power. A weaker effect of Cohen *F*=0.15 would require 90 participants, and so the study was powered conservatively for this effect, that is, we attempted to recruit approximately 45 participants in each group.

Following data analysis, a post hoc power analysis simulation, with 10,000 simulations, was conducted using the statistical platform R 3.4.3 [71] to more accurately simulate the post hoc power of the study. Scores were assumed to start at 0 and have an SD of 1 to detect a 0.5 (half deviation) change in the MT group and no true change in the control group, with an effect size *d*=0.5, which is considered moderate according to Cohen [72]. The simulation revealed this study (n=45 per group) had 65% power to detect the desired interaction effect. Using the simulation approach, the study would have needed a sample size of n=90 per group to achieve 80% power. The discrepancy between the G*Power and simulation approaches suggests a need for further research on power calculation methodology.

Data Exclusion

Participants were excluded from analysis if they did not adhere to the study protocol. Minimal adherence was defined as 10

min of practice per day, missing no more than 4 of the 21 days, and completing both the pre- and posttraining assessment measures.

Data Reduction

An exploratory factor analysis (EFA) was conducted on the scale measures listed above in the R statistical computing environment [71]. The number of factors required was first estimated using the paran library for performing Horn's parallel analysis of principal components or factors [73].

Group Comparisons

All statistical analyses were conducted using the statistical platform R 3.4.3 [71], with an alpha level of .05 for all tests. Demographics between groups were compared using a *t* test and a chi-square test. Before group comparisons, the questionnaire data were reduced using EFA to increase ease of interpretability and minimize type I error. Multilevel models were used to compare both state and trait measures of well-being between groups over time. Finally, the relationship between the state and trait measures of well-being were investigated through correlations.

Results

Participants

As shown in the participant flow diagram for the study (Figure 1), the final sample included 41 participants in the cognitive training group (mean age 19.78 [SD 2.43], 88% female) and 45 participants in the MT group (mean age 20.24 [SD 2.63], 80% female). A *t* test revealed that the groups did not significantly differ in terms of age ($t_{82.86}$=−0.85, 95% CI −1.56 to 0.62; *P*=.40), and a chi-square test revealed that the groups did not significantly differ in terms of gender (χ^2_2=5.5, *P*=.06). On average, participants practiced a total of 16.32 days (cognitive training=16 days and MT=16.59 days), 20.21 sessions (cognitive training=19.54 sessions and MT=20.74 sessions), and 5.05 hours (cognitive training=4.46 hours and MT=5.57 hours).

Statistical Analysis Assumptions

The data were inspected to make sure that assumptions that could affect the interpretation of the results were satisfied. Inspection of the normality of residuals, influential cases, autocorrelation of residuals, and homogeneity of variances revealed no major violation of assumptions (see Multimedia Appendix 5).

Data Reduction

Before conducting the EFA, the factorability of the 31 questionnaire subscales in this study was examined. It was determined that all of the subscales were suitable to include in the EFA (see Multimedia Appendix 5). Horn's parallel analysis of principal components [73] suggested that 4 factors should be retained in the EFA (Multimedia Appendix 6); however, as the fourth factor was well below the random eigenvalues generated during the analysis test, a 3-factor solution was chosen to be more suitable. The EFA was conducted using ordinary least squares to find the minimum residual solution using the psych package [74] in R, and an oblique rotation method, promax, was used to allow for correlations between factors.

The 3-factor solution (Table 1) explained 42.5% of the shared variance. It was determined that factor 1 (eigenvalue=6.45) was best labeled as acceptance, as this factor included subscales measuring acceptance and not avoiding or worrying about psychological discomfort. Factor 2 (eigenvalue=4.34) was best labeled as awareness because of the inclusion of subscales measuring psychological and physical awareness and attention regulation.

Figure 1. Participant flow diagram.

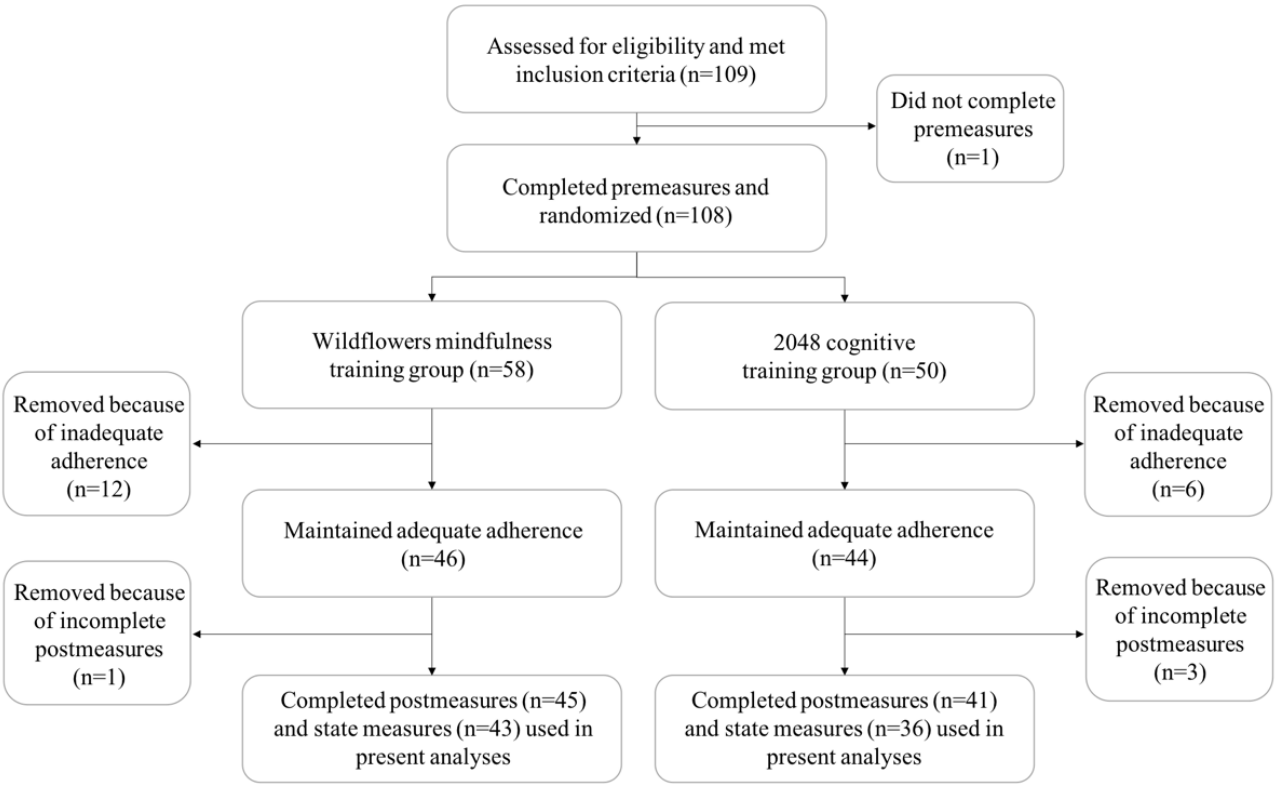


Table 1. Factor loadings of well-being questionnaires entered into the exploratory factor analysis.

Scale/subscale	Acceptance factor loadings	Awareness factor loadings	Openness factor loadings
PSS[a]-short version	−0.67[b]	0.06	−0.13
BFI[c]/Extraversion	0.38[b]	0.20	0.06
BFI/Agreeableness	0.29	0.32[b]	0.01
BFI/Conscientiousness	0.41[b]	0.04	0.26
BFI/Neuroticism	−0.65[b]	0.08	−0.06
BFI/Openness	−0.05	0.33	0.42[b]
PWBS[d]/Autonomy	0.50[b]	−0.01	0.38
PWBS/Environmental Mastery	0.76[b]	0.03	0.21
PWBS/Personal Growth	0.21	0.20	0.46[b]
PWBS/Positive Relations with Others	0.47[b]	0.25	−0.02
PWBS/Purpose in Life	0.65[b]	0.15	0.15
PWBS/Self-Acceptance	0.84[b]	−0.04	0.17
AAQ-II[e]	0.87[b]	−0.10	−0.01
PHLMS[f]/Awareness Subscale	−0.15	0.66[b]	0.20
PHLMS/Acceptance Subscale	0.73[b]	−0.30	−0.06
MAIA[g]/Noticing	−0.15	0.82[b]	−0.04
MAIA/Not Distracting	0.48[b]	−0.07	−0.23
MAIA/Not Worrying	0.35[b]	−0.17	0.26
MAIA/Attention Regulation	0.10	0.66[b]	0.08
MAIA/Emotional Awareness	−0.18	0.90[b]	0.02
MAIA/Self-Regulation	0.01	0.68[b]	0.11
MAIA/Body Listening	−0.04	0.66[b]	0.00
MAIA/Trusting	0.39	0.52[b]	0.09
SEI-R[h]/Support	0.05	0.24[b]	−0.11
SEI-R/Openness	0.19	0.12	0.36[b]
MLQ[i]/Presence of Meaning	0.59[b]	0.17	−0.13
MLQ/Search for Meaning	−0.40[b]	0.40	0.04
Mood Board/Intense Negative Emotions	−0.45	− 0.13	0.54[b]
Mood Board/Mild Negative Emotions	−0.56[b]	−0.12	0.47
Mood Board/Intense Positive Emotions	0.08	0.00	0.66[b]
Mood Board/Mild Positive Emotions	0.00	0.00	0.61[b]

[a]PSS: Perceived Stress Scale.

[b]Represents the strongest loadings for each latent factor.

[c]BFI: Big Five Inventory.

[d]PWBS: Psychological Well-Being Scale.

[e]AAQ-II: Acceptance and Action Questionnaire-II.

[f]PHLMS: Philadelphia Mindfulness Scale.

[g]MAIA: Multidimensional Assessment of Interoceptive Awareness.

[h]SEI-R: Spiritual Experience Index-Revised.

[i]MLQ: Meaning in Life Questionnaire.

Finally, factor 3 (eigenvalue=2.38) was best labeled as openness and included subscales measuring openness, personal growth, and the reporting of both negative and positive emotions. For the reliability analysis, a subscale was considered to be a part of a factor if its loading was greatest for that factor, relative to the other factors (values that show strongest loadings for each latent factor are shown in Table 1). Each of the factors demonstrated good evidence of internal reliability; the acceptance factor had an internal reliability of alpha=.89, the awareness factor had an internal reliability of alpha=.86, and the openness factor had an internal reliability of alpha=.70. In addition, acceptance and awareness (r=.32), acceptance and openness (r=.21), and awareness and openness (r=.35), each demonstrated a positive relationship with each other.

Longitudinal Training Effects

Subjective Well-Being

To test the hypothesis that trait well-being would improve over time as a result of MT, each of the 3 factors (acceptance, awareness, and openness) were analyzed in a multilevel model using the nlme package [75] in R.

Each of the 3 factors from the EFA were modeled as a function of time (pre- vs posttraining) and group (MT vs cognitive training). In addition, pairwise follow-up comparisons, Tukey Honest Significant Difference test corrected for multiple comparisons, using least-squares means were conducted using the lsmeans function from the lsmeans package [76] in R.

Analysis of subjective well-being data revealed a significant main effect of time for the acceptance factor (Table 2 and Multimedia Appendix 7) as well as a trend toward an interaction between time and group. Follow-up comparisons suggested that this marginal interaction was driven by a significant increase in acceptance (lsmean difference −0.42 [SE 0.08]; t_{84}=−5.02; P<.001) from pre- to posttraining for participants in the MT condition. In addition, a trend was observed where participants at postcognitive training had lower levels of acceptance than the participants at post-MT (lsmean difference −0.52 [SE 0.20]; t_{84}=−2.56; P=.06).

A significant main effect of time was observed for the awareness factor (Table 2 and Multimedia Appendix 7). Follow-up comparisons revealed that from pre- to post-MT, participants demonstrated increased levels of awareness (lsmean difference −0.43 [SE 0.11]; t_{84}=−3.98; P<.001). In addition, from pre- to postcognitive training, participants demonstrated increased levels of awareness (lsmean difference −0.30 [SE=0.11]; t_{84}=−2.65; P=.046).

There was no main effect of time or interaction between time and group observed for the openness factor (Table 2 and Multimedia Appendix 7). A main effect of group was observed, suggesting that randomization failed to equate openness. However, the effects for the acceptance and awareness factors were maintained after controlling for openness in the earlier analyses.

Uncorrected multilevel models were conducted for each of the individual questionnaire subscales (Multimedia Appendix 8). The results from these multilevel models mirror the results observed for the acceptance, awareness, and openness latent factors, suggesting that these 3 factors are an accurate summary of the well-being questionnaires.

Attentional Control

To test the hypothesis that attentional control would improve as a result of MT, each of the 3 network scores from the CRSD-ANT (orienting effect, alerting effect, and conflict effect) were analyzed in a multilevel model. Each of the network scores were modeled as a function of time (pre- vs posttraining) and group (MT vs cognitive training). In addition, pairwise follow-up comparisons were conducted.

Analysis of the CRSD-ANT revealed no main effects or interactions for the alerting effect (Table 2 and Multimedia Appendix 7) or for the orienting effect (Table 2 and Multimedia Appendix 7).

A significant interaction between time and group was observed for the conflict effect (Table 2 and Figure 2). Follow-up comparisons revealed that this interaction was driven by significant improvements in the conflict effect from pre- to posttraining for participants in the MT group (lsmean difference 0.37 [SE 0.14]; t_{84}=2.63; P=.05), but there was no evidence of change in the active control group.

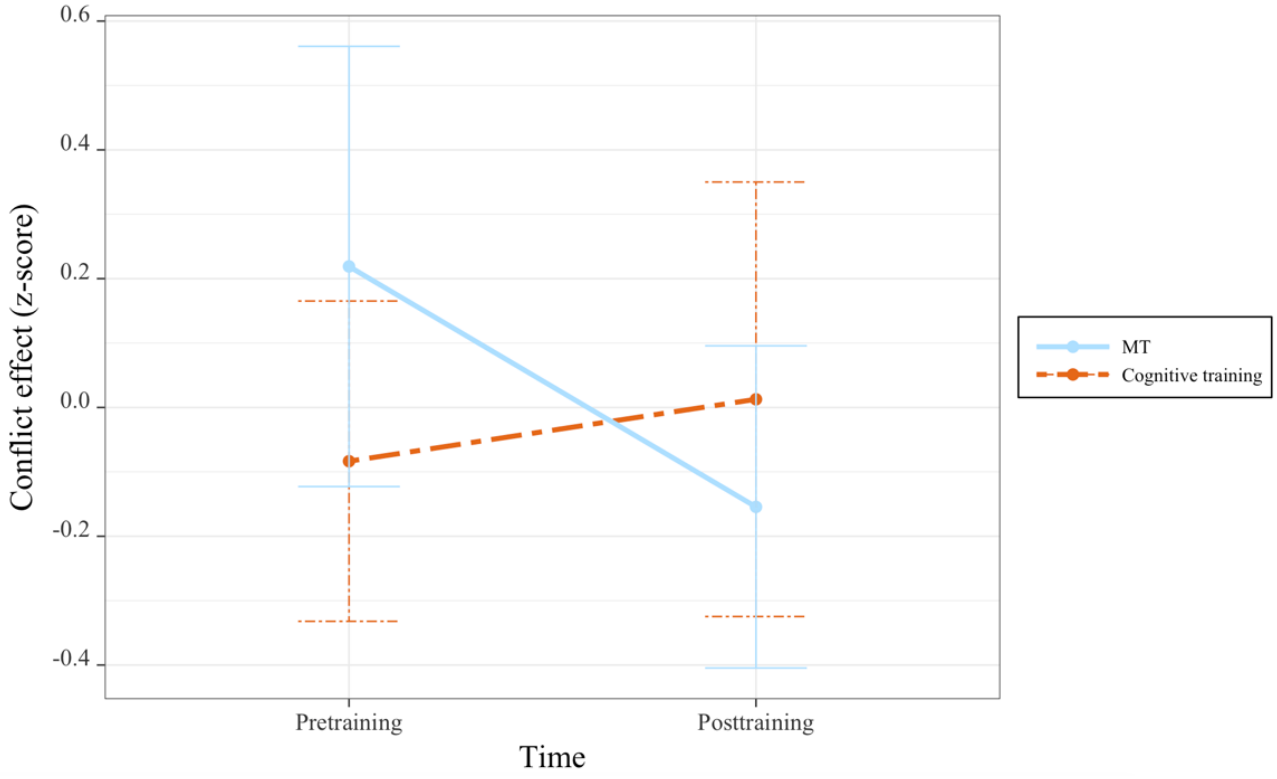
Table 2. Multilevel models of trait well-being measures.

Dependent and independent variable	Estimate (SE)	*t* value (*df*)	*P* value	Pearson *r* effect size
Acceptance				
Time	0.19 (0.09)	2.12 (84)	.04[a]	0.23
Group	0.28 (0.20)	1.40 (84)	.17	0.15
Time×group	0.24 (0.12)	1.93 (84)	.06[b]	0.21
Awareness				
Time	0.30 (0.11)	2.65 (84)	.01[a]	0.28
Group	0.26 (0.20)	1.28 (84)	.20	0.14
Time×group	0.13 (0.15)	0.83 (84)	.41	0.10
Openness				
Time	0.04 (0.10)	0.43 (84)	.67	0.05
Group	0.47 (0.19)	2.49 (84)	.01[a]	0.26
Time×group	−0.07 (0.14)	−0.50 (84)	.62	−0.05
Alerting effect				
Time	−0.03 (0.19)	−0.14 (84)	.89	−0.02
Group	−0.09 (0.22)	−0.43 (84)	.67	−0.05
Time×group	0.37 (0.26)	1.43 (84)	.16	0.15
Orienting effect				
Time	−0.03 (0.18)	−0.18 (84)	.85	−0.02
Group	−0.10 (0.22)	−0.45 (84)	.65	−0.05
Time×group	0.36 (0.25)	1.43 (84)	.16	0.15
Conflict monitoring				
Time	0.10 (0.15)	0.65 (84)	.52	0.07
Group	0.30 (0.22)	1.40 (84)	.16	0.15
Time×group	−0.47 (0.21)	−2.29 (84)	.02[a]	−0.24

[a]Represents significant findings.

[b]Represents marginal findings.

Figure 2. Changes in conflict effect before and after mindfulness training (MT) and cognitive training.



Interoceptive Integration

To test the hypothesis that behavioral interoceptive attention would improve as a result of MT, participants' scores from the RIT were analyzed in a multilevel model, modeled as a function of group (MT vs cognitive training), time (pre- vs posttraining), and condition (visual baseline vs breath integration). In addition, pairwise follow-up comparisons were conducted.

This analysis revealed a main effect of condition for the RIT, with the breath condition associated with better detection thresholds than the visual baseline condition (Table 3 and Figure 3). However, the results showed no indication of MT effects over time.

State Training Effects

Subjective Well-Being

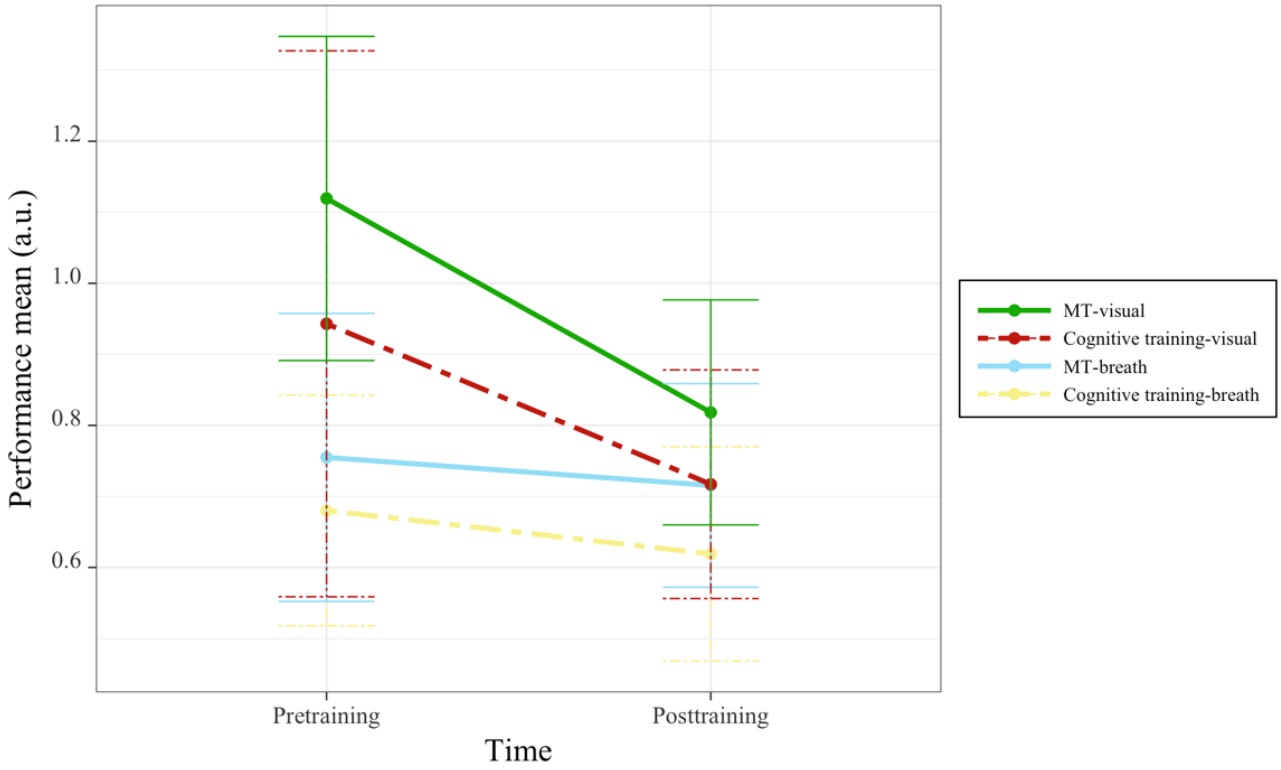
To test the hypothesis that participants in the MT group would demonstrate immediate effects on well-being, each of the in-app measures (mood, stress, and heart rate) were analyzed in a multilevel model. Each of these measures were modeled as a function of group (MT vs cognitive training), time (multiple training sessions per participant), and session (before vs after each training session), with subject, time, and session as random intercepts.

Table 3. Multilevel model of respiration integration task performance.

Independent variable	Estimate (SE)	*t* value (*df*)	*P* value	Pearson *r* effect size
Time	−0.06 (0.13)	−0.50 (213)	.62	−0.03
Group	0.09 (0.15)	0.57 (83)	.57	0.06
Condition	0.26 (0.12)	2.16 (213)	.03[a]	0.15
Time×group	0.02 (0.17)	0.12 (213)	.91	0.01
Time×condition	−0.16 (0.18)	−0.94 (213)	.35	−0.06
Group×condition	0.10 (0.17)	0.60 (213)	.55	0.04
Time×group×condition	−0.10 (0.24)	−0.41 (213)	.68	−0.03

[a]Represents significant findings.

Figure 3. Changes in respiratory integration task performance by task condition, group, and time. MT: mindfulness training.



Analysis revealed a significant interaction between group and session on mood (Table 4 and Figure 4). Follow-up comparisons revealed that participants in the MT group demonstrated a significant improvement in mood after each training session (lsmean difference −0.51 [SE 0.03]; t_{1190}=−15.15; P<.001), whereas participants in the cognitive training group did not.

A significant main effect of group; an interaction between group and session; and 3-way interaction between time, group, and session were demonstrated for ratings of stress level (Table 4 and Figure 5). Being a part of the MT group was generally associated with lower stress, even before practice sessions: follow-up comparisons revealed that participants in the MT group relative with the cognitive training group demonstrated significantly lower levels of subjective stress both in pretraining (lsmean difference 0.44 [SE 0.14]; t_{76}=3.11; P<.01) and posttraining sessions (lsmean difference 0.91 [SE 0.14]; t_{76}=6.42; P<.001). For the group by session interaction, follow-up comparisons revealed that participants in the MT group demonstrated a significant decrease in stress levels after each training session (lsmean difference 0.43 [SE 0.02]; t_{1190}=17.96; P<.001), whereas participants in the cognitive training group did not. For the 3-way interaction, significant reductions of stress over time were uniquely observed for participants in the MT group posttraining session (beta=−0.01 [SE 0.004]; t_{616}=−2.65; P<.01; r=−.11), but such time effects were neither observed pretraining in the MT group nor at pre- or posttraining for the cognitive training group. Together, these results indicate participants in the MT training group began daily training sessions with less overall stress, MT sessions uniquely produced a further reduction in stress, and the impact of training sessions in the MT group uniquely increased over the 3-week training period.

Table 4. Multilevel models of state measures of well-being.

Dependent variable and independent variable	Estimate (SE)	*t* value (*df*)	*P* value	Pearson *r* effect size
Mood				
Time (days)	−0.01 (0.01)	−1.65 (1117)	.10	−0.05
Group	−0.01 (0.15)	−0.07 (76)	.95	−0.01
Session (pre vs post)	0.02 (0.07)	0.31 (1190)	.75	0.01
Time×group	0.01 (0.01)	0.85 (1117)	.40	0.03
Time×session	0.004 (0.01)	0.63 (1190)	.53	0.02
Group×session	0.47 (0.09)	4.99 (1190)	<.001[a]	0.14
Time×group×session	−0.002 (0.01)	−0.21 (1190)	.84	−0.01
Stress				
Time (days)	−0.004 (0.01)	−0.75 (1117)	.45	−0.02
Group	−0.55 (0.16)	−3.48 (76)	.001[a]	−0.37
Session (pre vs post)	−0.01 (0.05)	−0.14 (1190)	.89	−0.004
Time×group	0.01 (0.01)	1.43 (1117)	.15	0.04
Time×session	0.01 (0.004)	1.13 (1190)	.26	0.03
Group×session	−0.31 (0.07)	−4.66 (1190)	<.001[a]	−0.13
Time×group×session	−0.02 (0.01)	−2.78 (1190)	.005[a]	−0.08
Heart rate				
Time (days)	0.001 (0.01)	0.17 (1064)	.86	0.01
Group	−0.08 (0.14)	−0.54 (75)	.59	−0.06
Session (pre vs post)	−0.01 (0.09)	−0.10 (1067)	.92	−0.003
Time×group	0.01 (0.01)	0.63 (1064)	.53	0.02
Time×session	0.01 (0.01)	1.72 (1067)	.09	0.05
Group×session	0.13 (0.13)	1.02 (1067)	.31	0.03
Time×group×session	−0.03 (0.01)	−2.18 (1067)	.03[a]	−0.07

[a]Represents significant findings.

Figure 4. Changes in mood before and after each training session over the course of training. MT: mindfulness training.

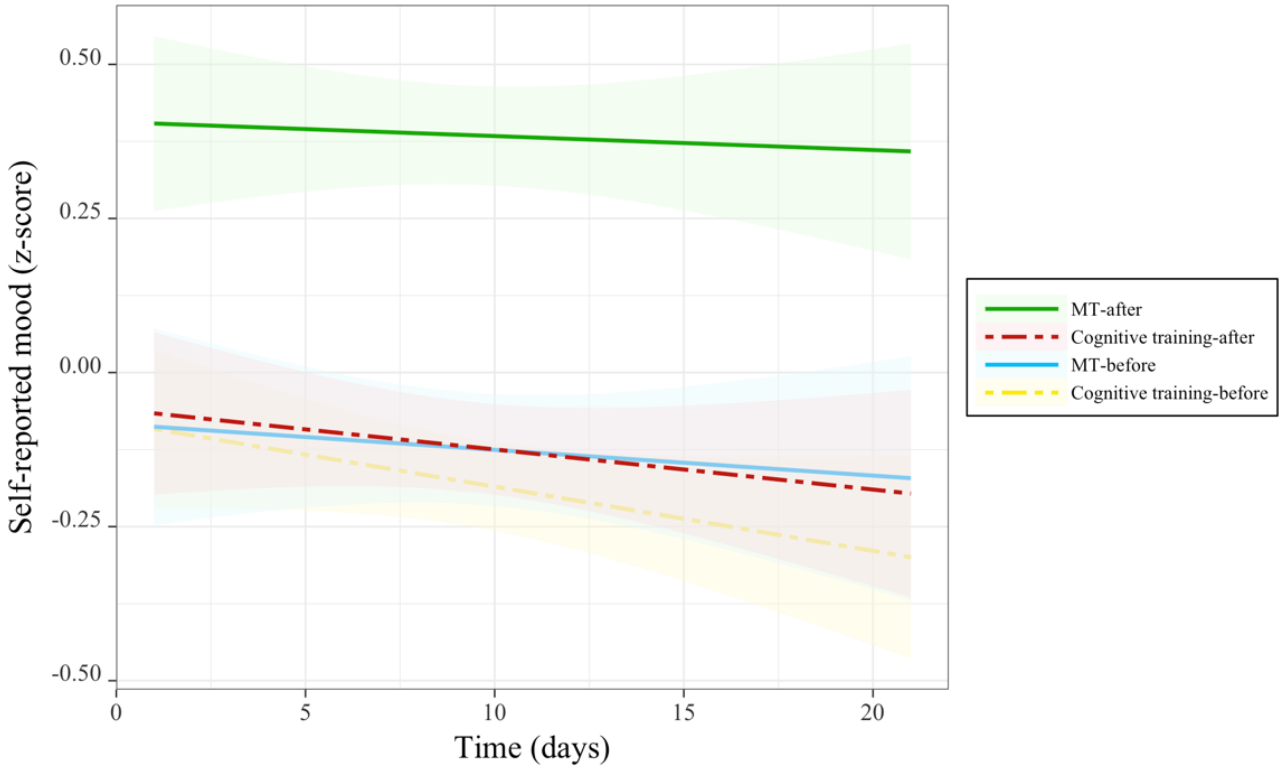


Figure 5. Changes in stress before and after each training session over the course of training. MT: mindfulness training.

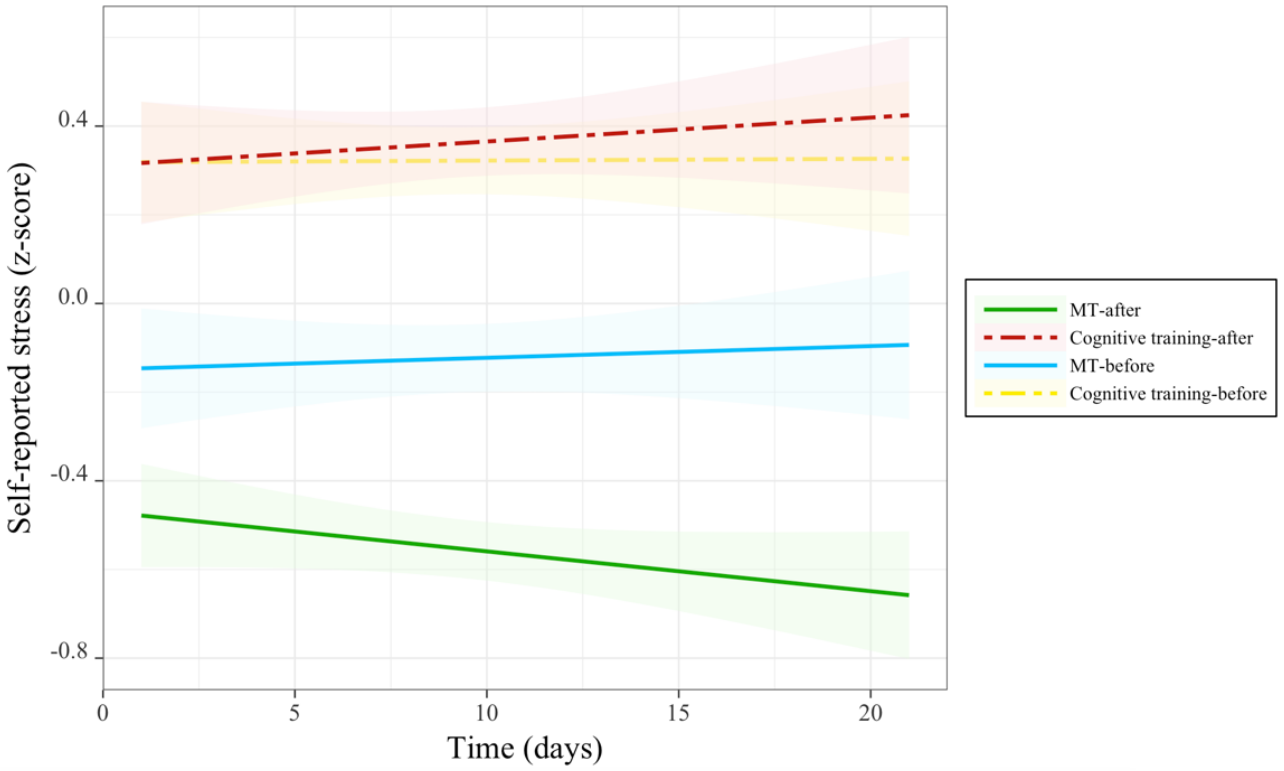
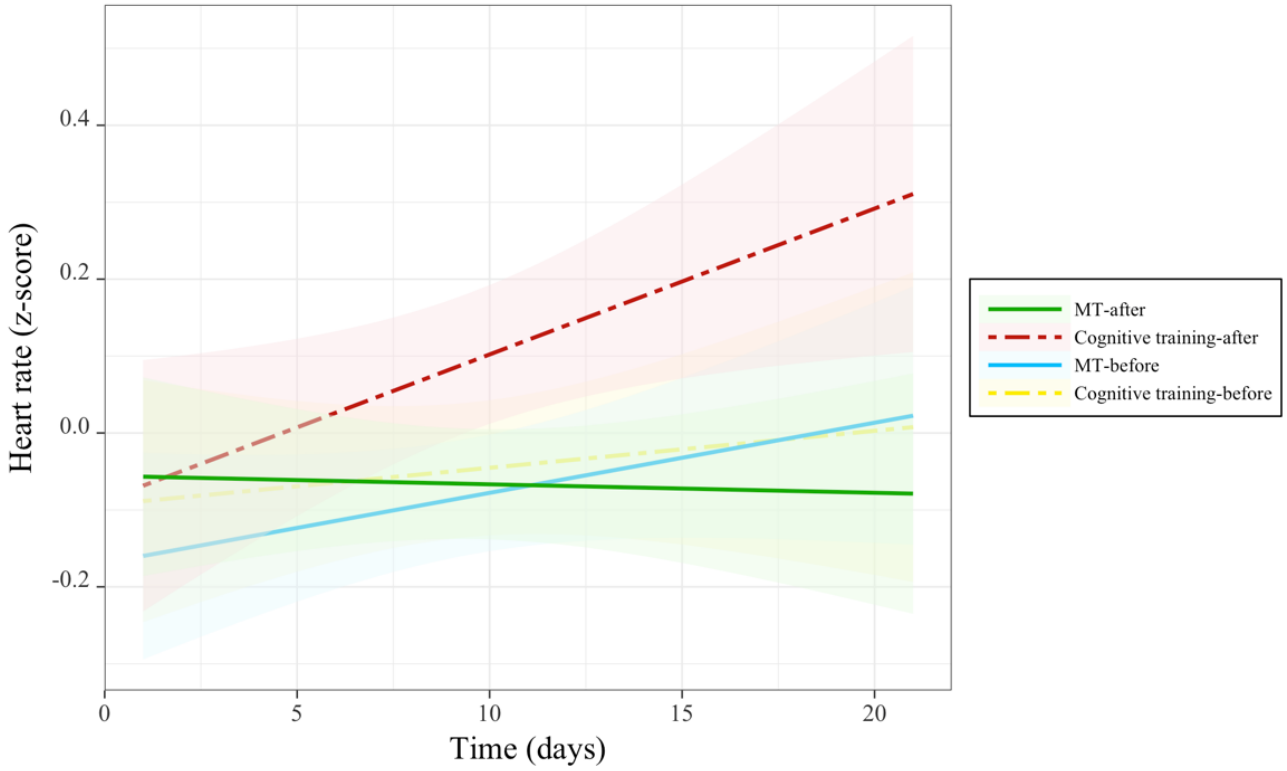


Figure 6. Changes in heart rate before and after each training session over the course of training. MT: mindfulness training.



A significant 3-way interaction between time, group, and session was observed for heart rate (Table 4 and Figure 6). Follow-up comparisons revealed that this interaction was driven by participants in the cognitive training group, for whom posttraining heart rate increased over the course of the training period (beta=−0.02 [SE 0.01]; t_{1011}=−2.03; P<.04; r=−.06), whereas pretraining heart rate in the cognitive training group and both pre- and posttraining heart rate in the MT group did not change with time. These results suggest that the cognitive training became increasingly arousing in terms of heart rate over the study period, but no such effects were associated with MT.

Association Between Trait and State Measures of Well-Being

An exploratory analysis of the associations between change scores for the trait measures (pre- and posttraining) and change scores for the state measures (pre- and postpractice session) were conducted via correlation analysis. Results (Table 5) revealed significant relationships between state and trait measures of well-being: changes in acceptance with changes in mood, changes in acceptance with changes in stress, and changes in orienting effect with changes in heart rate. In addition, there were significant relationships within trait measures such as changes in conflict effect with changes in acceptance and changes in orienting effect with changes in acceptance.

Table 5. Correlations between state (pre- and postsession) and trait (pre- and postintervention) measures of well-being change.

State and trait well-being	State well-being			Trait well-being					
	Heart Rate	Stress	Mood	Accept[a]	Aware[b]	Open[c]	Alerting	Orienting	Conflict
Stress	−.19								
Mood	−.17	−.34[d]							
Acceptance	−.18	−.34[e]	.42[d]						
Awareness	.01	−.17	.20	.25[e]					
Openness	.18	−.08	.19	.14	.40[f]				
Alerting	−.47[e]	.11	−.07	−.06	−.12	−.09			
Orienting	.06	−.22	.25	.22[e]	.02	−.01	.22[e]		
Conflict	.03	.11	−.10	.29[d]	−.04	−.01	.14	.13	
Group	−.33	−.61[f]	.57[f]	.21	.09	−.05	.15	.15	−.24[e]

[a]Accept: acceptance.

[b]Aware: awareness.

[c]Open: openness.

[d]*P* value<.01.

[e]*P* value<.05.

[f]*P* value<.001.

Discussion

Principal Findings

This was the first actively controlled study to investigate whether MT apps can promote the therapeutic effects associated with validated group MT interventions, namely, subjective well-being, attentional control, and interoceptive integration. A data-driven approach was used to allow for a broad canvassing of well-being, while also providing a parsimonious interpretation of observed changes in well-being. This approach yielded 3 latent factors: acceptance, awareness, and openness. The clear distinction between loadings onto an acceptance and awareness factor reflect the 2 subfactors of the PHLMS [61], suggesting that these latent variables provided an accurate summary of well-being domains associated with MT. In addition, the openness factor provided a new source of variability that is not commonly measured separately in a mindfulness study.

Subjective well-being was assessed both in terms of trait (pre- and posttraining) and state (pre- and postpractice session) self-reports. A trend toward MT-specific changes in acceptance from pre- to posttraining was observed, and closer inspection of the data suggested that the MT group might have driven a general increase in acceptance over time. This result was complemented by MT effects at the state level; relative to the cognitive training group, participants in the MT group demonstrated improved mood and reduced stress following each training session. Importantly, changes in acceptance across the intervention were correlated with session-specific changes in stress and mood. Although the overall effect of training on acceptance was weak, this is one of the first documented reports of state-effects of meditation contributing to interventional level effects on dispositional mindfulness.

These findings are consistent with a broader literature in which dispositional acceptance has been associated with reduced experiential avoidance [15-17], decreased negative affect, and reduced stress reactivity [77,78]. At the state level, brief mindfulness interventions have been linked to beneficial effects on stress and mood [24,48]. However, few studies have described how changes at the dispositional or trait level relate to individual training session effects. Here, we provide some of the first evidence that it is precisely these session-level effects on mood and stress appraisals that manifest as trait-like changes in distress tolerance. Specifically, it seems that app-guided MT may have immediate effects on mood and stress and that these effects help to explain broader changes in the self-appraised capacity to cope with negative experiences. Such a finding is in keeping with the principles of MT in which practitioners are taught to engage rather than avoid negative emotions and reduce their impact on more general mood and stress appraisals. Encouragingly, the beneficial impact of MT on subjective stress in the MT group increased over time. This effect is evidenced by a significant decline over the course of training in postsession stress levels for the MT group. Therefore, over a longer time course, accumulating state effects of MT practice may support greater changes in acceptance, especially with greater adherence to practice than what was observed in this study; however, further research is warranted to support this hypothesis.

Contrary to the study hypotheses, participants in the MT and cognitive training groups reported significant increases in both acceptance and awareness over the study period. One explanation for this finding may be the fact that participants in both groups recorded their mood and stress levels before and after each training session. Research has shown that recording mood and stress in and of itself may contribute to improvements in negative symptomatology by increasing emotional

self-awareness [79] and could promote acceptance of negative emotion by exposing participants to the natural variation in daily affective experience. Both groups performed daily ratings on mood and stress before and after each training session, a reflective practice that could itself foster awareness and insight around emotional experience. Furthermore, the general increase in acceptance and awareness may help to explain why MT-specific increases in acceptance were so modest: change acceptance and awareness were moderately correlated and the active control group may have benefitted from the increased awareness inherent to a daily reflection study design. This result not only suggests a benefit to even minimal daily reflection on emotional experience but also supports the importance of including an active control group in contemplative research. Without such a control group, the increase in awareness in the MT group may have suggested that this change was related to the mindfulness component in the MT smartphone app. However, with the cognitive training group in the study, it was possible to further ascertain benefits unique to MT above and beyond general effects of the daily reflection paradigm.

There were no training effects for either group observed for the openness factor. This result is not entirely surprising in the context of research that has shown that those who choose to practice mindfulness demonstrate greater openness [80], and openness was not predicted a priori to emerge as a factor for analysis. In this study, participants in the MT group demonstrated overall greater openness than participants in the cognitive training group. However, openness did not appear to be impacted by training in either group, and controlling for individual differences in openness did not alter the other study findings. As participants were unaware of randomization condition at baseline assessment, it is unlikely that the group difference was caused by experimental condition and more likely reflects the difficulty in equating all study variables through random assignment.

Attentional control was assessed on a trait level using the CRSD-ANT, which yielded alerting, orienting, and conflict effect scores. Analyses revealed training effects specific to MT; relative to the cognitive training group, 3 weeks of MT led to greater improvements in conflict monitoring. However, training effects were not observed for alerting effect or orienting effect. These results are in line with Tang and colleagues [49] who measured attentional control using the 20-min version of the ANT and found that after 5 days of integrated body-mind training (IBMT), which included MT along with several other body-mind techniques, participants in the IBMT condition demonstrated improvements in executive functioning relative to the relaxation group. In addition, no differences in orienting effect or alerting effect were found. Similarly, Zeidan and colleagues [23] found improvements in executive functioning after 4 days of MT relative to an active control group, and Ainsworth and colleagues [81] found improvements in executive function after focused attention and open monitoring MT, relative to a control group. The present results are also reflected in studies comparing naïve meditators with experienced meditators, which have found that experienced meditators demonstrate greater cognitive flexibility [82-84]. Taken together, the results of this study suggest that using an MT app may provide similar benefits as other MT interventions for increasing attentional control and cognitive flexibility.

Conflict monitoring, also known as executive attention or switching [85], is a form of attention regulation that includes self-regulation (cognitive, emotion, and behavior) [85,86]. In this study, improvements in conflict monitoring observed in the MT group may reflect improved self-regulation skills, and indeed, changes in conflict monitoring scores were moderately correlated with changes in acceptance. Improved self-regulation skills have been associated with improvements in trait mindfulness [87], which in this study may be evidenced by the significant positive correlation observed between conflict monitoring and acceptance. Moreover, previous research has found that greater emotional acceptance may mediate the effects of MT on executive control [88]. Although here both the MT and cognitive training groups demonstrated an equivalent increase in acceptance, with a larger sample or dose of MT, it is possible that MT-specific enhancement in conflict monitoring may promote later MT-specific increases in acceptance.

Interoceptive attention was assessed with the respiration integration task. In terms of interoceptive attention, there were no training effects. However, participants in both groups demonstrated greater accuracy when using their breath to judge the circle rather than just using their visual abilities. These results suggest that interoceptive attention might facilitate accuracy on discrimination tasks but that such attention was not particularly impacted by the training paradigm.

Only 1 unique effect of cognitive training was observed: participants in the cognitive training group demonstrated an increase in heart rate over time postpractice session but not for the prepractice session or pre- and postpractice in the MT group. This result may suggest that with an increased focus on negative symptoms during mood monitoring, participants in the cognitive training group may have experienced increased negative reactivity [89]. However, the cognitive training group did not demonstrate concurrent changes in mood or stress. Therefore, the results of this study may also suggest that as participants continued to play the cognitive training game, they may have become increasingly engaged with beating past performance and gaining a sense of achievement. It is not possible to conclude why postpractice heart rate was increasingly elevated for participants in the cognitive training group, but these results suggest that not all forms of physiological arousal are diagnostic of changes to mood or stress reactivity.

It is interesting that changes in heart rate were not observed for the MT group, especially as previous research has found decreases in heart rate following the completion of an 8-week mindfulness-based intervention [90]. However, this result highlights the fact that MT is not inherently *relaxing*. Instead, people may experience distress during MT as they initially approach difficult emotions, even if they experience less distress at the end of their practice [4], as observed in this study. Moreover, it has been shown that MT can concurrently decrease psychological distress and increase subjective energy levels [91]. Taken together, the results of this study suggest that changes in heart rate may not be required to reduce subjective stress levels.

Limitations

Although this study provides evidence for the beneficial effects of MT using a smartphone app, there are several limitations that should be noted. First, studying app training inherently reduces the generalizability of findings to the richest segments of the global population. More specifically, our sample was limited to participants with Apple devices. Second, this study used a female-dominated sample, a factor that may also reduce generalizability. However, these limitations highlight the importance of replicating the present results across different operating devices and with a more diverse participant group. Third, although practice was monitored, participants were only reminded to practice if they missed 3 consecutive days. Therefore, participants did not necessarily practice with their assigned app (Wildflowers or 2048) every day, which might affect the extent of the significant findings observed. On the other hand, this limitation adds more ecological validity to this study as people in the real world would not be monitored closely to ensure they are practicing every day. Fourth, state mindfulness was not measured during daily training sessions, so it is hard to know if the benefits to mood and stress observed were a result of transiently increased state mindfulness or a result of another factor that was not considered in this study. However, a study design that promotes daily reflection on state mindfulness may have introduced further unintended training effects to the control group. Fifth, although the results strongly support benefits of MT on state measures of subjective well-being, the marginal pre- to postintervention results on the acceptance factor make it inappropriate to draw strong conclusions about the relative efficacy of MT relative to active control. These marginal results may be because of the power of this study or to the short intervention time of only 3 weeks. Although the *a priori* power analysis suggested adequate power, a post hoc simulation-based power analysis suggested that the study was underpowered for addressing these group by time interactions. Therefore, a future study with better power, and over a longer period, should attempt to replicate and extend our understanding of the relationship between the state and trait well-being factors. Sixth, it is possible that participants in the cognitive training group may have used their assigned app as a form of avoidance from daily stressors, which could have contributed to the increase in acceptance and awareness observed in this study. However, if participants were using the cognitive training app as a source of experiential avoidance, it would be expected that state stress ratings would have been reduced after a cognitive training session. Therefore, although it is not completely clear why changes in acceptance and awareness were observed in this group, it is more likely that these changes are related to increases in emotional self-awareness when recording mood and stress levels before each use of the app [79]. Finally, although the data were reduced with an exploratory factor analysis, a number of statistical models were still conducted to test each of the outcome variables. However, a binomial test was conducted, which indicated that the probability of finding the number of significant results observed in this study was low (P<.001; 95% CI 0.11-0.36).

Future Directions

This study provides preliminary evidence on the benefits of using an MT smartphone app. These findings suggest that future work should continue to investigate the benefits of MT apps in clinical populations. In addition, future studies should investigate the longitudinal effects of using MT apps. Finally, the results of this study on improvements in attention regulation warrant studies exploring neural changes as a result of MT using a smartphone app. For example, Tang and colleagues observed that 2 weeks of brief mindfulness training altered the resting state functional connectivity of large-scale brain networks [92]. Therefore, it may be fruitful for future studies to explore both the self-reported, behavioral, and neural benefits of MT using a smartphone app.

Conclusions

The results of this study suggest that MT with a smartphone app may provide immediate effects on mood and stress while also providing long-term benefits for attentional control. Although further investigation is warranted, there is evidence that with continued usage, MT via a smartphone app may provide long-term benefits in changing how one relates to his or her inner and outer experiences.

Conflicts of Interest

BJS is the Chief Scientist and CEO of Mobio Interactive Inc, and he owned approximately 40% of the company at the time of manuscript acceptance. BJS exclusively served as a technical liaison for the study and did not contribute to study design, did not contribute to selecting the active control, or the primary surveys, nor did he directly contribute to, or have influence over, data collection or analysis. NASF is a scientific advisor and mindfulness guide for Mobio Interactive Inc, and he owned approximately 2% of the company at the time of manuscript acceptance. NASF was involved in all aspects of study design and data analysis, but did not directly contribute to, or have influence over, data collection; nor did he directly perform any of the analyses. No other authors have connections to Mobio Interactive Inc. None of the authors in this study received financial compensation or any other form of compensation for the research undertaken herein. Mobio Interactive Inc did, however, contribute Can $5000 to the Ontario Centre of Excellence research grant that, in part, funded this study, as mandated by the funding agency.

Editorial notice: This randomized study was only retrospectively registered. The editor granted an exception of ICMJE rules for prospective registration of randomized trials because the risk of bias appears low and the study was considered formative. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Multimedia Appendix 1

Screenshots of Wildflowers mindfulness training condition.

[PDF File (Adobe PDF File), 2MB - mental_v6i1e10844_app1.pdf]

Multimedia Appendix 2

Screenshots of 2048 cognitive training control conditions.

[PDF File (Adobe PDF File), 283KB - mental_v6i1e10844_app2.pdf]

Multimedia Appendix 3

Additional details and psychometric properties of the questionnaires.

[PDF File (Adobe PDF File), 69KB - mental_v6i1e10844_app3.pdf]

Multimedia Appendix 4

Theoretical rationale for the newly developed respiration integration task.

[PDF File (Adobe PDF File), 83KB - mental_v6i1e10844_app4.pdf]

Multimedia Appendix 5

Additional details for statistical analyses.

[PDF File (Adobe PDF File), 492KB - mental_v6i1e10844_app5.pdf]

Multimedia Appendix 6

Scree plot of Horn's Parallel Analysis of Principal Components used to determine the appropriate factor solution for the exploratory factor analysis.

[PDF File (Adobe PDF File), 144KB - mental_v6i1e10844_app6.pdf]

Multimedia Appendix 7

Multilevel model figures for acceptance, awareness, openness, alerting, and orienting.

[PDF File (Adobe PDF File), 389KB - mental_v6i1e10844_app7.pdf]

Multimedia Appendix 8

Multilevel model results for the individual questionnaire subscales.

[PDF File (Adobe PDF File), 66KB - mental_v6i1e10844_app8.pdf]

Multimedia Appendix 9

CONSORT‐EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 589KB - mental_v6i1e10844_app9.pdf]

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Abbreviations

AAQ-II: Acceptance and Action Questionnaire-II
ANT: Attention Network Test
BFI: Big Five Inventory
CRSD-ANT: Centre for Research on Safe Driving Attention Network Test
EFA: exploratory factor analysis
IBMT: integrated body-mind training
MAIA: Multidimensional Assessment of Interoceptive Awareness
MBCT: mindfulness-based cognitive therapy
MBSR: mindfulness-based stress reduction
MLQ: Meaning in Life Questionnaire
MT: mindfulness training
PHLMS: Philadelphia Mindfulness Scale
PSS: Perceived Stress Scale
PWBS: Psychological Well-Being Scale
REB: Research Ethics Board
RIT: Respiration Integration Task
SEI-R: Spiritual Experience Index-Revised

Edited by G Eysenbach; submitted 20.04.18; peer-reviewed by L Chittaro, A Daros; comments to author 02.09.18; revised version received 23.09.18; accepted 01.11.18; published 08.01.19.

Please cite as:
Walsh KM, Saab BJ, Farb NAS
Effects of a Mindfulness Meditation App on Subjective Well-Being: Active Randomized Controlled Trial and Experience Sampling Study
JMIR Ment Health 2019;6(1):e10844
URL: https://mental.jmir.org/2019/1/e10844/
doi:10.2196/10844
PMID:30622094

Original Paper

Sexual Desire, Mood, Attachment Style, Impulsivity, and Self-Esteem as Predictive Factors for Addictive Cybersex

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Abstract

Background: An increasing number of studies are concerned with various aspects of cybersex addiction, the difficulty some persons have in limiting cybersex use despite a negative impact on everyday life.

Objective: The aim of this study was to assess potential links between the outcome variable cybersex addiction, assessed with the Compulsive Internet Use Scale (CIUS) adapted for cybersex use, and several psychological and psychopathological factors, including sexual desire, mood, attachment style, impulsivity, and self-esteem, by taking into account the age, sex, and sexual orientation of cybersex users.

Methods: A Web-based survey was conducted in which participants were assessed for sociodemographic variables and with the following instruments: CIUS adapted for cybersex use, Sexual Desire Inventory, and Short Depression-Happiness Scale. Moreover, attachment style was assessed with the Experiences in Close Relationships-Revised questionnaire (Anxiety and Avoidance subscales). Impulsivity was measured by using the Urgency, Premeditation (lack of), Perseverance (lack of), Sensation Seeking, Positive Urgency Impulsive Behavior Scale. Global self-esteem was assessed with the 1-item Self-Esteem Scale.

Results: A sample of 145 subjects completed the study. Addictive cybersex use was associated with higher levels of sexual desire, depressive mood, avoidant attachment style, and male gender but not with impulsivity.

Conclusions: Addictive cybersex use is a function of sexual desire, depressive mood, and avoidant attachment.

(JMIR Ment Health 2019;6(1):e9978) doi:10.2196/mental.9978

KEYWORDS

sex; internet; addictive behavior; impulsivity

Introduction

Background

The internet is widely used in everyday life, including for health-related queries [1-4] and sexual health–related purposes [5]. Cybersex is a common behavior that refers to sexually oriented Web-based activities that aim to provide erotic fulfillment or sexual gratification [6]. Cybersex includes various activities such as chatting, dating, searching for offline dates, sexual role-playing, webcam interactions, virtual reality, and pornography. These activities can be categorized as solitary-arousal (ie, watching porn), partnered-arousal (ie, chatting), and nonarousal activities (ie, sex-related information seeking) [7].

Moderate use of cybersex may contribute to the expansion of sexual knowledge and enhance offline intimate interactions and sexual communications with partners [8]. Similar to those who engage in other internet-related behaviors such as gaming [9-11], however, some cybersex users may develop addictive patterns of use with possible negative consequences [12,13]. These patterns are usually described as excessive and poorly controlled use of internet-based sexual activities that lead to problems or functional impairment and persist despite such difficulties [14,15]. No consensus has been achieved about the

conceptualization of this disorder [12,16], although it is often referred to as cybersex addiction [17-20]. Nevertheless, as reported for other internet-related problem behaviors [21], it is probably an umbrella term that refers to different types of cybersex activities (solitary internet porn, sex webcams, chat, etc) and to different mechanisms (ie, positive reinforcement such as sexual gratification and arousal from porn, social rewards from chat, or negative reinforcement through escape from daily stress) [12,22,23].

Several studies have reported similarities between addictive cybersex and other addictive disorders, including reduction in executive prefrontal control (the ability to select actions or thoughts in relation to internal goals) [24], association between subjective pornographic cue-related arousal and excessive cybersex [25,26], association between striatal cue reactivity (neuroimaging showing ventral striatum activity during exposure to cybersex cues) and sexual desire [27], and subjective symptoms of cybersex addiction (feeling a loss of control in using it) [23] and patterns of positive and negative reinforcement of Web-based sexual behaviors [28]. Although it seems to be of scientific significance, research on cybersex addiction is still limited [25]. In particular, factors related to the development and maintenance of addictive cybersex remain understudied [12]. This can partly be explained by the lack of consensus about such behavioral addictions.

Possible determinants of addictive cybersex have nonetheless received preliminary attention. Sexual desire reflects the powers that draw a person toward or away from sexual behavior [29] and motivate people to sexually interact. Yet, despite the importance of sexual desire as a determinant of sexual behaviors [22,30], studies on the association between sexual desire and cybersex are still lacking. In concordance with other reports on behavioral addictions and excessive internet use [9,31], several studies on the psychopathological correlates of addictive use of cybersex frequently described an association with psychiatric disorders such as depressive moods [22]. Low self-esteem was also associated with sexting (sharing sexual photos) [32], compulsive behavior [33], and sexual addiction [34]. In addition, in agreement with other studies on addictive internet gaming [35], some studies suggested that addictive cybersex is at least partly a coping behavior that aims to regulate negative emotions [20,36].

The attachment theory argues that as a result of their childhood interactions with parents and relatives, people develop beliefs about their relations to others that come to shape their future affective, intimate, and sexual relationships and behaviors according to their attachment styles [37]. In particular, they may develop insecure attachment styles. For instance, an avoidant attachment style is linked to discomfort with close relationships, avoidance of affective commitment, and a possible increase in the search for casual interactions. In contrast, anxious attachment is related to anxiety about rejection and abandonment, possibly leading people to overengage in behaviors that aim to ensure partner availability and validation and to repeatedly check for such security [38].

Such adult attachment styles seem to influence sexual experiences, intimate relationships, and sexual behaviors and satisfaction [39]. A positive correlation was previously reported between anxious and avoidant attachment and sexual addiction [40]. Furthermore, it was [41] shown that problematic pornography use is elevated in individuals with emotional insecurities such as anxious or avoidant attachment [42] and traumatic souvenirs of the past [19].

Moreover, impulsivity is a multifaceted psychological and neuropsychological construct leading to the fulfillment of behaviors without careful anticipation [43]. Impulsivity is a transdiagnostic factor involved in addictive behaviors [44], including problem gaming [45] and internet gambling [21]. Nonetheless, to date, the association between addictive cybersex and impulsivity has also received little attention [20], and in those studies that have examined this association, mixed results were found. In some studies, lack of executive prefrontal control [25,26] and impulsivity facets were associated with addictive cybersex [25,26]. In contrast, Wetterneck et al [46] did not find any differences in impulsivity measures between addictive and nonaddictive pornography use.

A recent self-report measure of impulsivity is the Urgency, Premeditation (lack of), Perseverance (lack of), Sensation Seeking, Positive Urgency (UPPS-P) Impulsive Behavior Scale, which has been translated with stable factor structure into numerous languages [47-50]. The acronym is related to the different impulsivity facets assessed by the scale: negative urgency (the tendency to act impulsively when experiencing negative emotions), premeditation (lack of), perseverance (lack of), sensation seeking, and positive urgency (the tendency to act impulsively when experiencing positive emotions). A recent study [20] showed that negative urgency and negative affect interact in predicting addictive cybersex, whereas no other associations were found with the other impulsivity dimensions assessed, such as lack of premeditation, lack of perseverance, or positive urgency (the tendency to act impulsively when experiencing positive emotions).

Despite a possible broader conception, sexual orientation can be described as homosexuality, bisexuality, or heterosexuality [51]. In previous studies, males with a homosexual and a bisexual orientation reported differences in the use of cybersex (more frequent Web-based sexual interactions than those reported by heterosexual males) [52]. Furthermore, people in sexual minority groups, partly due to stigma, are at increased risk of health inequalities, such as addictive disorders [53] and depression [54].

Objectives

The aim of this study was to assess the links between cybersex addiction and several psychological and psychopathological factors, including sexual desire, mood, attachment style, and impulsivity, by taking into account the age, sex, and sexual orientation (heterosexual, homosexual, or bisexual) of cybersex users. We expected to find an influence of the selected variables on cybersex addiction.

Methods

Recruitment Procedure

The participants consisted of users of cybersex sites and forums recruited via advertising on specialized forums and websites (pornographic sites, chat rooms, and dating sites). To be included, participants had to be more than 18 years old and to understand the languages of the questionnaires (French or English). There was no incentive for participation. The participants gave consent and then completed the questionnaires anonymously via SurveyMonkey links. The survey responses were sent over a secure—Secure Sockets Layer—encrypted connection. Internet protocol addresses were used only to check for double participation. The study did not use the participants' names, nicknames, or email addresses, and the data were analyzed anonymously. The study protocol was approved by the Ethical Committee of the Geneva University Hospitals.

Sample

The recruitment procedure resulted in 761 people clicking on the link to participate in the study, of whom 605 gave their consent. The participant completion rate decreased along the length of the questionnaire. Among the 605 subjects who gave their consent, 358 continued past the demographics section. Only 226 subjects continued to the last part, the questionnaire section. After missing values were removed, the final sample included 145 participants.

Instruments

Compulsive Internet Use Scale

The Compulsive Internet Use Scale (CIUS) [55] consists of 14 items rated on a 5-point Likert scale ranging from 0 (never) to 4 (very often). Higher scores indicate more severe addictive use. Previous studies reported good factorial stability across time and across different samples [55]. The scale involves items related to different aspects of addictive behaviors such as loss of control, preoccupation, withdrawal, coping, and conflict. In different samples and linguistic validations of the CIUS, a 1-factor solution was repeatedly retained as the best-fit model [55-59]. The items of the CIUS ask about general use of the internet (ie, "Do you find it difficult to stop using the internet when you are online?"). To specifically assess cybersex activities, we asked participants to answer the questions while keeping in mind that the word *internet* specifically refers to cybersex use. The CIUS and other internet addiction scales have previously been successfully adapted to focus on a specific internet use to assess internet gaming, internet gambling [60], and cybersex [20,61] without alterations of their psychometric properties.

Sexual Desire Inventory

Consisting of 14 items on a Likert scale, the Sexual Desire Inventory (SDI) was used to evaluate sexual desire (eg, "When you first see an attractive person, how strong is your desire?") [62].

Four items are scored from 0 (not at all) to 7 (more than once a day). The other items are answered on a 9-point Likert scale ranging from 0 (no desire) to 8 (strong desire). Higher SDI scores reveal higher sexual desire.

Short Depression-Happiness Scale

The Short Depression-Happiness Scale (SDHS) was used to evaluate mood variation from depressive mood (eg, "I felt dissatisfied with my life") to happiness (eg, "I felt happy") during the last 7-day period. It consists of 6 items, 3 positive and 3 negative, rated on a 4-point Likert scale ranging from 0 (never) to 3 (often). The lower the score, the higher the depressive symptoms [63].

Experiences in Close Relationships-Revised Questionnaire

This Experiences in Close Relationships-Revised (ECR-R) questionnaire was used to evaluate attachment style [64,65]. The inventory includes 18 items for anxious attachment characterized by possessive love and fear of loss (eg, "I often worry that my partner will not want to stay with me") and 18 items for avoidant attachment characterized by fear of romantic love and low relationship success (eg, "I prefer not to show a partner how I feel deep down"). The items are rated on a 7-point Likert scale ranging from 1 (completely disagree) to 7 (completely agree). Several studies showed good test-retest reliability and a good association of the subscale scores with other ratings of daily anxiety and avoidance faced with a close companion [66].

Urgency, Premeditation (Lack of), Perseverance (Lack of), Sensation Seeking, Positive Urgency) Impulsive Behavior Scale Impulsive Behavior Scale

The UPPS-P Impulsive Behavior Scale [67], in its short 20-item version [47], is used to measure impulsivity according to 5 dimensions: positive urgency (strong reactions while experiencing intense positive emotions), negative urgency (strong reactions while experiencing intense negative emotions, eg, "When I am upset I often act without thinking"), lack of premeditation (tendency to disregard the consequences before acting), lack of perseverance (difficulty staying focused on a difficult or boring task), and sensation seeking. Responses are rated on a 4-point Likert scale ranging from 1 (strongly agree) to 4 (totally disagree). Good test-retest stability was previously reported [47]. In consideration of its multicomponents, the scale was of particular interest for the assessment of addictions [68]. In some studies, some of the impulsivity facets assessed with the UPPS-P, in particular negative urgency [69-72] and, depending on the assessed behaviors and sample, positive urgency [71], lack of premeditation [69], lack of perseverance [73], and sensation seeking [68], were previously associated with addictive behaviors.

Single-Item Self-Esteem Scale

This 1-item scale ("I have high self-esteem") was used to measure global self-esteem [74]. Participants complete the single item on a 5-point Likert scale ranging from 1 (not very true of me) to 5 (very true of me). The Single-Item Self-Esteem Scale (SISE) showed good convergent validity with other assessments of self-esteem such as the Rosenberg Self-Esteem Scale [74]. Due to the single-item composition of the SISE, internal

consistency is supposed to be perfect by definition and cannot be estimated. In this sample, this scale was normally distributed.

Age, gender (male or female), marital status (single, in a relationship—married, in a relationship—not married, widow, or widower), and sexual orientation (measured with a question asking whether the subject described himself or herself as heterosexual, homosexual, or bisexual) were also assessed.

Analyses

Due to the small sample size for sexual orientation and marital status, demographics were compared between men and women by using the Fisher exact test, whereas the Wilcoxon rank sum test was performed for age. Regarding the different scales, when missing items represented less than or equal to 10% of all items on a specific scale (16.6% for the SDHS because it has only 6 items), the missing answer was replaced with the mean of the subject's responses to the items on that scale (person-mean imputation). Internal consistency was assessed with Cronbach alpha [75]. To assess the variables associated with a high score on the CIUS, we performed a linear mixed model. The dependent variable was the CIUS score, and the independent variables were the SDI score, the SDHS score, the ECR-R subscales, the UPPS-P subscales, the SISE, sex, and sexual orientation. An interaction term between sex and sexual orientation was also included in the model. As there were 19 subjects who did not report their year of birth, age was not included in the model. This should not introduce bias into the analysis because the correlation between age and the CIUS score was close to 0 and did not reach statistical significance.

A linear mixed model is a statistical model containing both fixed effects, as in a classical linear regression, and random effects [76]. Random effects are useful for modeling cluster data; therefore, this type of model is suitable for correlated measurements, as it accounts for the lack of independence of the observations. In this sample, it could be assumed that subjects who filled in the French version of the questionnaire were more similar to one another than subjects who filled in the English version of the questionnaire; therefore, language was modeled as a random effect.

To determine whether the tested model was valid, we performed residual analyses and collinearity diagnostics. Residual analysis showed graphically that residuals were normally distributed, that there were no extreme values, and that they were homoscedastic. Regarding collinearity diagnostics, no variance inflation factor was higher than 4, which suggests that no collinearity problems were present [77]. Analyses were done with R 3.1.0 (R Core Team, 2014) [78]. The package nlme (R Core Team, 2017) was used to run the linear mixed model.

Results

Demographics of the Participants

The study involved 145 participants. When we compared the 145 included subjects with those who at least provided their age, sex, and sexual orientation, no statistical differences were found.

Table 1 shows the demographics of the participants. The sample was composed of 60.0% (87/145) men and 40.0% (58/145) women. The median age of the sample was 31 years (range: 18-70 years). Women were younger than men (28 years vs 36.5 years, respectively, *P*=.014). Regarding marital status, 37.9% (55/145) of the participants were single, 39.3% (57/145) in a relationship—not married, 20.7% (30/145) in a relationship—married, and 2.1% (3/145) widows or widowers. Sexual orientation and sexual orientation within sex were also measured: 77.9% (113/145) of the participants reported being heterosexual, 7.6% (11/145) being homosexual, and 14.5% (21/145) being bisexual. Among men, 79% (69/87) reported being heterosexual, 6% (6/87) being homosexual, and 13% (12/87) being bisexual; among women, 75% (44/58) reported being heterosexual, 8% (5/58) being homosexual, and 15% (9/58) being bisexual.

Table 1. Demographics of the participants.

Characteristic	Whole sample	Women (n=58)	Men (n=87)	*P* value
Age, median (range)	31 (18-70)	28 (18-70)	36.5 (18-70)	.014[a]
Sexual orientation[b], n (%)				0.87
Heterosexual	113 (77.9)	44 (38.9)	69 (61.1)	
Homosexual	11 (7.6)	5 (45.5)	6 (54.5)	
Bisexual	21 (14.5)	9 (42.9)	12 (57.1)	
Marital status[c], n (%)				0.49
Single	58 (40.0)	21 (36.2)	37 (63.8)	
In a relationship	87 (60.0)	37 (42.5)	50 (57.5)	

[a]W statistic for the Wilcoxon rank sum test is 2500.5.

[b]Women/men proportions are within sexual orientation categories.

[c]Women/men percentages are within marital status categories.

Instruments

Table 2 shows the means and SDs of the instruments used as well as Cronbach alpha [75] as a measure of internal consistency and its 95% confidence interval. Every instrument had good (>0.80) to excellent (>0.90) internal consistency, but the UPPS-P positive urgency scale fell into the acceptable range (>0.70).

Results of the Linear Mixed Model

The results of the linear mixed model are reported in Table 3. The most important influences on the CIUS scores (see standardized coefficients) were lower SDHS scores (meaning more depressive scores), followed by higher avoidant attachment style scores, male gender, and higher sexual desire. The other variables (anxious attachment, UPPS-P subscales, SIUS, sexual orientation, and interaction between gender and sexual orientation) did not reach statistical significance on the CIUS scores.

Table 2. Description of the instruments.

Instrument	Mean (SD)	Cronbach alpha	95% CI
Compulsive Internet Use Scale	14.64 (9.84)	.89	0.89-0.91
Sexual Desire Inventory	70.83 (17.66)	.87	0.84-0.90
Short Depression-Happiness Scale	11.29 (4.38)	.86	0.83-0.90
Experiences in Close Relationships-Revised questionnaire			
Anxious attachment	3.39 (1.33)	.92	0.91-0.94
Avoidant attachment	3.07 (1.04)	.89	0.86-0.91
UPPS-P[a] Impulsive Behavior Scale			
Positive urgency	10.44 (2.57)	.74	0.67-0.81
Negative urgency	8.64 (3.04)	.86	0.82-0.89
Lack of premeditation	7.45 (2.64)	.80	0.75-0.85
Lack of perseverance	7.34 (2.66)	.84	0.80-0.88
Sensation seeking	11.31 (2.70)	.80	0.74-0.85
Single-Item Self-Esteem Scale	2.61 (0.83)	—[b]	—

[a]Urgency, Premeditation (lack of), Perseverance (lack of), Sensation Seeking, Positive Urgency.

[b]Not applicable.

Table 3. Results of the linear mixed model.

Characteristics and measures	Regression coefficient	Standard error	*t* value (degrees of freedom)	*P* value	Standardized coefficients
Female versus male	−3.82	1.75	−2.18 (128)	.03	−0.19
Sexual orientation (reference group: heterosexual)					
Homosexual	0.08	3.67	0.02 (128)	.98	0.07
Bisexual	−1.37	2.61	−0.52 (128)	.60	0.10
Interaction (female)					
Homosexual	1.62	5.58	0.29 (128)	.77	0.08
Bisexual	5.81	4.13	1.41 (128)	.16	0.29
Sexual Desire Inventory	*0.11* [a]	*0.04*	*2.48* (128)	*.01*	*0.19*
Self-esteem	−0.68	1.00	−0.67 (128)	.50	−0.06
UPPS-P[b] Impulsive Behavior Scale					
Positive urgency	0.19	0.33	0.57 (128)	.57	0.06
Negative urgency	−0.15	0.37	−0.39 (128)	.69	−0.04
Lack of premeditation	0.31	0.34	0.92 (128)	.35	0.08
Lack of perseverance	−0.07	0.36	−0.20 (128)	.84	−0.02
Sensation seeking	0.07	0.30	0.25 (128)	.80	0.02
Short Depression-Happiness Scale	*− 0.85*	*0.22*	*− 3.95* (128)	*>.001*	*− 0.38*
Experiences in Close Relationships-Revised					
Anxiety	−0.56	0.70	−0.81 (128)	.42	−0.08
Avoidance	*2.20*	*0.79*	*2.79* (128)	*.006*	*0.23*

[a]Italics represents significant regression parameters.

[b]Urgency, Premeditation (lack of), Perseverance (lack of), Sensation Seeking, Positive Urgency.

Discussion

Principal Findings

The aim of this study was to study cybersex addiction and to assess the links between cybersex addiction and possible determinants of such behavior, namely, sexual desire, mood, attachment style, and impulsivity, by taking into account the age, sex, and sexual orientation of cybersex users. We concluded that addictive cybersex use, as assessed by the CIUS adapted for sexual activities, is associated with sexual desire, depressive mood, an avoidant attachment style, and male gender. As shown in Table 3 (standardized coefficients), the results suggest that the most important influence on the CIUS scores is depressive mood, followed by avoidant attachment style, male gender, and sexual desire. UPPS-P impulsivity subscores, self-esteem, and sexual orientation do not have a significant influence on addictive cybersex.

Sexual desire is an important drive for sexual behavior and is positively associated with emotional intimacy [79]. In this study, elevated sexual desire was significantly associated with addictive cybersex use. This finding is consistent with the gratification hypothesis [26] and with previous findings showing an association between cybersex use and arousal and craving for specific porn cues [80]. The results suggest that at least part of addictive cybersex use is linked to such positive reinforcement. Sexual desire is also known for its modification related to depressive mood [81]. Possible fluctuations between sexual desire, mood modification, and cybersex use could be assessed in future studies by using methods that are based on ecological momentary assessment [82].

Our finding of an association between addictive cybersex use and depressive mood is congruent with other studies that showed the importance of links between addictive cybersex and diverse assessments of psychological distress and mood [22,26]. This finding is also in line with other reports of the association between excessive internet gaming [83] or internet gambling [21] and depressive mood. Such associations suggest that addictive cybersex is at least partly a coping behavior that aims to regulate negative emotions [20,35,36,84]. This finding opens the debate, as has occurred for other internet addictive-like behaviors, about an appropriate diagnostic framework [16] and adequate understanding of such an association [85]. The possible development of psychopathological distress, which could lead to a more pronounced depressive mood secondary to the negative impact of addictive cybersex (interpersonal isolation and reduction of offline sexual activities), cannot be ruled out [86], and thus, further prospective studies are warranted.

We also found an association between addictive cybersex use and avoidant attachment but not anxious attachment. These results are congruent with those of other studies showing the

implications of insecure attachment in excessive internet use [19] and cybersex [41]. Beutel et al [42] found an increase in the intensity of internet sex use with the importance of anxious attachment. Their results failed, however, to reach statistical significance for the link between the importance of internet sex use and avoidant attachment. Such differences could possibly be explained by differences in cybersex use assessment methods. In fact, Beutel et al's study used more items related to cybersex use (eg," I have searched for sexual materials online...") and only 2 items related to addictive cybersex (ie, "I believe that I am an internet sex addict" and "I have promised myself to stop using the internet for sexual purposes"). Furthermore, items were on a dichotomous scale (true or false), which may limit the ability to detect variability. The association found with avoidant attachment could be explained by displeasure and fear of close relationships, which lead to an increase in cybersex activities that less often involve closeness in relationships. In this study, the lack of association between addictive cybersex and anxious attachment style was possibly because of the limitations in sample size. One could hypothesize differences in attachment style across specific cybersex activities (ie, anxious attachment may have more Web-based interactions with potential partners because of anticipated fear of rejections). Further studies should assess specific cybersex activities in more detail. Despite such differences across studies, insecure attachment styles play an important role in cybersex addiction. As suggested elsewhere [19], such findings deserve clinical investigation and treatment of attachment style for patients who are involved in addictive cybersex.

Impulsivity and cybersex addiction were not significantly associated in our study. The results of the study at hand contrast with those of other studies regarding the links between the UPPS-P and internet-related addictive behaviors [21,45]. The results of this study are contrary to those of previous studies showing some associations between addictive cybersex and impulsivity [20,46]. Furthermore, using the same UPPS-P scale, Wery et al [20] showed that in a group of male participants, negative urgency interacted with negative affects in predicting addictive cybersex. However, the strength of the association was not strong, as shown by the authors' reported odds ratio of 1.03 (95% CI=1.01-1.06). In another study, Wetterneck et al [46] showed a small correlation between a measure of impulsivity and the number of hours of porn use by week. However, they did not report significant differences in impulsivity between a group of addictive porn users and controls.

In light of such observations across studies, one may hypothesize that some impulsivity facets may contribute to addictive cybersex without having a main determinant effect on such behavior. This may contribute to disparities between studies. Furthermore, such differences are possibly influenced by sample size, the specific type of cybersex activities (ie, possible differences between porn use and sex dating), and other assessments involved in the analyses. For instance, our study included measures of attachment, a construct not included in the previously mentioned studies. However, we cannot exclude the possibility of modifications in executive functions when an individual faces specific cybersex cues [24] or during interactions with negative states and cybersex use [20]. Further studies on the possible role of impulsivity constructs in addictive cybersex are needed.

Self-esteem had no impact on CIUS scores. This result contradicts those of other studies that show, for instance, an association between low self-esteem and adolescent sexting (sharing sexual photos) [32]. These differences between studies may be because of sample characteristics, participants' specific cybersex activities, or the assessment methods. This study, for example, assessed general self-esteem with only 1 question. Furthermore, the impact of specific cybersex activities on self-esteem cannot be ruled out. Prospective studies on the links between such activities and self-esteem, including possible mediators of effects such as fear of negative evaluation [33], are needed.

This study also showed an association between addictive cybersex and male gender, as has repeatedly been found [17,42,46,87,88]. Sociocultural differences may contribute to this phenomenon. Moreover, possible differences between men and women in sexual desire, sexual arousal, and their interplay may contribute to the observed difference [89]. The design of sex-related websites and mobile phones apps may also influence gender differences in cybersex use. Gender differences were commonly reported in addictive disorders; additional studies are required to understand the underlying mechanisms [90].

Among a population of cybersex users, our study showed no association between age and cybersex addiction. Most studies on cybersex have involved adolescents and young adults [17]. Some earlier studies (in the early 2000s), however, showed that adults older than 50 years were less prone to cybersex use than younger adults [91]. The findings of this study are possibly explained by a focus on cybersex addiction (and not on cybersex use) and by societal evolution and wider access to the internet in all age ranges.

In this study, sexual orientation had no effect on the assessed behavior. Similarly, no effect was found in the interactions between gender and sexual orientation. However, sexual orientation was assessed in only 3 main categories (heterosexual, bisexual, and homosexual). Future studies would benefit from more refined evaluations of sexual orientation [51] and its possible components (eg, erotic fantasy and social interactions) [92] as well as from evaluations of gender identity and its related distress [93].

Cybersex is associated with addictive use for only a small number of users [20]. This observation is also illustrated by the mean (Table 2) and median (13 of 56) of the CIUS scores in this study. Nonetheless, for those with addictive patterns of use, treatment options are still sparse and understudied; most of the few preliminary studies in the field have tried to reproduce what is already known from the psychotherapy of addictive disorders [12].

The findings of this study have clinical implications. It seems important to consider cybersex addiction in terms of its principal connections with several psychological dimensions. Particular attention should be given to the patient's patterns of attachment. Psychotherapeutic treatment has to be tailored to the specific

needs of each patient. People with avoidant attachment, for example, may benefit from a psychotherapeutic approach designed to integrate treatment of addiction and attachment disturbances. Future studies for the assessment and treatment of cybersex addiction are needed in clinical settings.

Limitations

Several limitations of the study must be considered. The sample was relatively small but adequate for the study statistics. Furthermore, the sample was exposed to self-selection biases [94]. The cross-sectional design did not allow assessment of longitudinal interplay between the assessed variables. Furthermore, the study did not take into consideration the different cybersex activities that could influence cybersex use across different behaviors and cybersex communities. Finally, there is no consensus related to cybersex addiction, and thus, the study used the CIUS adapted to cybersex as a proxy. Using a continuous approach rather than a categorical one, however, allows assessment of some determinants of the severity of addictive cybersex use with an adequate research instrument related to addictive use of internet-delivered services.

Conclusions

Despite these limitations, this study indicates that addictive cybersex is influenced by an avoidant attachment style, depressive mood, and sexual desire. Males are at increased risk. Self-esteem and impulsivity do not seem to have a significant influence on addictive cybersex. Further research, including prospective studies, is needed in the field.

Acknowledgments

No funding was received for this study. The authors thank the study participants.

Authors' Contributions

NV, YK, FBD, and SR were involved in the study concept and design. SR, YK, and NV were involved in statistical analysis and interpretation of data. TL, KJ, and YK were involved in the recruitment of participants. NV, YK, KJ, TL, SR, and FBD were involved in writing of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CIUS: Compulsive Internet Use Scale
ECR-R: Experiences in Close Relationships-Revised
SDHS: Short Depression-Happiness Scale
SDI: Sexual Desire Inventory
SISE: Single-Item Self-Esteem Scale
UPPS-P: Urgency, Premeditation (lack of), Perseverance (lack of), Sensation Seeking, Positive Urgency) Impulsive Behavior Scale

Edited by G Eysenbach; submitted 01.02.18; peer-reviewed by L McDonagh, E Brivio; comments to author 28.07.18; revised version received 01.11.18; accepted 12.12.18; published 21.01.19.

Please cite as:
Varfi N, Rothen S, Jasiowka K, Lepers T, Bianchi-Demicheli F, Khazaal Y
Sexual Desire, Mood, Attachment Style, Impulsivity, and Self-Esteem as Predictive Factors for Addictive Cybersex
JMIR Ment Health 2019;6(1):e9978
URL: https://mental.jmir.org/2019/1/e9978/
doi:10.2196/mental.9978
PMID:30664470

Corrigenda and Addenda

Correction: Reaching Those At Risk for Psychiatric Disorders and Suicidal Ideation: Facebook Advertisements to Recruit Military Veterans

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Related Article:

Correction of: http://mental.jmir.org/2018/3/e10078/

(JMIR Ment Health 2019;6(1):e13035) doi:10.2196/13035

The authors of "Researching Those At Risk for Psychiatric Disorders and Suicidal Ideation: Facebook Advertisements to Recruit Military Veterans" (JMIR Ment Health 2018;5(3):e10078) incorrectly labeled some column headers in Table 2. Currently, the columns list the click-through rate as a percentage ("CTR[a], n (%)"). They should be labeled as simply the number and click-through rate ("Number (CTR[a])").

The correction will appear in the online version of the paper on the JMIR website on January 9, 2019, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article also has been resubmitted to those repositories.

Edited by G Eysenbach; submitted 05.12.18; this is a non–peer-reviewed article;accepted 12.12.18; published 09.01.19.

Please cite as:
R Teo A, Liebow SBL, Chan B, Dobscha SK, Graham AL
Correction: Reaching Those At Risk for Psychiatric Disorders and Suicidal Ideation: Facebook Advertisements to Recruit Military Veterans
JMIR Ment Health 2019;6(1):e13035
URL: http://mental.jmir.org/2019/1/e13035/
doi:10.2196/13035
PMID:30626563

Publisher:
JMIR Publications
130 Queens Quay East.
Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org