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Digital mental health: Interventions and assessment

Edited by
Cristina Costescu, Ioana Roxana Podina and
Alexandra Voinescu

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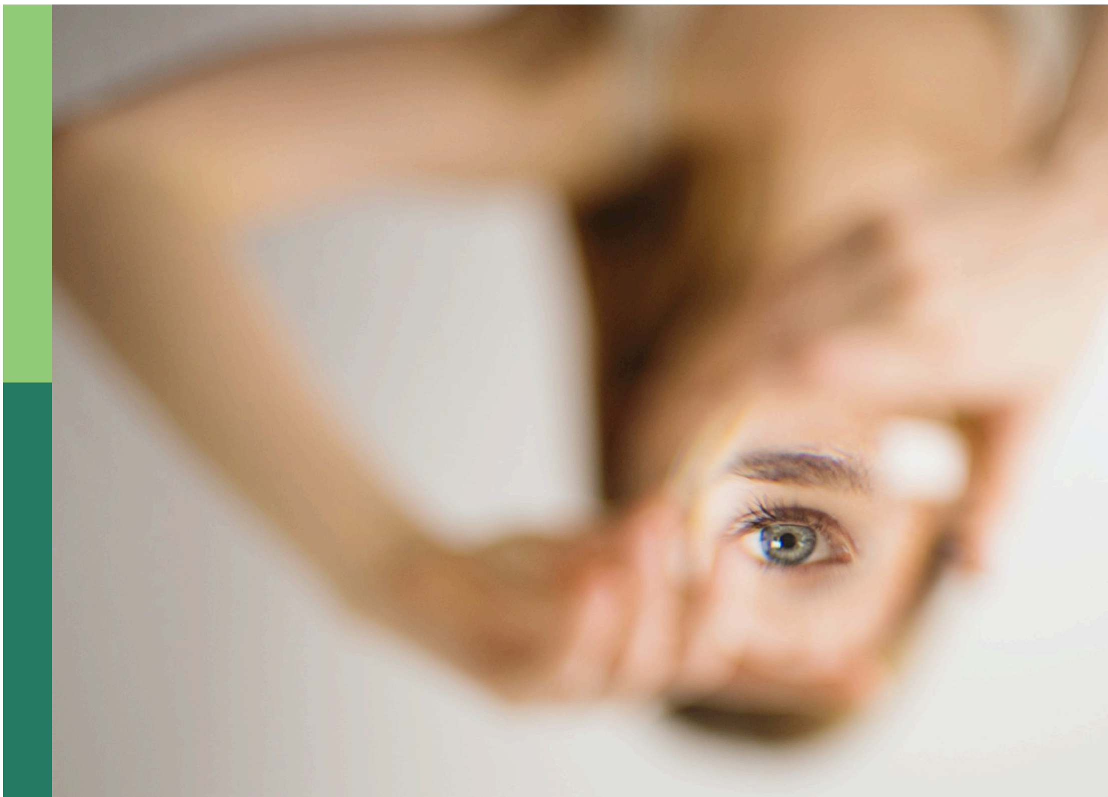

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Digital mental health: Interventions and assessment

Topic editors
Cristina Costescu — Babeș-Bolyai University, Romania
Ioana Roxana Podina — University of Bucharest, Romania
Alexandra Voinescu — University of Bath, United Kingdom

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Editorial: Digital mental health: Interventions and assessment

Cristina Costescu[1]*, Ioana R. Podina[2,3] and Alexandra Voinescu[4]

[1]Department of Special Education, Babeş-Bolyai University, Cluj-Napoca, Romania, [2]Laboratory of Cognitive Clinical Sciences, University of Bucharest, Bucharest, Romania, [3]Department of Applied Psychology and Psychotherapy, University of Bucharest, Bucharest, Romania, [4]Department of Psychology, University of Bath, Bath, United Kingdom

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Editorial on the Research Topic
Digital mental health: Interventions and assessment

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EDITED BY
Gian Mauro Manzoni,
University of eCampus, Italy

REVIEWED BY
Joan Carles Medina,
Fundació per a la Universitat Oberta de Catalunya, Spain

*CORRESPONDENCE
Cristina Costescu
christina.costescu@gmail.com

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Robotic, web-based, virtual reality (VR), or mobile-based digital mental health interventions (DMHI) offer tremendous potential to promote mental health and well-being across a range of age groups (Neguț et al., 2016; Aboujaoude et al., 2020; Voinescu et al., 2021). More than 70% of young people use digital devices, but their mental health problems remain under-diagnosed and under-treated (UNICEF, 2018; World Health Organization, 2020). Therefore, DMHIs could provide excellent opportunities to expand access to diagnostic and intervention services, as well as to improve empowerment, participation, help-seeking, and essential resources to address the stigma associated with mental health (Kaushik et al., 2016; Freeman et al., 2022). In addition, interventions designed to enhance psychological well-being may lessen the negative consequences of the COVID-19 epidemic (De Kock et al., 2022). Several investigations during the COVID-19 epidemic in the community showed a strong negative correlation between psychological well-being and anxiety, despair, and distress (see meta-analysis Salari et al., 2020). DMHIs may improve accessibility, can bridge social gaps, and allow users to log in anonymously whenever they want (Sorkin et al., 2021).

Because DMHIs are believed to be an effective tool to address underutilization of professional mental health services (Garrido et al., 2019), several studies assessed their effectiveness. Overall, these studies supported the effectiveness of DMHIs in reducing anxiety and depression symptoms and showed that digital mental health programs can be as effective as in-person programs and sometimes more effective for adults (Cuijpers et al., 2010; Prescott et al., 2022) and children (Păsărelu et al., 2017). Several reviews of technology applications for mental health found positive outcomes and important benefits (Firth et al., 2017; Garrido et al., 2019). However, more research is required for vulnerable populations such as older adults with mental health problems, as they are at high risk of being excluded from DMHI due to a number of factors such as lack of knowledge and support in using digital tools (Seifert et al., 2019). Another problem with using DMHIs among the general population is that the dropout rates are very high (Torous et al., 2018).

It is important to take into account some of the drawbacks of DMHI, such as how well these interventions might work for severe mental health conditions (such as psychosis, bipolar disorder, or personality disorders) (Bucci et al., 2018). Potential validity issues and level of accessibility are also major challenges. As in other research domains with a focus on human machine interfaces such as designing computer interfaces for older adults or people with special needs, the need to use adaptable and usable interfaces is highly recognized (Fisk et al., 2004; Morgan et al., 2017). The main drawback of using new technologies is that they may be too difficult to use, that could lead to a decrease in user engagement. This is due to the new types of technologies used to deliver the interventions and the rapid technological improvements (Borghouts et al., 2020). Other drawbacks and potential barriers to the use of DMHIs include data privacy, data storage, and user confidentiality (Lustgarten et al., 2020).

In this issue, the studies address some of the limitations discussed above and aims to suggestr solutions and future directions.

The session wants and need outcome measure: The development of a brief outcome measure for single-sessions of web-based support

The paper developed by de Ossorno Garcia et al. described the planning, development, and usability evaluation of the Brief Outcome Measure for Single-Sessions of Web-Based Support, an online web-based mental health platform for children and young people (Kooth). A key implication of the study conducted by de Ossorno Garcia et al. concerns the importance of engaging various categories of end users (e.g., experts, practitioners and students that access the service) during the developmental stage of the SWAN-ON. This approach highlighted the importance of applying well-known co-design approaches currently used in the development of e-health interventions (Thabrew et al., 2018) to the developmental stage of an instrument that measures the effects of digital interventions such as the SWAN-ON.

Investigating the persuasive effects of testimonials on the acceptance of digital stress management trainings among university students and underlying mechanisms: A randomized controlled trial

In this experimental study, Apolinário-Hagen et al. investigated the effect of various features of narrative information in supplemented testimonials on the acceptance of digital mental health services (digi-MHSs) among students. Overall, results showed that adding testimonials to written information was associated with higher intentions to use and more positive attitudes toward digi-MHSs for stress prevention. No significant effects of testimonials were identified for the attitudes toward online interventions for stress coping or therapy. A significant mediation effect of source credibility on attitudes revealed that student testimonials were more credible than those by experts, but no significant mediation effect was observed for intentions to use.

A randomized controlled trial of clinician-guided internet-based cognitive behavioral therapy for depressed patients in singapore

The study conducted by Lu et al. investigated if a clinician-guided internet-based Cognitive Behavioral Therapy (iCBT) programme is effective in improving symptoms of depression, anxiety, psychological distress and functional impairment among outpatients with depression in a psychiatric hospital in Singapore. The study consisted of two arms: the iCBT and a waiting list control group. The iCBT intervention used a blended approach with three face-to-face sessions and six online sessions. Results showed positive and significant effects in improving depressive symptoms. This study was among the first studies conducted in Singapore and included other samples than the Western culture. Its significant results support the effectiveness of using an iCBT intervention in Asian culture.

Case report: Feasibility of a novel virtual reality-based intervention for patients with schizophrenia

Vass et al. described a case report study with a focus on a novel immersive VR-based intervention designed to reduce symptoms associated with schizophrenia. A 50-year-old person with a diagnosis of schizophrenia took part in the study. The 9-week VR-based intervention (1 h/session/week) took place in an individual setting and was led by a licensed clinical psychologist under the supervision of an experienced psychotherapist. Several outcomes were measured before, after, and at follow-up: mood and emotions, pragmatic language skills and quality-of-life and theory of mind-related outcomes. Authors reported improvements at post-test and follow-up on theory of mind and communicative-pragmatic skills.

Developing a brief tele-psychotherapy model for COVID-19 patients, and their family-members

Biagianti et al. focused on the development of a brief tele-psychotherapy model for COVID-19 patients and their family members. The intervention was based on a literature review on the topic of psychotherapeutic interventions for COVID-19-related symptoms. The program consisted of eight individual weekly remote sessions (50 min each) that will be delivered using secure video conference software. The paper is part of a larger project with the aim to evaluate acceptability, feasibility, efficacy, and effectiveness of the proposed program. In the context of social and participatory restrictions and with the aim of increasing accessibility to psychological interventions for people who live in geographical zones without an easy access to these services, remote tele-psychotherapy would be of great impact.

Innovating technology-enhanced interventions for youth suicide: Insights for measuring implementation outcomes

In a review, Szlyk et al. analyzed 12 randomized clinical trials (RCTs), that assess the efficacy and effectiveness of technology-enhanced suicide interventions. Their aim was to explain how technology-enhanced interventions for youth suicide can be categorized using behavioral intervention technologies and how implementation outcomes can be measured in future effectiveness trials. The results showed increased heterogeneity due to the technology provider and support, and its content. The results also suggested that outcomes defined in the continuum of behavioral interventional technology can raise considerations for how outcomes could be integrated in more implementation focused studies.

Access to nature *via* virtual reality: A mini-review

The paper published by Li et al. described the results of a mini-review that included 15 studies, to answer questions concerning the benefits of using virtual nature and if VR exposure in VR produces similar effects with traditional media for nature scenes. Their results showed that the benefits from virtual nature are generally consistent with those from exposure to real nature, meaning that current VR app can facilitate a restorative natural environment with positive psychological outcomes.

Keeping connected with school: Implementing telepresence robots to improve the well-being of adolescent cancer patients

The work developed by Powell et al. aimed to improve well-being of adolescent cancer patients by using telepresence robots. They interviewed 47 participants with various vulnerable participants such as: adolescent with cancer, healthcare professionals, schoolteachers, and parents of adolescents with cancer. The aim of the first study was to investigate the benefits, acceptability, barriers, and enablers of utilizing robots in schools for adolescents with cancer. In the second phase of their study, they interviewed the participants about their experience in using a robot to enable adolescents to attend school remotely. In conclusion, the social and academic connections facilitated by the robot improved the mood of the adolescents and reduced their feelings of stress and loneliness.

Can we boost treatment adherence to an online transdiagnostic intervention by adding self-enhancement strategies? Results from a randomized controlled non-inferiority trial

Isbăşoiu et al. focused on comparing two intervention strategies for decreasing symptoms of anxiety and depression and increasing the self-parameters. They compared the UP intervention for transdiagnostic treatment of anxiety and affective disorders that was developed by Barlow et al. (2011) and contain 9 modules web-based with a Self-enhanced 9UP version with enhancement strategies that address self-concepts. All primary outcomes that target anxiety and depression symptoms and secondary outcomes that address the self-concept were administrated online at pre-treatment, post-treatment, and 6 months follow-up. 284 participants with at least one clinical disorder were randomly allocated to one of the two conditions. Overall, both groups produced significant increases in both primary and secondary outcomes in post-test and at 6-months follow-up, however, there were no significant differences between the two groups neither in primary and secondary outcomes nor in terms of treatment adherence.

Research on the method of depression detection by single-channel electroencephalography sensor

Lei et al. developed a model to detect depressive mood based on the attention and mediation signals produced by a single channel EEG headset. They hypothesized that when the participants have depression an M-shaped pattern appears in their attention and/or mediation signals. They recruited 158 senior high school students, for their first study and respectively 73 and 69 participants aged 18–60 for the second and third studies. They compared the results gained through EEG headset with other psychological tests that measured depressive symptoms, such as PHQ9, Hamilton Depression Rating Scale, and House-Tree-Person drawing test. Results showed that the consistency rate of the two methods was 61.4% in the first study, 63.38% in the second study, and 91.3% in the third study.

Making a virtue out of necessity: COVID-19 as a catalyst for applying internet-based psychological interventions for informal caregivers

A compelling opinion piece was also included in the current special issue. According to Simonella et al. the COVID-19 pandemic was a glass half empty, but also a glass half full situation. The negative consequences were frequently acknowledged, but the unforeseen positive effects were less discussed. One such significant advantage was a decrease in resistance to using digital technologies. The authors argue that the world must use this opportunity right away to create and extensively disseminate internet-based treatments to those in need. Their opinion piece exemplifies the benefits of internet-based interventions for informal caregivers, family members, neighbors, friends, or other non-kin and who provide unpaid assistance to someone who is disabled, frail, or ill.

Remote vs. in-person delivery of LearningRx one-on-one cognitive training during the COVID-19 pandemic: A noninferiority study

One other study that capitalized on the remote online delivery of interventions during the COVID-19 pandemic was conducted by Lawson Moore et al.'s study. Three hundred eighty-one children and adults received cognitivetraining (ThinkRx) from 18 cognitive training facilities. One group received the cognitive training face-to-face, whereas another received it *via* Zoom teleconferencing. In terms of total IQ score, processing speed, fluid reasoning, long-term memory, and visual processing, remote delivery was comparable to the in-person delivery. The authors concluded that delivering cognitive training remotely may represent a good substitute for in-person instruction.

Efficacy of an ACT and compassion-based eHealth program for self-management of chronic pain (iACTwithPain): Study protocol for a randomized controlled trial

In a study by Carvalho et al., Acceptance and Commitment Therapy (ACT) was designed to be part of an e-Health program for the self-management of chronic pain. Given that ACT is frequently used to treat trauma and recover from mental health problems, testing its effectiveness for chronic pain is represents a novel attempt, particularly in a digital setting. The efficacy of the study will be assessed at baseline, post-intervention, and 3- and 6-month follow-up with treatment as usual, ACT-only intervention, and an iACTwithPain + self-compassion as arms of the trial. Outcomes such as the impact of pain, subjective discomfort, and quality of life are still being tested in the trial.

A self-applied multi-component psychological online intervention based on UX, for the prevention of complicated grief disorder in the mexican population during the COVID-19 outbreak: Protocol of a randomized clinical trial

The current issue also includes protocol research by Dominguez-Rodriguez et al.. Through a multifaceted online intervention that combines components of ACT, CBT, Mindfulness, and Positive Psychology, the study protocol focused on investigating complicated grief. The intervention was ompared with a a waitlist control group using an RCT design with a-priori power size computations, pre-post efficacy assessment accompanied by a 3- and 6-month follow-up. As before, the article is a worthwhile read for those interested both in the design as well as the components of the proposed intervention.

Engagement in digital mental health interventions: Can monetary incentives help?

Because of the high dropout rates, engagement with DMHIs is a serious concern. Few studies focused on engagement factors that can boost involvement with DMHIs, such as financial incentives, according to Boucher et al.. The authors questioned whether monetary incentives (MI) are a workable tactic for increasing user engagement with DMHIs. Therefore, the article begun with a review of the literature and then presented a pilot research where they assessed the effects of different degrees of MI on user engagement. In short, results suggested that monetary incentives were effective "only on technological engagement" when interventions are spread out over multiple sessions. There was no one-size-fits-all-method to increase involvement since "more money does not necessarily imply more benefit" and "there is large variability in how people respond to MI."

Screening social anxiety in adolescents through the eyes of their careers

Additionally, psychometric research written by Garcia-Lopez et al. was included in the present special issue. The parent version of "The Social Phobia and Anxiety Inventory, Brief form" (SPAIB), was administered online, was assessed for its psychometric qualities. The sample consisted of 179 parents and legal guardians of children. Results showed good factor structure, internal consistency, and construct validity. As a result, parents now have a valid screening tool for their children's social anxiety that remains underdiagnosed. Nonetheless, future studies should test SPAIB's psychometric properties on other samples.

Remote assessment of depression using digital biomarkers from cognitive tasks

The authors of this paper used three standard cognitive tasks (D2 Test of Attention, Delayed Matching to Sample Task, and Spatial Working Memory Task) where people with depression are known to perform differently than healthy people. The performance of the users on these tasks was used to predict depression scores as measured with Patient Health Questionnaire (PHQ-9). These tests were made available online in a series of two trials. Results supported the use of the model with all three tests compared to using them individually.

The development of explicit and implicit game-based digital behavioral markers for the assessment of social anxiety

The current special issue also contained a study on behavioral biomarkers, that targeted social anxiety. Dechant et al. argued that one extract of digital behavioral markers from game-based behavior and use them to assess social anxiety. Digital distance from other game characters was one such marker that mimics the real-life behavior of a socially anxious person. The study's findings suggested that social anxiety's hallmark behaviors can be seen in the world of video games. Higher levels of social anxiety led to altered movement patterns toward non-playing characters (NPCs). There were several other interesting results highlighted in the paper and including cueing how game-based digital behavioral markers can be used in the future for the assessment and screening of social anxiety.

The therapeutic goals set by university students in an anonymous web-based therapy and support setting

Another interesting study using descriptive student data from the Kooth Student web-based therapy platform is that of Hanley et al.. The goal of the study was to extract the characteristics common to students using web-based therapy services, the therapeutic goals students typically set for themselves, and how well they are progressing toward those goals. The study analyzed anonymous data from 211 students who reported their goals on the platform. The most common goals expressed by students focused on getting additional support in exploring emotions. Some other findings indicate that women are more likely to achieve their goals, while students regardless of gender are more likely to seek help than self-help. The article also offers some insights into the barriers to collecting meaningful outcome data from anonymous services.

Conclusion and discussions

The research from this special issue addressed most of the issues concerning effectiveness of the DMHI. First, it's important to consider user-related factors including demographics (age, sex, education, and socioeconomic status), diagnosis and severity of symptoms, attitudes toward the use of digital technologies, personality features, and the availability of treatment. Secondly, the level of assistance the users require and its adaptability.

Thirdly, the technological characteristics of the devices and platforms used (i.e., the costs of the device, the necessary resources to make it functional, and technical issues/problems the user may encounter) and privacy and data collection are also important assets.

Although there are thousands of studies that supported the effectiveness of DMHI, this special issue showed that research may focus more on examining the attitudes of different users toward technology and digital content. In addition, the practice of co-designing technology-mediated interventions, where the users collaborate with the developers, has emerged as a current need in several studies. Another concept wort exploring in other studies concerns the importance of cultural differences and their effects on the effectiveness of DMHI. We could also compare the effectiveness of different types of technologies ns, such as computer-generated scenarios vs. 360° videos, different designs of content interactivity, and VR vs. 2D content. Particularly given challenges posed by COVID, research adapted rapidly and addressed important and challenging issues concerning well-being and offered potentially effective solutions such as remote interventions delivered with DMHI.

In the current special issue, most studies used various DMHI platforms ranging from traditional technical devices, web-based content, smartphones, to digital tablets. However, there were also studies that used immersive solutions such as VR or telepresence, robots and wearable devices. VR-based solutions that use machine learning and algorithms and wearable technologies, are notable prospects that could be included in future studies. Although many of the studies in this special issue analyzed the effects of DMHI on mood disorders, distress, or psychological well-being, two studies described the use of DMHI for schizophrenia and suicidal ideation (Szlyk et al.; Vass et al.).

We also mention the importance of involving multiple stakeholders in the therapeutic process (e.g., teachers or parents), and the adaptability of the program to suit the needs of the participants as important issues. One study attempted to address one of the main problems in this area, treatment adherence, using self-enhancement methods (Isbăşoiu et al.). Previous studies by Zarski et al. (2018) suggested that self-regulatory effort was a predictor of treatment adherence, so the use of self-enhancement techniques could be a valid way to increase treatment adherence. However, no significant results were found. Another study (Boucher et al.) examined whether financial incentives could increase user engagement. Although it discussed several studies, it concluded that monetary incentives can only be effective in increasing engagement in the use of the technology, but not necessary in the delivery of the treatment, that usually lasts several sessions. Taken together, results suggest that treatment adherence and user engagement are key issues that need further study.

While two of the studies in this special issue focused on the use of DMHI for assessment of cognitive processes; the majority were intervention oriented. However, more research is needed to determine the effectiveness and precision of digital evaluation tools especially delivered *via* telepresence (e.g., remote and automatized neuropsychological assessment). The next generation of evaluation methods for emotional symptoms mayd be developed using new technologies such as VR, social robots, or wearable devices. One advantage of using immersive solutions would be the ability to quantify physiological symptoms more accurately and objectively in real time. For psychological interventions, all of the research in this special issue included intervention strategies from different therapeutic paradigms.

Overall, current issue offers unique insights into the use of DMH assessments and interventions. Although several studies support the efficacy of DMHIs in reducing symptoms associated with psychological disorders, there are several important issues to consider when developing interventions that aim to reduce psychological distress. Co-designing digital interventions with end users, increasing user motivation and engagement, and considering the cost and ease of use of the technology used, are only some of the factors that should be pondered in. Future research could examine treatment adherence and accessibility of DMHIs for across a wide range of population ranging from people with less prevalent mental disorders (e.g., personality disorders, psychosis) and people from disadvantaged backgrounds and other cultures than Western culture. In addition, future studies could evaluate the impact of different technological tools and tailor them to the specific population they are most appropriate for.

Author contributions

CC, IP, and AV wrote and revised the manuscript. All authors contributed to the article and approved the submitted version.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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CASE REPORT
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Case Report: Feasibility of a Novel Virtual Reality-Based Intervention for Patients With Schizophrenia

Edit Vass[1]*, **Viktória Simon**[1], **Zita Fekete**[2], **Balázs Kis**[3] **and Lajos Simon**[1]

[1] Department of Psychiatry and Psychotherapy, Faculty of Health, Semmelweis University, Budapest, Hungary, [2] Institute of Behavioral Sciences, University of Debrecen, Debrecen, Hungary, [3] Department of Psychiatry, Szabolcs-Szatmar-Bereg County Hospital and University Teaching Hospital, Nyíregyháza, Hungary

Schizophrenia is a severe and disabling mental illness, associated with persistent difficulties in social functioning. While gaining and retaining a job or staying socially integrated can be very difficult for the patients, the treatment of poor functionality remains challenging with limited options in pharmacotherapy. To address the limitations of medical treatment, several interesting and innovative approaches have been introduced in the field of psychotherapy. Recent approaches incorporate modern technology as well, such as virtual reality. A potential therapeutic benefit of virtual reality is particularly significant when an interpersonal dimension of the problem needs to be addressed. One example is a Virtual Reality based Theory of Mind Intervention (VR-ToMIS), a novel method, which enables patients to practice complex social interactions without the burden of real-life consequences. Our paper presents a case report showing promising results of VR-ToMIS. Ms. Smith is a 50- year-old patient who has been suffering from schizophrenia for 20 years. Although in her case there was no problem with compliance throughout the years, she had severe problems regarding social functionality. With VR-ToMIS, she improved in ToM and communicative-pragmatic skills. The effects of the intervention went beyond the increased scores of the tests. Before the intervention there was a risk of the patient becoming unemployed as she was unable to follow the main principles of communicative exchange. Usually, her contribution was more informative than was required. After the intervention her communication became more balanced and she could retain her job. This case suggests that VR-ToMIS may be a promising tool for treating social disfunction in schizophrenia.

Keywords: virtual reality, case report, theory of mind, schizophrenia, simulation

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Alexandra Voinescu,
University of Bath, United Kingdom

Reviewed by:
Shiho Ubukata,
Kyoto University Hospital, Japan
Liviu Andrei Fodor,
Babes-Bolyai University, Romania

****Correspondence:***
Edit Vass
vass.edit@med.semmelweis-univ.hu

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INTRODUCTION

Schizophrenia is a chronic mental disorder affecting up to 1% of the population (Saha et al., 2005). While medical treatment primarily aims at the elimination of positive and negative symptoms, it has limited effect on concomitant functional deficits (Leifker et al., 2009; Kovács, 2011). To address this limitation several novel and innovative approaches have been introduced in the field of psychotherapy. During this process, social cognitive interventions have also recently become popular (Kurtz and Richardson, 2012; Vass et al., 2018).

Published findings on the functional significance of social cognitive deficits provide a stable theoretical basis for new developments (Penn et al., 1997; Mancuso et al., 2011; Green et al., 2015). The role of one of the subcomponents, the Theory of Mind (ToM), is considered to be more directly related with functional outcomes (e.g., employment) than other fields of cognition, which highlights ToM deficit as a potential treatment target (Brüne, 2006; Bell et al., 2009; Bora et al., 2009).

Despite early attempts at improving ToM skills in schizophrenia leading to promising results, these methods have often been criticized for not being able to fully cover the complexity (both cognitive and affective aspects) of ToM(Kurtz and Richardson, 2012; Vass et al., 2018). Typically, these interventions use the technique of analyzing social interactions observed in short film clips or displayed on comic strips or by using story vignettes (Kurtz et al., 2016; Tan et al., 2016). Such training materials may not be suitable for grasping the interpersonal dimension of ToM. However, incorporating modern technology, especially immersive virtual reality (VR) might be a promising option in resolving the problem (Vass et al., 2018). VR technology enables the simulation of social interactions where patients have the possibility to practice social skills without the burden of real-life consequences. One of the recently developed interventions that combines cognitive and behavioral therapy techniques and VR technology aims to take advantage of the potential of immersive simulation. VR-ToMIS (=**VR** based **ToM I**ntervention in **S**chizophrenia) is a VR based targeted ToM intervention, especially designed for stable outpatients with schizophrenia. VR-ToMIS primarily uses virtual roleplays to help patients improve their social skills (Vass et al., 2018, 2019). During its development, an iterative testing process was used, based on the published guidelines of the UK Medical Research Council (MRC) on the development and evaluation of multi-component interventions (Craig et al., 2013). The process has proved quite promising and pilot results on its feasibility have already been published. VR-ToMIS improved several aspects of ToM ($\eta_p^2 = 0.24–0.46$) and pragmatic skills ($\eta_p^2 = 0.22–0.39$), while negative symptoms ($\eta_p^2 = 0.58$) were significantly reduced when compared to control conditions. Self-reported Quality-of-Life scores did not change significantly. Yet, close relatives of the patients reported observable and obvious changes in the patients' attitudes and behavior during social interactions. Furthermore, patients found the intervention interesting and tolerated it well. Although the mentioned results show that VR-ToMIS might be beneficial for schizophrenic patients, further study on a larger sample is needed to confirm its short-term and possible long-term effects (Vass et al., 2020).

Here, we present a case report of a chronic schizophrenia patient, showing the advantages of this novel intervention. Ms. Smith has been suffering from schizophrenia for 20 years. Although she responded well to antipsychotic medication, she still suffers from severe functional deficits. She has become socially isolated throughout the years, and before the VR-ToMIS intervention she also had difficulties in retaining her job.

CASE PRESENTATION

History of the Patient

Ms. Smith, a divorced Caucasian female in her fifties, has been suffering from schizophrenia for the last 20 years. Although most of her symptoms have been alleviated, she still has severe functional difficulties.

She experienced her first symptoms in 2000, after having severe familial conflicts. She started to think that even her family had been conspiring against her, which caused her to make reports against her family members to the police. She experienced thought-reading and showed disorganized behavior. She was hospitalized and first diagnosed with "Schizophreniform disorder," based on the diagnostic criteria of DSM-IV in 2000, and Haloperidol was started (electronic database was only introduced after 2004 in Hungary, therefore, only information obtained from the patient is available for that period) (American Psyhicatric Association, 2000). Although she suffered from unpleasant side-effects, she had good insight and accepted the treatment. In 2001, considering the frequent delusions and behavioral changes, paranoid type schizophrenia was diagnosed.

While her symptoms improved with medication, management of various life situations caused her severe problems and she also noticed a decline in her social skills. She often found it hard to recognize others' needs, intentions or feelings. She considered these difficulties as a life-changing aspect of her illness, which radically altered her life in many ways: Saha et al. (2005). She often had conflicts with her ex-husband and with her colleagues (Leifker et al., 2009). She was on the verge of dismissal several times (Kovács, 2011). Finally, she lost the few friends she had, even her sons turned away from her.

She was hospitalized four times (three times before 2005, and once in 2018), and tried various medications (**Table 1**). Additionally, she received psychotherapy that helped her understand how her way of thinking differed from others' (**Table 1**). However, she had difficulties in transferring the learned skills into real life interactions.

At the time of the baseline visit, the patient was stabilized on Paliperidone. Her last psychotherapy finished 1 year prior. Ms. Smith received antihypertensive medication and had no other condition requiring medical treatment.

TREATMENT METHODS – COURSE OF THE INTERVENTION

Upon the first time we met, Ms. Smith expressed suspiciousness without reaching the severity of delusion. She was unable to follow the main principles of communicative exchange. Usually, her contribution was more informative than was required. She still had her job, but she was on the verge of dismissal due to the above-mentioned problems with communication.

Clinical assessment for symptomatology was administered by a trained psychiatrist (BK) using the Positive and Negative Syndrome Scale (PANSS) (Kay et al., 1987; Shafer and Dazzi, 2019). Assessments for ToM, pragmatic language skills and

TABLE 1 | Pharmacological treatments and psychotherapeutic interventions.

Medication	Dosage	Treatment duration	Comments
Pharmacological treatments			
Haloperidol	Unknown	2000–2007	No data is available in electronic database before 2007 According to the patient she was hospitalized three times before 2005. In all three cases, only the dosage was changed. Medication was stopped because of side effects: dizziness, headache, muscle-weakness, tremor
Risperidone	2 × 2 mg/day	2007.07.12–2013.02.07.	Instead of Haloperidol Stopped because of galactorrhea
Aripiprazole	15 mg/day	2013.05.09–2018.08.30.	Instead of Risperidone. Stopped because of anemia and thrombocytopenia.
Quetiapine	50 mg/day	2017.12.14–2018.05.05.	In conjunction with Aripiprazole No details on the reasons of adding. Stopped because of hallucinations, and depressed mood.
Olanzapine	10 mg/day	2018.04.05–2018.04.12.	Instead of Aripiprazole and Quetiapine Dosage reduction because of sedative side effects.
Duloxetine	30 mg/day	2018.04.05–2018.09.28.	Started in conjunction with antipsychotic medication because of depressed mood.
Olanzapine	5 mg/day	2018.04.12–2018.06.13.	Reduced dose Stopped because of agitation, disorganized behavior, paranoid delusions and impulsivity. Hospitalization was needed.
Paliperidone	150 mg/4 weeks	2018.06.13–ongoing	Started in replacement of Olanzapine Same dosage throughout the study, no additional medication was needed.
Psychotherapeutic interventions			
Psychoeducation	During hospitalization and before any changes in medication		The patient found the information useful, which helped her to accept the diagnosis.
Supportive therapy	1 h/session/ week	for 10 weeks in 2015	The patient found the process too slow.
Problem solving group	2 h/week	for 20 weeks in 2017	It was found useful by the patient in solving specific problems, but the coping skills didn't improve in general, based on her subjective evaluation.
Metacognitive training	1 h/sessions, 2 times/week	for 9 weeks in 2018	The patient liked the training and found it interesting, but she had problems with using the learnt skills in real life situations.

Quality-of-Life on the other hand was ascertained by a licensed clinical psychologist (ZF), consisted of Repeated Battery for the Assessment of Neuropsychological Status (RBANS), Wisconsin Card Sorting Test (WCST-64), Baron-Cohen Minds in the Eyes Test (BCMET- as main inclusion criteria was <22 points, indicating Theory of Mind deficit), Faux pas test, Cartoon stories task, the Hungarian Metaphor and Irony test, and Lancashire Quality-of-Life Profile (LQoLP) (Baron-Cohen and Knight, 1998; Randolph et al., 1998; van Nieuwenhuizen et al., 2001; Varga et al., 2008; Fernández-Abascal et al., 2013; Heaton et al., 2021). Ms. Smith completed all evaluations at baseline, post-treatment and at 3 months after the end of the intervention.

Informed consent was obtained prior to inclusion, including permission for the publication of this case report (Reference number of the ethical approval of the Local Research Ethics Committee: SE-TUKEB 150/2016).

VR-Based Intervention

Ms. Smith participated in a 9 week VR-based intervention (1 h/session/week) in an individual setting led by a licensed clinical psychologist (EV) under the supervision of an experienced psychotherapist (LS). We used the protocol of the ongoing efficacy study/previously published feasibility study of VR-ToMIS (Vass et al., 2020). VR-ToMIS applies an immersive VR software (vTime), with a Samsung GearVR head mounted display built in a Samsung S7 smartphone, and a Simple Controller (www.vTime.net).

Education Session

Education sessions served the purpose of familiarizing Ms. Smith with the used technology. Thus, she had the possibility to explore various virtual destinations and meet avatars provided by vTime. VR environments consisted of realistic simulations of various places (e.g.,: Chinese restaurant, coast, office) and an avatar visible from a first-person perspective. Ms. Smith learned to navigate between the virtual locations, and also had the opportunity to design her own avatar (including hair, body type, skin color, dress). In the second part of the session, she met another avatar. She was requested to express her feelings and impressions on the avatar and the situation, so we could redesign it to make the situation more comfortable for her (even the outfit of the avatar, or distance between the avatars). This step also served as the basis for an initial cognitive intervention with the aim of highlighting the possible effects of environmental factors on the interpretation of both the situation and her behavior. At the end of the session, possible side effects and a sense of presence were assessed by using Simulator Sickness Questionnaire and Presence Questionnaire (Kennedy et al., 1993; Witmer and Singer, 1998).

VR-Sessions

The structure of each session was the same (**Figure 1**). After a short warm-up, a brief description of the VR-simulation was given to Ms. Smith (e.g.,: session 8: "You are having dinner in a restaurant. A man approaches you"). Then the patient was given the opportunity to ask questions about the situation and design her own avatar appropriate to the situation. The other avatar was designed by the therapist prior to the session.

During the simulation Ms. Smith was asked to participate in a virtual conversation with the avatar in one of the immersive VR destinations of vTime. The dialogs were quite short and aimed to reveal ToM deficits to address in future therapeutic interventions. The virtual conversations were initiated by the avatar controlled by the therapist. All sentences of the dialogues were pre-recorded and played one-by-one following the patient's reaction. To avoid communication dead ends, in the case of some sentences, alternative responses were recorded so that the therapist could choose one which best fits the patient's reaction.

Each simulation was followed by an interactive task using another software, called Temporal Disc Controller (TDC), which is a validated tool to assess emotion perception (Takács and Kiss, 2003; Csukly et al., 2004). The TDC task served as an aid to visualize the inferred emotions of the therapist-controlled avatar ("the other") by the patient after the simulation. The TDC shows an avatar's 3D face on the computer screen. The emotions on the face can be displayed by moving a cursor on the screen. Right after the TDC task the therapist used cognitive and metacognitive techniques to help Ms. Smith understand how her thoughts and feelings play an influential role in her behavior, and identify maladaptive behavioral patterns applied during the simulation. For instance, when the avatar was bald, it evoked bad memories and made her attitude more sensitive toward him. When circumstances were changed (the avatar had hair) her suspicion became moderated.

After the therapeutic interventions Ms. Smith was encouraged to re-enter the same simulation to "virtually" test the validity of the therapeutic interventions and new behavioral patterns. Minor differences might have occurred between the simulations based on the patient's feedbacks (e.g., the outfit of the other avatar, the distance between the avatars). The described process (simulation-TDC task-CBT intervention – re-simulation) could be repeated up to 3 times per session.

Simulations on different topics were used in each session characterized by different levels of complexity. At the end of each session, individualized homework was given to the patient with the aim of facilitating learning transfer effects. Possible side effects and sense of presence were examined at the end of each session, as outlined above.

OUTCOME

Qualitative Results

Impressions – Psychologist

At the beginning Ms. Smith gave extreme reactions within VR simulations. She either didn't respond to the avatar, or her responses were long and more detailed than was required. Environmental factors also had an effect on her attitude during the simulation (e.g., when she found the virtual room too tidy, she thought that she didn't deserve to be there and assumed that the other person thought so too and might have bad thoughts about her. Hence, her interpretations of the situation were based on the thoughts and feelings mentioned above and not on the actual behavior of the other person). As she explained, these reactions were consistent with her real-life behavior. Initially, cognitive and metacognitive techniques proved insufficient to make her realize how her experiences, feelings and thoughts affected her reactions during a particular social interaction. However, when virtual environmental factors were changed and she was encouraged to participate in the same simulation again, she recognized that her feelings or reactions had indeed changed accordingly. As the intervention progressed, virtual behavioral experiments helped the patient to also become more receptive to cognitive techniques.

TDC also had an interesting effect on her. At first, she found it hard to display the inferred feelings on an avatar's 3D face on a computer screen. Sometimes her difficulties with this task caused her to refuse even attempting it. Encouraging Ms. Smith to verbally express and imitate emotions intended to display prior to the actual TDC task helped her slowly become accustomed to it. After a while the presented and verbally described emotions almost completely overlapped.

Despite initial difficulties Ms. Smith enjoyed VR-ToMIS, and even minor successes reinforced her efforts.

At the end of the intervention the communication style of Ms. Smith became more balanced. She adhered more to the main principles of communication described by Grice (Mazza et al., 2008). She was more able to pay attention to the other person's mental state, and was less prone to mistrust.

Impressions – Ms. Smith and Her Employer

After the intervention, a short post-intervention semi-structured interview was used to evaluate Ms. Smith's thoughts and feelings toward VR-ToMIS. She found VR-ToMIS interesting, enjoyable, realistic and easy to use. She highlighted that VR-ToMIS had an important role in her rehabilitation and that it helped her improve her communication and retain her job. Although she

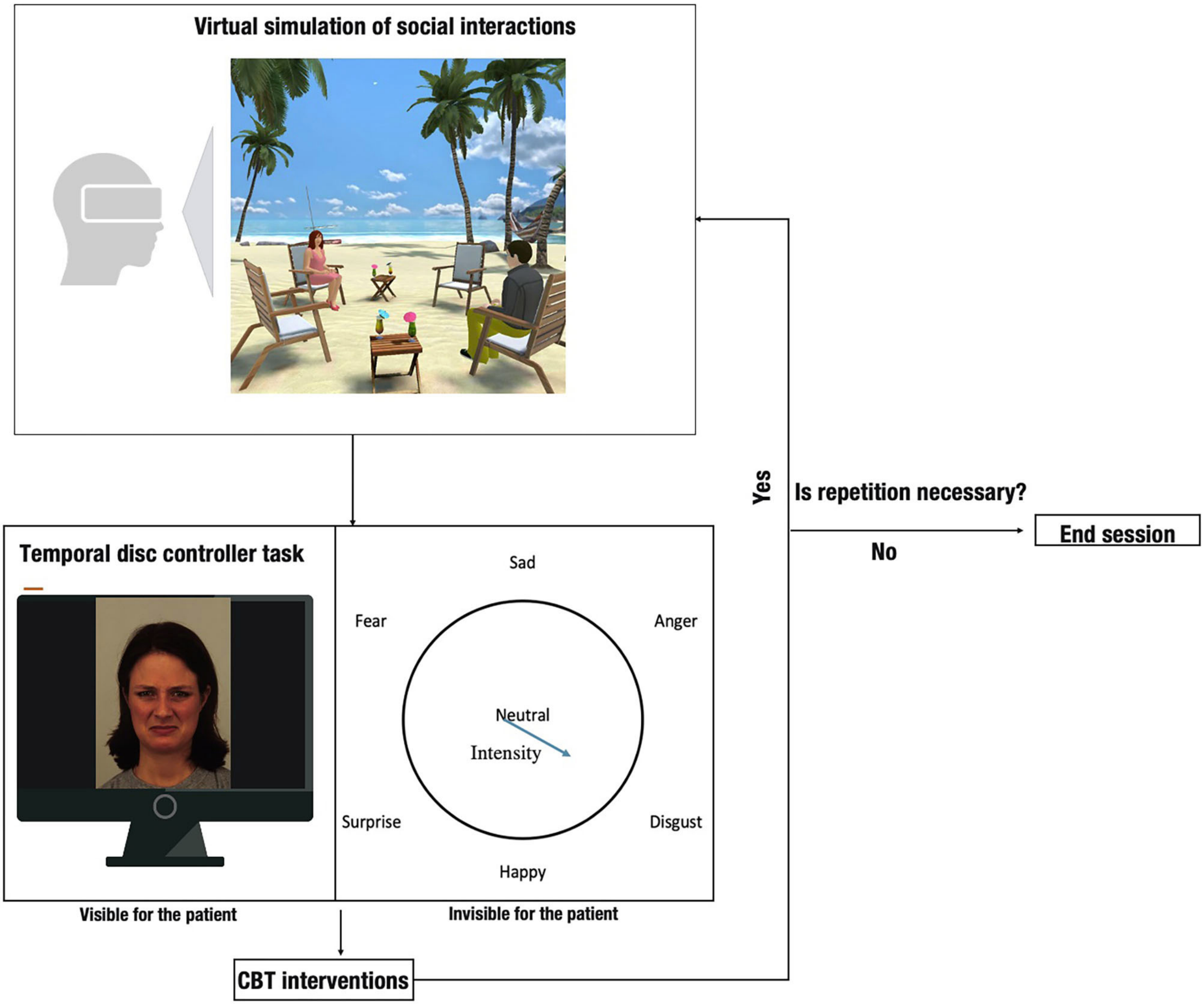

FIGURE 1 | Structure of the intervention (The image illustrating the virtual simulation was used with permission from vTime).

still felt isolated, she also felt more capable of getting involved in meaningful relationships.

Our intention was to also evaluate the changes in Ms. Smith's behavior attributed to the intervention from the perspective of someone close to her. As we couldn't reach any of her close relatives, we visited her employer with Ms. Smith's permission. They have been working together for 19 years and are in daily contact. The employer noticed positive changes in Ms. Smith's willingness to initiate a conversation and in her willingness of being engaged in them. She also noticed that Ms. Smith was able to better control the amount of communication with respect to the person she is in contact with. Misunderstanding others' intentions was also less frequently observed. As a most visible change, the employer highlighted that Ms. Smith's communication style changed reflecting that she had become more considerate of others' mental state during a conversation. On the other hand, no changes in self-determination were observed. At the time of the follow-up assessment, Ms. Smith still had her job. Her employer still noticed the above-mentioned changes in her behavior. However, she added, that the changes are not as explicit as they were before. This observation was most characteristic in the field of initiating a conversation. Accordingly, the patient also indicated during the 3-months follow-up that she become uncertain about her skills, especially in complying with communication rules, but no deterioration in ToM skills was perceived by her.

Objective Results

Objective results were calculated compared to the baseline scores, considering the maximum scores available on the tests (**Figure 2**). Considering the ToM assessment, there was a 21% increase in the BCMET scores. The improvement remained at 19% at the 3-months follow-up. Cartoon total scores showed a 5% increase after the intervention but vanished at the 3-months

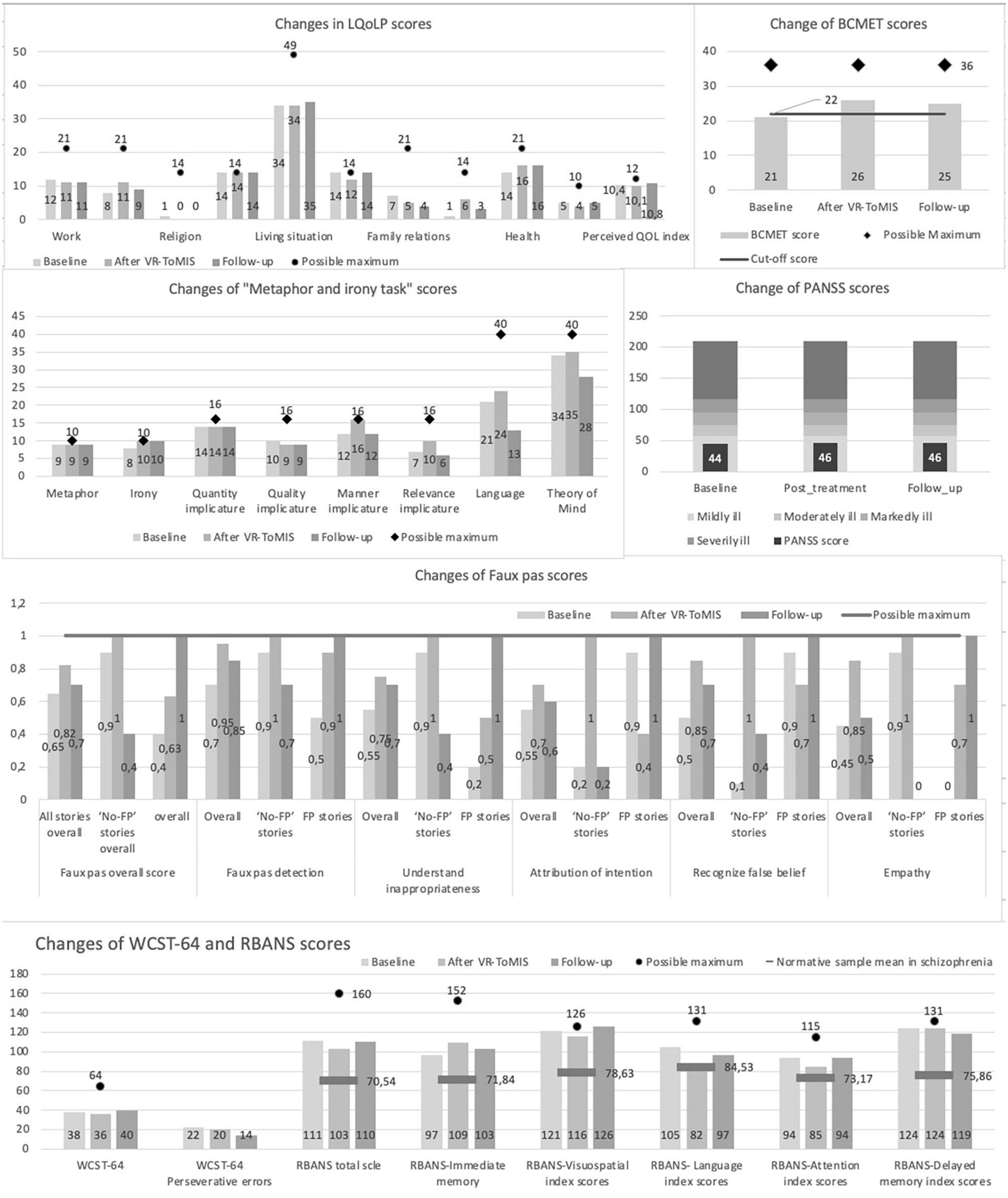

FIGURE 2 | Changes is scores form pre-to post intervention and after 3-month follow-up.

follow-up. Almost all subscales of the Faux pas test showed improvement within the range of 11–88% after treatment. In 37% of the cases, improvement on Faux pas scores were sustainable at the follow-up assessment. Regarding pragmatic language skills, 33% improvement on manner implicatures and 44% on relevance implicatures were detected. However, in line with qualitative results 3-months after the treatment this change was no longer detectable. In contrast to subjective feedback, in the case of quantity implicatures, no changes were detected. With respect to symptomatology and neurocognition, no changes were observed after VR-ToMIS. However, our patient's scores were above the normative sample means in schizophrenia even at baseline (Loughland et al., 2007). Regarding Quality-of-Life scores, only the subjective evaluation of Social Relationships showed remarkable change, which stayed notable also at the follow-up (**Figure 2**). A high sense of presence and no side-effects were reported during treatment (Realism sub-score on Presence questionnaire: 83%).

DISCUSSION

Our case report describes a case of a chronic schizophrenic patient with good compliance. She responded well to antipsychotic medication and most of her symptoms have been alleviated. However, she still suffered from persistent social disfunctions. Lacking options to improve her complaints, she applied for our experimental VR-based intervention as soon as she heard of it.

Despite the initial difficulties, Ms. Smith enjoyed VR-ToMIS, and during the intervention she improved in a way that proved to be transferable to real life interactions and changes were even noted by her employer. Moreover, many of these improvements remained stable 3-months after the end of the intervention. With VR-ToMIS Ms. Smith learned to identify other people's mental states more accurately, which was also indicated by the BCMET and Faux pas scores. In line with literature data, suggesting the sense of presence as a core element of successful VR interventions, the mentioned experiences were associated with the subjective feeling of presence during the simulation (Diemer et al., 2015).

Consistent with the changes observed in the patient's behavior and attitude, increased scores on relevance and manner implicatures tasks were also noticed, suggesting that Ms. Smith's performance improved in complying with the main communication principles. On the other hand, implicature subtasks of Metaphor and Irony seem to be only sufficiently informative to notify the breaching the principles and not for following them. This assumption is supported by the fact that although her contribution became appropriately informative during an interaction after VR-ToMIS, this change wasn't followed by the improved scores in the quantity implicatures subtask. In contrast to our previously published pilot results, the effect of VR-ToMIS on ToM and pragmatic language skills wasn't accompanied by any change in symptomatology and neurocognition. Since the strong relationship between ToM deficits and negative symptoms is well-supported by the literature, the lack of improvement assumes a complex mechanism behind the intervention, which requires further research (with larger sample size) to be understood (Harrington et al., 2005; Sprong et al., 2007). With respect to Quality-of-life, only subjective evaluation of social relationships changed during the intervention. Surprisingly, no improvement was detected in "work" sub-scores. When we tried to explore the background of her evaluation Ms. Smith explained that, in the end, nothing changed, as she's still working at the sheltered workshop. Although low internal consistency of Work domain on the scale can also be a possible explanation, in addition to the above there were no other changes detected in Quality-of-Life domains after the intervention at the follow-up assessment (Gaite et al., 2000; Vass et al., 2020). Considering the contradiction between the objective and subjective results at this point, choosing the inappropriate measuring tool to assess the desired changes can be a probable explanation.

Beyond the results described, there are some advantages and disadvantages of using VR-ToMIS worth mentioning. It seems that VR-ToMIS may have a strong learning transfer effect, helping the patient utilize the learnt skills in everyday life, as was supported by the patient, her employer and also by our observations. This conclusion is in line with the observable trend in the development of ToM interventions, suggesting that the use of VR technology in ToM development might further the advantages of classic ToM interventions in schizophrenia (Vass et al., 2018). Furthermore, as the problem of compliance is usually a major obstacle in psychiatric care for schizophrenic patients, using a method that is interesting and enjoyable is crucial. Based on patients' feedbacks, VR-ToMIS is well-tolerated and enjoyable, which holds the promise of taking a step toward solving the problem of compliance. Additionally, this is a low budget development, which is technically based on a free downloadable software. However, although the program is well-designed and we are in contact with the company, keeping in mind their primarily entertainment purposes, the number of available virtual destinations that can be adapted to our goals is limited, which also limits our scope for expanding the intervention. In addition, VR-ToMIS requires the simultaneous use of more technical devices by the clinician, that may make use of the method challenging.

The overall experiences suggest that VR-ToMIS is well-tolerated and, despite the disadvantages, the initial results are quite promising. However, some limitations also must be mentioned. Only a pilot RCT study and a single case report suggest the feasibility of VR-ToMIS, which clearly indicates the need for further research, with a larger sample size. In addition, follow-up results on the possible long-term effects of the intervention haven't been published yet, which makes this case report a single point of reference. Finally, conflicting results of Quality-of Life scale and subjective observations on the patient's improvement highlight that the choice of appropriate assessment tools can influence the interpretation of the experiences, which we need to pay more attention to in future studies. Furthermore, in light of the observed difference between short-term effects and detectable effects during the 3-months follow-up, future studies may also consider the possibility of increasing the length of the intervention, which might be more beneficial in maintaining the improvement.

CONCLUSION

The presented case suggests that VR-ToMIS may be a useful tool for rehabilitation in schizophrenia even in chronic cases where the patient exhibits severe difficulties in social functioning.

DATA AVAILABILITY STATEMENT

The datasets presented in this article are not readily available because Research data is confidential. Requests to access the datasets should be directed to Edit Vass, vass.edit@med.semmelweis-univ.hu.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Semmelweis University, Local Research Ethics Committee. The patients/participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

AUTHOR CONTRIBUTIONS

ZF and BK collected data on the patients. EV and LS led the interventions. EV and VS wrote the paper. All authors provided critical comments and approved the final version of the manuscript.

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STUDY PROTOCOL
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Efficacy of an ACT and Compassion-Based eHealth Program for Self-Management of Chronic Pain (iACTwithPain): Study Protocol for a Randomized Controlled Trial

Sérgio A. Carvalho[1], Inês A. Trindade[1]*, Joana Duarte[2], Paulo Menezes[3,4], Bruno Patrão[3,4], Maria Rita Nogueira[4,5], Raquel Guiomar[1], Teresa Lapa[6,7], José Pinto-Gouveia[1] and Paula Castilho[1]

[1] University of Coimbra, Center for Research in Neuropsychology and Cognitive Behavioral Intervention, Coimbra, Portugal, [2] Lund University, Department of Psychology, Lund, Sweden, [3] University of Coimbra, Department of Electrical and Computer Engineering, Coimbra, Portugal, [4] Institute of Systems and Robotics, Coimbra, Portugal, [5] University of Coimbra, College of Arts, Coimbra, Portugal, [6] Coimbra Hospital and University Center, Pain Unit, Coimbra, Portugal, [7] Faculty of Health Sciences, University of Beira Interior, Covilhã, Portugal

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***Correspondence:**
Inês A. Trindade
ines.almeidatrindade@gmail.com

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Background: Chronic pain (CP) has serious medical and social consequences and leads to economic burden that threatens the sustainability of healthcare services. Thus, optimized management of pain tools to support CP patients in adjusting to their condition and improving their quality of life is timely. Although acceptance and commitment therapy (ACT) is considered an evidence-based psychological approach for CP, evidence for the efficacy of online-delivered ACT for CP is still scarce. At the same time, studies suggest that self-compassion mediates the change in disability and psychopathological symptoms in ACT interventions for CP, although self-compassion is not a specific target in ACT. Thus, an explicit focus on self-compassion might increase the efficacy of ACT interventions for CP, although this hypothesis has not been tested. This study aims to develop an eHealth ACT and compassion-based self-management intervention for CP, the iACTwithPain, and to compare its efficacy in improving health outcomes to a similar ACT-only intervention and a medical TAU group.

Methods: The eHealth platform that will host the interventions will be developed using a flat design identity and will be interactive. The iACTwithPain intervention will comprise eight weekly self-management sessions and will be developed taking into consideration the psychological flexibility model applied to CP, with the addition of explicit compassion-based components. To analyze whether the iACTwithPain intervention will present superiority in improving CP's impact and related health markers over the two other conditions, this study will follow an RCT design with three arms. CP patients will be recruited through direct contact with patient associations and healthcare services and a national press release in Portugal. Outcome measurement will be conducted at baseline, post-intervention and at 3- and 6-month follow-ups. The interventions' acceptability will also be assessed.

Discussion: The iACTwithPain intervention is expected to improve CP patients' psychosocial functioning, quality of life, and empowerment, by promoting adaptive disease management and regulation of pain-related internal experiences. Results will contribute to a better understanding on the pertinence of adding compassion elements to ACT for CP and to reach an optimized intervention for CP.

Clinical Trial Registration: This trial has been registered at ClinicalTrials.Gov (NCT04200183; 16 December 2019; https://clinicaltrials.gov/ct2/show/NCT04200183). The current manuscript comprises the first version of this clinical trial's protocol.

Keywords: acceptance and commitment therapy, chronic pain, compassion-based intervention, eHealth, ICT-delivered interventions, mindfulness, self-management

BACKGROUND

Chronic pain (CP), defined as sporadic or constant pain or discomfort lasting for more than 3 months (Elliott et al., 1999), is a major public health issue that affects 19% of adult Europeans and impairs the quality of their social and working lives (Breivik et al., 2006). In Portugal, a recent study estimated that CP has a median duration of 10 years, with 85% of CP patients with recurrent or continuous pain and 68% of CP patients with moderate to severe pain intensity (Azevedo et al., 2012). In addition, CP yields a great economic burden to the healthcare system and society at large. It is estimated that CP presents serious costs to economics and health services (Phillips, 2009). Moreover, evidence suggests that up to 50% of non-malignant pain patients are addicted to pain medication (Højsted and Sjøgren, 2007), which leads to further health problems (Højsted and Sjøgren, 2007) and imposes a cost burden on health systems (Shei et al., 2015).

Chronic pain is a multifaceted experience that results from an interplay of physiological states and psychological processes (i.e., thoughts, emotions), and current approaches to CP recognize the value of addressing the cognitive and affective aspects of pain (Eccleston et al., 2013). Studies show that CP is associated with psychiatric disorders (Dominick et al., 2012), with a significant impact on the quality of life and functioning of CP patients (Breivik et al., 2006). However, the current provision of care to CP sufferers vastly disregards psychological interventions. Also, traditional psychological interventions for CP focus primarily on controlling pain and overall symptoms' reduction. Nonetheless, research has shown that an exclusive and overly focus on pain control might be frustrating and damaging and actually result in more disability (McCracken, 1998), higher pain intensity, pain-related anxiety, and depression (McCracken and Vowles, 2006).

In contrast, for the last two decades the evidence has suggested that acceptance of pain is a major key process in successfully adapting to CP (Vowles et al., 2007; Vowles and McCracken, 2008) and is associated with less pain, disability, depression, and pain-related anxiety (McCracken and Eccleston, 2003). This led to a growing interest in acceptance-based approaches, focusing not so much in reducing and controlling pain, but rather in increasing the acceptance of pain (Costa and Gouveia, 2013; Pinto-Gouveia et al., 2015).

Acceptance and commitment therapy (ACT), which focuses on function improvement rather than symptom reduction, is an empirically supported intervention for CP (APA Presidential Task Force on Evidence-Based Practice, 2006). An ACT intervention for CP aims to promote emotional acceptance and engagement with values-consistent actions, despite CP symptoms (Hayes et al., 1999; Vowles et al., 2007; Vowles and McCracken, 2008). Recently, some studies suggested that ACT interventions also promote self-compassion (Yadavaia et al., 2014; Luoma and Platt, 2015), a non-judgmental and mindful approach to one's pain and suffering (Neff, 2003), which presents known links with pain regulation systems, such as heart-rate variability (Rockliff et al., 2008), and oxytocin-endorphin systems (Rockliff et al., 2011). Self-compassion has been the focus of growing attention in CP due to its protective role against depressive symptomatology in this condition (Carvalho et al., 2019), its negative association with pain disability (Wren et al., 2016), and the promising results showing the positive effects of compassion-based interventions in CP (Chapin et al., 2014; Ziemer et al., 2015; Parry and Malpus, 2017; Gooding et al., 2020).

Interestingly, self-compassion appears be associated with important ACT processes (Costa and Pinto-Gouveia, 2013; Carvalho et al., 2018a; Edwards et al., 2019), and although ACT interventions do not specifically incorporate explicit self-compassionate exercises, self-compassion was found to mediate the change in disability and psychopathological symptoms in an ACT intervention for CP (Vowles et al., 2014). This raises the possibility that self-compassion may be an under-recognized mechanism of change in ACT and that an explicit focus on self-compassion in ACT might increase the efficacy of ACT interventions. Further, although ACT interventions with elements from compassion-based approaches seem to significantly improve mental health in a number of clinical populations (Skinta et al., 2015; Palmeira et al., 2017; Pinto-Gouveia et al., 2017; Trindade et al., 2020), the individual role of self-compassion in ACT for CP and the benefit of adding explicit compassionate exercises to such interventions are still unclear.

There is a growing interest in using online interventions to improve health (i.e., eHealth). In fact, eHealth is expected to contribute to the sustainability of healthcare systems, with advantages such as reducing therapist time and waiting lists, increased cost-effectiveness, ability of patients to work at their own pace, accessibility to large clinical samples, and accessibility to rural and remote clinical cohorts (Bergmo, 2015). Also, it seems to provide an effective way of dealing with the inadequate training of health professionals in the psychological aspects of CP and of bypassing the shortage of psychological therapists in the national healthcare system. Some studies tested the efficacy of online ACT interventions for CP (Buhrman et al., 2013; Trompetter et al., 2014; Fledderus et al., 2015; Vilardaga et al., 2020), which resulted in reduction of pain intensity, pain-related distress, anxiety and depressive symptoms, and an increase of activity engagement and pain-willingness (Buhrman et al., 2013). However, there were several methodological limitations to these studies (small sample size and non-randomization). Further research is thus needed to better comprehend the efficacy of eHealth ACT interventions for CP and, in addition, the contribution of self-compassion to this approach.

Aims of This RCT

This study has three main aims: (1) to develop an ACT and compassion-based eHealth tool for CP management (iACTwithPain); (2) to analyze whether the iACTwithPain intervention will present superiority in improving CP's impact and related health and quality-of-life markers over an ACT-only intervention and a wait-list condition; and (3) to examine whether the interventions' efficacy will be explained by changes in therapeutic processes (e.g., self-compassion and psychological flexibility).

We hypothesize that the platform will present high acceptability and that both the ACT-only and iACTwithPain interventions will have efficacy in improving CP's impact, mental health, and quality of life. Further, we also hypothesize that the intervention with explicit self-compassion components, the iACTwithPain, will present superiority in decreasing self-criticism and increasing self-compassion, quality of social relationships, and social safeness through the activation of the affiliative system and subsequent stimulation of oxytocin activity. The efficacy of the ACT-only intervention is expected to be explained by increases in psychological flexibility and mindfulness abilities, and decreases in cognitive fusion and rumination. The iACTwithPain intervention's efficacy is expected to be explained by changes in the same processes and, in addition, by changes in self-compassion and self-criticism (**Figure 1**).

METHODS/DESIGN

This study is funded by the Portuguese Foundation for Science and Technology and is registered at ClinicalTrials.gov (Identifier: NCT04200183, date assigned 16/12/2019). Ethical approval has been obtained from the Ethics Committee of the Faculty of Psychology and Education Sciences of the University of Coimbra. Eventual protocol amendments will be communicated to this Committee.

Participant Recruitment

Recruitment will be facilitated by advertisement in Portuguese press and social media. Individuals interested in the study will sign up in the platform and then be asked to sign an informed consent fill out questionnaires designed to assess inclusion and exclusion criteria.

Participant Selection

Patients are eligible to participate if they:

- are aged between 18 and 50 years;
- have had a CP diagnosis for the last 3 months;
- have access to internet and willingness to do it regularly (at least once a week);
- are willing to be randomized;
- can read and write Portuguese; and
- can give informed consent.

Patients are ineligible to participate if they:

- are undergoing any other form of psychological intervention for CP;
- present a severe psychiatric problem (e.g., severe depression, psychotic illness, bipolar disorder, and borderline personality disorder)—assessed using several questions (self-reported) based on the diagnostic criteria according to DSM-V; and
- present pain due to malignancy, trauma, or surgery.

Participants who do not meet the eligibility criteria will be given feedback and advised to seek medical/psychological/group support.

Sample Size

Results from G*Power calculations for repeated measures analysis, assuming a p-value = 0.05, an effect size of $f = 0.25$ (Scott et al., 2018), with a statistical power of 0.95, three groups, and four measurements, recommend a sample size of 171. Giving the 30% drop-out rate in previous ACT-based intervention studies (Melville et al., 2010), the total sample size to be collected will be 246 (each group will be composed of 82 participants).

Randomization of Participants

Participants will be randomized (computer-generated random allocation) to one of three conditions: experimental condition 1 (ACT-only intervention); experimental condition 2 (iACTwithPain + self-compassion); and control condition (medical TAU). All participants will continue their treatment as usual for CP. Each participant will be randomly assigned with a number between 1 and 246; after number assignment, participants with numbers 1–82 will be allocated to experimental condition 1, 83–164 to experimental condition 2, and 84–246 to the control condition. Only participants from the experimental conditions will be blind to their allocation; we do not expect any need for unblinding participants in these conditions.

Participants in the two experimental conditions will then access to the respective version of the platform, where they will be asked to complete pre-intervention questionnaires (T0). The control group will only be provided access to the questionnaires.

Intervention Development

The iACTwithPain intervention will be developed by the psychologist members of this research team taking into consideration the psychological flexibility model applied to CP (e.g., Vowles et al., 2009; Dahl and Lundgren, 2016),

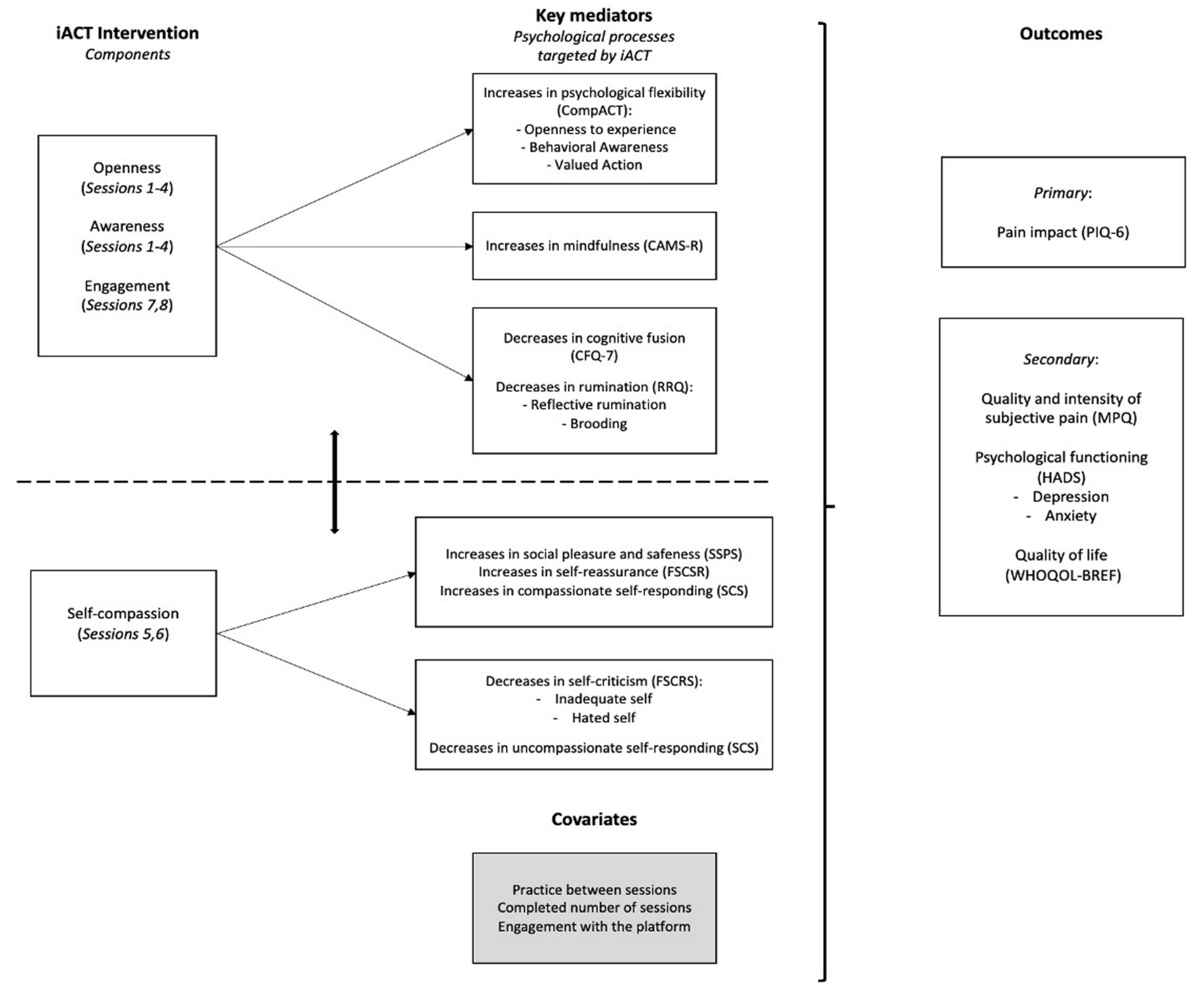

FIGURE 1 | Examples of session screens. This study's team holds the copyright of this image.

with the addition of compassion-based elements (Gilbert, 2009; Neff and Germer, 2018) specifically adapted to CP. The research team's experience on CP's psychosocial impact and related psychological processes (Carvalho et al., 2018a,b, 2019, 2020), and in developing and delivering ACT and compassion-based interventions to chronically ill populations such as CP, cancer (Trindade et al., 2020), inflammatory bowel disease (ClinicalTrial.gov NCT03840707, undergoing), as well as psychiatric populations (Pinto-Gouveia et al., 2017; ClinicalTrial.gov NCT04101032, undergoing) will be integrated to assure the development of an adequate and rigorous intervention.

The iACTwithPain Intervention

The iACTwithPain intervention (**Table 1**) will comprise core themes: (a) theme 1: pain acceptance (psychological flexibility in the presence of thoughts, feelings and behaviors associated with pain through mindfulness and acceptance practices); (b) theme 2: values-based action (promotion of behaviors consistent with personal goals, despite pain symptoms); and (c) theme 3: self-compassion (fostering a compassionate stance toward one's struggles and suffering), which will only be incorporated in the intervention for experimental condition 2. These themes will be delivered through eight sessions that will be available to participants throughout an 8-week period. Each session will be composed of video-animations, real-image videos, complementary texts, and audio files with the experiential exercises/practices targeting the specific topic of the session. An introductory brief session (session 0) will welcome the participant to the intervention and guide him/her through the use of the platform. From session 1, all sessions will begin with a brief soft-landing exercise. Participants will be asked to complete between-session mindfulness and/or compassion-based meditative exercises as often as they can. These between-session assignments will aim to promote skills introduced in the previous session.

TABLE 1 | Overview of the iACTwithPain intervention.

Session	Topics	In-session exercises/metaphors	Between-session assignments
0	Introduction to the intervention and the platform	Contemplative exercise "Exploring my motivations to do this intervention"	–
1	Psycho-education about chronic pain; The problem with our problem-solving minds (controlling is the problem); Promotion of creative hopelessness; Introduction to mindfulness practice	Mindfulness of breathing practice	Mindfulness of breathing practice
2	Mindfulness as a key aspect to manage suffering; Therapists' personal experience with mindfulness: Tips for maintaining regular practice; The body as an anchor to the present moment	Mindful movement exercise	Mindful movement exercise; Body scan practice
3	Exploration of the costs of trying to avoid/control pain; Promotion of willingness and acceptance	"What have I stopped doing because of pain?"; Passengers on a bus metaphor; Physicalizing exercise; Quicksand metaphor	Inviting a difficulty exercise
4	The power of thoughts; Promotion of cognitive defusion; Identification of the conceptualized self; Development of the observing self	Imagining an apple exercise; Labeling experiences exercise; The observing self exercise	Mindfulness of sounds and thoughts practice
5	Introduction to compassion: What it is and why we need it; Promotion of feelings of compassion for the self and others	Identification of compassionate sentences exercise; Loving Kindness practice	Informal compassion practice; Loving Kindness practice
6	Continuation of the development of self-compassion; Common obstacles to self-compassion	Safe place and compassionate friend exercise	Informal compassion practice; Safe place and compassionate friend exercise
7	Values definition and clarification	80th birthday exercise; Bull's eye exercise	Open awareness practice
8	Promotion of committed action; Summary of the intervention and maintenance "kit"; Gratitude practice as farewell	Plans of committed action exercise (choosing values, objectives, and actions, and identifying internal experiences that may pose as obstacles to committed action); Bicycle factory metaphor; Gratitude practice	–

The ACT-Only Intervention

The ACT-only intervention will follow the same structure and contents as iACTwithPain's, with the exception of sessions 5 and 6, which, instead of presenting compassion elements, will reinforce and further address willingness, acceptance, defusion, and observing self topics, without adding new information or practices. This intervention will be delivered via the same platform as the iACTwithPain intervention.

Treatment Integrity

Several aspects of treatment integrity guidelines for ACT (Plumb and Vilardaga, 2010) will be followed during the development of the intervention: (a) integrity was thought as a crucial part of the study, in which therapists′ competence was ensured by previous training in ACT and compassion-based approaches as well as supervision throughout the intervention; (b) the intervention was developed having in mind issues of integrity, by including ACT-consistent informative texts, exercises, and therapist lines and tips in videos; and (c) the intervention was developed following clearly operationalized processes of change from the ACT and compassion-based models.

Platform Development

The platform will aim at offering access to the interventions' contents via either personal computers or mobile devices. The platform will have an app-like functioning when accessed from a mobile device. It is based on a well-established CMS that will integrate new modules to support the user registration, enquities, and content delivery on pre-established sequence. The platform will include a set of sessions, each one composed of explanations, video animations, experimental exercises, supplementary texts, support material, daily tasks, audio meditation, and other practices.

Upon the agreement of the patients, usage data will be collected that will have two different purposes: (1) identifying usability issues and (2) understand how pain and suffering should be considered in the interaction design processes. With the exception of data that are required for the RCT, such as usage frequency, most of the usage-related data will be anonymized only keeping the relationships strictly necessary to guide the usability studies. The result of this effort will be to try to maximize the adherence and avoid dropouts due to usability issues and therefore contribute to retain participants in the study.

The platform's interface design will be based on a calmness-related message. Taking into consideration the target users and the fact that possibly they may be experiencing pain during the usage, all the elements will be designed taking that into account. The simple and flat design approach chosen is expected to eliminate or reduce to a minimum the existence of misleading cues that may induce frustration or distraction.

TABLE 2 | Schedule of enrollment, interventions, and assessments.

	Study period					
	Enrollment	Allocation	Post-allocation			
Timepoint	**-t_2**	**-t_1**	**t_0**	**t_1**	**t_2**	**t_3**
Enrollment						
Informed consent	X					
Eligibility screen	X					
Blinded randomization	X					
Allocation		X				
Interventions						
iACTwithPain			←	→		
ACT-only intervention			←	→		
Waiting list						
Assessments						
Primary outcome						
PIQ			X	X	X	X
Secondary outcomes						
MPQ			X	X	X	X
HADS			X	X	X	X
WHOQOL-bref			X	X	X	X
RRQ			X	X	X	X
FSCRS			X	X	X	X
SCS			X	X	X	X
SSPS			X	X	X	X
CAMS-R			X	X	X	X
CFQ-7			X	X	X	X
CompACT			X	X	X	X
*Intervention's acceptability questions**				X		

**only for the active conditions.*

Implementation of the Interventions

Participants will follow the sessions in a given order (from session 1 to 8, one session per week). All data will be linked to a data hub tracking participants' interaction with the platform (i.e., number of logins, duration of interaction with platform, number of visualization of videos/audios, and feedback on each session). Each week, participants will receive an email prompting them to login to the platform and complete the week's session (that becomes available 1 week after the previous session was completed by the participant). Participants will also receive automatically generated reminders via email with supporting messages: (a) if they do not login for more than 3 days and (b) if they practice continuously (contingency management by reinforcing frequent engagement and practice). This will be particularly important to remind participants to practice the between-session assignments. Contact with the research team will be made available to participants during the intervention period through a one-to-one chat incorporated in the platform. As neither intervention will present risks to participants, a data monitoring committee is not expected to be involved. Adverse events are also not expected. Participants who skip more than two sessions will not be considered for the RCT (in the iACTwithPain group participants who do not complete both of the compassion sessions will be additionally excluded).

Primary and Secondary Outcomes in the RCT

Before (T0) and after (T1) the interventions, and in the 3-month (T2) and 6-month (T3) follow-ups, participants in the experimental conditions and in the waiting-list control condition will be assessed through several self-report questionnaires. Participants will receive notifications via email to complete the self-report measures. These data will be collected in the iACTwithPain platform using high standard security mechanisms which will ensure confidentiality. Only the research team will have access to the collected data, including the final dataset, which will be managed by the study's PI (PC) and kept for 5 years after the study ends. Participants will only be identified by a generated code.

Participants will provide sociodemographic and clinical information and complete self-report measures (in their validated Portuguese versions) to assess primary and secondary outcomes see **Table 2**.

Primary Outcome

Pain impact

The six-item Pain Impact Questionnaire (PIQ-6; Becker et al., 2007; Cavalheiro et al., 2011) will be used to assess participants' perceived pain severity (1 item rated on a 6-point scale) and impact on emotional well-being, leisure activities, and work functioning (five items rated on a 5-point scale).

Key Mediators

ACT-Related Variables

Psychological flexibility, as conceptualized by ACT, will be measured by the comprehensive assessment of ACT processes (CompACT; Francis et al., 2016; Trindade et al., under review), an 18-item measure with three subscales: openness to experience, behavior awareness, and valued action, in which items are rated on a 7-point response scale (0—"Strongly disagree" to 6—"Strongly agree"). Mindfulness abilities will be measured using the Cognitive and Affective Mindfulness Scale-Revised (CAMS-R; Feldman et al., 2007; Teixeira et al., 2017) which presents 12 items answered on a 4-point Likert scale from 1 (Not at all) to 4 (Almost always). Cognitive fusion will be assessed by the seven-item Cognitive Fusion Questionnaire (CFQ-7; Gillanders et al., 2014; Pinto-Gouveia et al., 2020), in which the response scale ranges from 1 ("Never true") to 7 ("Always true").

Rumination

This outcome will be assessed by the Ruminative Responses Questionnaire (RRQ; Treynor et al., 2003; Dinis et al., 2011), a 10-item measure with two subscales, reflective rumination and brooding, which are rated on a 4-point Likert scale (0—Almost Never; 3—Almost Always).

Self-criticism, self-reassurance, self-compassion, and social safeness

Self-criticism will be measured by the Forms of Self-Criticizing/Attacking and Self-Reassuring Scale (FSCSR;

Gilbert et al., 2004; Castilho et al., 2015b), a scale with 22 items measuring self-criticism (inadequate self and hated self) and the ability to self-reassure. Respondents rate items on a 5-point Likert scale (0 = not at all like me; 4 = extremely like me). Further, the Self-Compassion Scale (SCS; Neff, 2003; Castilho et al., 2015a) will provide the measurement of self-compassion. The SCS is composed of 26 items that assess six components: Self-Kindness, Self-Judgment, Common Humanity, Isolation, Mindfulness, and Over-Identification. Each item is rated on a 5-point Likert scale accordingly to how frequently participants act that way toward themselves in difficult times (1—"Almost never" to 5—"Almost always"). To assess social safeness, the Social Safeness and Pleasure Scale (SSPS; Gilbert et al., 2009) will be used. This is a 11-item instrument that measures, on a 5-point Likert scale, current feelings of safeness, belonging, acceptance, and a sense of connectedness.

Secondary Outcomes

Quality and Intensity of Subjective Pain

The McGill Pain Questionnaire (MPQ; Melzack, 1975; Figueiral, 2002), a three-part pain assessment tool, will be used to evaluate several dimensions of the participants' pain experience—location, intensity, and verbal description.

Psychological Functioning

Anxiety and depression symptoms will be assessed by the Hospital Anxiety and Depression Scales (HADS; Zigmond and Snaith, 1983; Pais-Ribeiro et al., 2007), in which participants rate the 14 items (7 items for each subscale) on a 4-point scale between 0 and 3 (the scale varies). For each subscale, scores between 0 and 7 are considered normal, 8–10 mild, 11–14 moderate, and 15–21 severe.

Quality of life

To assess this outcome, the World Health Organization Quality of Life—Bref (The WHOQOL Group, 1998; Vaz Serra et al., 2006), a 26-item multidimensional measure of subjective quality of life, will be used. This instrument measures four dimensions of quality of life (physical, psychological, social relations, and environment) on a 5-point Likert scale.

Acceptability Assessment

The intervention's acceptability will be assessed in the experimental conditions by analyzing (a) participants' adherence (attrition rate) and (b) results from the Client Satisfaction Questionnaire (Attkisson and Zwick, 1982) adapted to the eHealth intervention context.

Statistical Analysis

The efficacy of the iACTwithPain will be assessed by comparing pre-intervention, post-intervention, and 3- and 6-month follow-up questionnaires' scores through MANOVAs, repeated measures, within-between interaction (with Bonferroni correction). Changes in the primary outcome and in the secondary outcomes between pre-intervention, post-intervention, and follow-ups will be compared between the three conditions (iACT, iACTwithPain, and waiting-list). MANOVAs' assumptions (multivariate normality, linearity, absence of multicollinearity, and equality of covariance matrices) will be analyzed prior to analysis.

Additionally, changes in painkillers dependence and hospital visits (self-disclosed) will also be compared between the three groups. Cohen's d will be calculated to measure the between-group effect size on both primary and secondary outcomes. Changes in psychological processes (e.g., self-compassion, mindfulness, and psychological flexibility) will also be tested as potential mechanisms of change of the iACTwithPain intervention, using mediation modeling procedures. Missing data will be imputed with PASW Missing Value Analysis (SPSS Inc., United States) (Blankers et al., 2010).

DISCUSSION

To our current knowledge, iACTwithPain will be the first eHealth intervention that incorporates ACT and explicit self-compassion elements. This intervention is expected to improve CP patients' psychosocial functioning and quality of life, by promoting adaptive disease management and regulation of pain-related internal experiences. By providing access to specialized treatment with an online delivery format and self-management nature, the intervention is also expected to promote patients' empowerment and accessibility to treatment. Results will contribute to better understand self-compassion's individual role in ACT for CP, the pertinence of adding compassion-promoting exercises to those interventions, and to reach an optimized intervention for this population.

One of this study's strengths is the analysis of the potential mechanisms of change of the tested interventions, which will shed light on which therapeutic processes are responsible for improvements in CP, in both the iACTwithPain intervention and the ACT-only intervention. Another strength is the platform itself, which will be developed aiming at being intuitive and graphically attractive and which will track participants' interaction, providing objective data on participants' between-session practice and engagement with the interventions, which will be examined and accounted for in the efficacy test.

One of the most significant challenges will be the prevention of drop-outs. A strategic way of decreasing this risk will be to email participants with supportive and motivating messages every time the platform registers inactivity for more than 3 days. Another limitation will be that participants allocated to the control group (medical TAU) will not be blind to their allocation due to the nature of this condition, which might influence self-reported outcomes.

In conclusion, this study will contribute with a new eHealth self-management intervention for CP, which, if proven effective, will significantly help CP patients manage their pain and improve their mental health and quality of life and improve accessibility to treatment of remote clinical cohorts or with limited mobility. With this RCT, specific knowledge will be obtained about the role of self-compassion in ACT for CP and the potential benefits of adding explicit self-compassion elements to ACT.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Comité de Ética e Deontologia (CEDI), Faculty of Psychology and Education Sciences, University of Coimbra. The patients/participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

AUTHOR CONTRIBUTIONS

PC, JP-G, SC, JD, PM, BP, and TL wrote this project's grant proposal and attracted funding. IT adapted the proposal to this manuscript. All authors read, provided feedback, and approved the final manuscript.

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A Self-Applied Multi-Component Psychological Online Intervention Based on UX, for the Prevention of Complicated Grief Disorder in the Mexican Population During the COVID-19 Outbreak: Protocol of a Randomized Clinical Trial

Alejandro Dominguez-Rodriguez[1]*, *Sofia Cristina Martínez-Luna*[2], *María Jesús Hernández Jiménez*[1], *Anabel De La Rosa-Gómez*[3], *Paulina Arenas-Landgrave*[2], *Esteban Eugenio Esquivel Santoveña*[4], *Carlos Arzola-Sánchez*[4], *Joabián Alvarez Silva*[5], *Arantza Mariel Solis Nicolas*[6], *Ana Marisa Colmenero Guadián*[5], *Flor Rocio Ramírez-Martínez*[4] and *Rosa Olimpia Castellanos Vargas*[4]

[1] Health Sciences Area, Valencian International University, Valencia, Spain, [2] Facultad de Psicología, Universidad Nacional Autónoma de México, Mexico City, Mexico, [3] Iztacala College of Higher Education, National Autonomous University of Mexico, Mexico City, Mexico, [4] Department of Social Sciences, Universidad Autónoma de Ciudad Juárez, Ciudad Juárez, Mexico, [5] Independent Researcher, Ciudad Juárez, Mexico, [6] Independent Researcher, Tijuana, Mexico

Edited by:
Ioana Roxana Podina,
University of Bucharest, Romania

Reviewed by:
Liviu Andrei Fodor,
Babeş-Bolyai University, Romania
Andreea Iuliana Luca,
University of Bucharest, Romania
Ana Toma,
University of Bucharest, Romania

***Correspondence:**
Alejandro Dominguez-Rodriguez
alejandro.dominguez.r@campusviu.es

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Background: COVID-19 has taken many lives worldwide and due to this, millions of persons are in grief. When the grief process lasts longer than 6 months, the person is in risk of developing Complicated Grief Disorder (CGD). The CGD is related to serious health consequences. To reduce the probability of developing CGD a preventive intervention could be applied. In developing countries like Mexico, the psychological services are scarce, self-applied interventions could provide support to solve this problem and reduce the health impact even after the pandemic has already finished.

Aims: To design and implement a self-applied intervention composed of 12 modules focused on the decrease of the risk of developing CGD, and increasing the life quality, and as a secondary objective to reduce the symptomatology of anxiety, depression, and increase of sleep quality. The Intervention Duelo COVID (Grief COVID) follows the principles of User Experience (UX) and is designed according to the needs and desires of a sample of the objective participants, to increase the adherence to the self-applied intervention, considered one of the main weaknesses of online interventions.

Methods: A Randomized Controlled Trial will be conducted from the 22nd of December of 2020 to the first of June 2021. The participants will be assigned to an intervention with elements of Cognitive Behavioral Therapy, Acceptance and Commitment Therapy, Mindfulness and Positive Psychology. The control group will be a wait-list condition, that will receive the intervention 1.5–2 months after the pre-measurement were taken. The Power Size Calculation conducted through G*Power indicated the need for a total of 42 participants, which will be divided by 21 participants in each group. The platform will be delivered through responsive design assuring with this that the intervention will adapt to the screen size of cellphones, tablets, and computers.

Ethics and Dissemination: The study counts with the approval of the Research Ethics Committee of the Autonomous University of Ciudad Juárez, México, and it is registered in Clinical Trials (NCT04638842). The article is sent and registered in clinical trials before the recruitment started. The results will be reported in future conferences, scientific publications, and media.

Keywords: grief, COVID-19, online intervention, user experience, randomized controlled (clinical) trial

INTRODUCTION

Background

The Coronavirus disease 2019 (COVID-19) pandemic continues indefinitely, and the number of cases is growing exponentially worldwide. Even though more about this virus is being learned every day, there are still several questions about how the disease behaves and why one of its consequences is the high mortality that it causes, mainly in people over 60 years old (Serra Valdes, 2020). It has been proven that advanced age, the presence of diabetes mellitus, hypertension and obesity significantly increases the risk of hospitalization and death in patients with COVID-19 (Muniyappa and Gubbi, 2020).

According to the World Health Organization (WHO), the number of infected people and deaths caused by this virus as of December 19, 2020 has risen to 74,299,042 and 1,669,982, respectively (World Health Organization, 2020).

The pandemic has caused psychological consequences (Li et al., 2020), among which fear, anxiety, post-traumatic stress disorder, depression, suicidal or addictive behaviors stand out, as well as domestic violence as a collateral effect of the confinement (Mengin et al., 2020). Also, financial difficulties could reduce the access to receive mental health treatment (Sher, 2020).

In addition, among the psychological consequences, the grief due to the loss of loved ones cannot be ignored, and it should also be noted the importance of the suffering derived from the mandatory physical separation of family members who are sick with COVID-19 (Singer et al., 2020).

The grieving process has been studied and analyzed by various authors, the psychiatrist Kübler-Ross stands out among the experts on this topic, who defined the five phases in which a person transits during grief: denial, anger, pact/negotiation, depression, and acceptance (Miaja Ávila and Moral De La Rubia, 2013). A person can go through these phases in different ways, therefore, there is no correct way to grieve, since each experience is unique, individual, and requires necessary and adequate support in each particular situation.

Grief is a common human response to loss (Archer, 2003; Weir, 2020). Most people adapt to the death of their loved ones and the changes that occur in their lives (Goveas and Shear, 2020). At the present time, grief is being experienced in different ways, on the one hand there is some uncertainty in the face of daily losses, such as social distancing, economic losses, health losses and the lack of contact with family and friends. On the other hand, there is anticipatory grief, usually is the normal grief that appears when the death of a relative or of oneself is feared (Shore et al., 2016), and it can be experienced in the form of high concern for other people who may be affected due to the disease (Wallace et al., 2020).

As the pandemic progresses and with it the large number of deaths, as well as the lack of preparation for the imminent death of close relatives, the recommended restrictions to reduce the infection and transmission of the virus, the physical, mental, and social consequences of distancing, such as not being able to say goodbye to loved ones, and therefore to not celebrate the traditional social and cultural rituals of grief (Goveas and Shear, 2020; Morris et al., 2020), sometimes necessary to heal the wound caused by the death of the loved person, the pathological or chronic grief may appear complicated (Lobb et al., 2010; Wallace et al., 2020).

Complicated grief is characterized by intense emotional distress that can last longer than socially expected and that causes a disability in the person's daily functioning, endangers their health and well-being, and can last for years and even become indefinitely chronic (Barreto et al., 2012). There are other factors that can contribute to increase it, such as sudden or traumatic death, which results in the lack of preparation for it and the lack of social support at the time of the event (Burke and Neimeyer, 2014). These are factors present at this moment with COVID-19 and they may have a significant impact on the individual and on the social experience of death and grief due to the measures of social isolation and the lack of the usual support structures (Mayland et al., 2020).

Recognizing the uniqueness of each individual with respect to their process of loss and pain will provide opportunities to develop personalized strategies that facilitate psychological flexibility (Hayes et al., 2015) and functional adaptation to the

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Abbreviations: 2019-nCoV, Novel Coronavirus; BAT, Behavioral Activation Therapy; CBT, Cognitive Behavioral Therapy; CES-D, Center for Epidemiologic Studies Depression Scale; COVID-19, Coronavirus disease 2019; DASS-21, Depression Anxiety Stress Scale; GAD-7, Generalized Anxiety Disorder 7-item; PP, Positive Psychology; WHO, World Health Organization; WHOQoL, World Health Organization Quality of Life; UX, User Experience.

loss, which will promote mental health and well-being in this crisis (Zhai and Du, 2020).

It is therefore clear that grief is inevitable and multidimensional for people with losses. The loss of a loved one is perhaps one of the most shocking events that occur in a person's life (Zhai and Du, 2020). In few periods of human history, grief and pain have been as present in people's lives as they are today (Goveas and Shear, 2020).

It should be noted, considering the reviewed bibliography, that grief will not always need a psychotherapeutic approach, since most people who experience the loss of a loved one cope with their grief in a natural way and without emotional discomfort implying a deterioration in their daily functioning, managing over time to continue with their lives and their activities (Neimeyer et al., 2002; Neimeyer, 2014).

On the other hand, survivors experience a series of consequences in their health (physical and mental) and social interaction that make it difficult for them to continue with their daily lives and lead to considerable wear and tear that triggers the development of complicated grief (Prigerson, 2004), or a mental disorder, such as depression (Boelen and Prigerson, 2007) or post-traumatic stress disorder (Payás, 2010; Christiansen et al., 2013), and in more severe cases, suicidal behavior (Szanto et al., 2006).

In this sense, Litz et al. (2014), suggest that it is possible to prevent complicated grief by intervening in the early stages for people who present significant preclinical symptoms after the loss, reducing the possibility of developing a considerable deterioration in their loss during the following months, functioning on the daily basis and allowing to alleviate emotional suffering gradually.

Regarding the evidence of effective psychological interventions that could be implemented to provide support to the population that suffered a loss, it is important to start with Cognitive Behavioral Therapy (CBT). The CBT proposes that the way we think affects the way we feel and behave (Litz et al., 2014). Thus, helping people to learn how to evaluate their thinking and generate more realistic or accurate thought patterns improves both their emotional and behavioral state (Beck, 2006). The cognitive model provides a framework to identify and challenge inappropriate thoughts or beliefs that can lead to feelings of guilt, anger, or rage (Bayés, 2006). Yahya and Khawaja (2020) study found that internet-based CBT is effective in a series of small randomized controlled trials.

In addition, CBT can be nourished by the practice of Mindfulness. Jon Kabat-Zinn is recognized for being, mainly, one of the first authors who introduced Mindfulness within the field of Western psychology, developing the Mindfulness-Based Stress Reduction Program (MBSR). Mindfulness has become an allied technique of psychotherapy, more focused on acceptance than on change (Simón, 2010). According to Hayes et al. (2006), the component of acceptance of cognitions and sensations in Mindfulness would decrease emotional reactance and would allow a healthier and more effective coping in patients subjected to some type of trauma, such as grief. In relation to mindfulness-based treatments that have been highly investigated in recent years, a systematic review published by Goldberg et al. (2017), corroborated that Mindfulness-Based Interventions (or MBI) are effective for depression, grief, and pain conditions, smoking, and other addictions. The basis of these programs is not to change the patient's experience, promoting psychological acceptance by giving importance to the values of the patient or the therapist. It allows patients to learn skills, reduce worry, ruminant thoughts, and emotional cognitive reactivity. They are programs that are carried out in a group mode and can improve the quality of life of patients in a broad sense (Segal et al., 2004).

Other effects of bereavement include loss of pleasure and interest in activities (Craske et al., 2019). Focused attention on the meaning of the loss, positive reinforcement for the actions taken (Bartone et al., 2019), behavioral activation techniques, such as activities, reinforcement of self-care and contact and support among the peer group (Lacasta and Aguirre, 2020) and the performance of rituals, attention to spirituality and the need for a farewell are presented as the central axis to avoid complicated grief (Barbero et al., 2014).

It should be noted that although Psychotherapy in Mexico is mainly carried out in private practice, it is expanding to public institutions, like hospitals and ambulatory clinics (Sánchez-Sosa, 2007), however mental health services are still insufficient (Martinez et al., 2017).

Zhang et al. (2006), proposed that clinical interventions can focus on the following elements: (a) differentiate between expected grief reactions and those of complicated grief; (b) detect the risk factors that make people more vulnerable to develop complications in grief; and (c) establish intervention actions to prevent maladaptive responses to loss.

Taking into account the reduction in the availability of carrying out psychological interventions, it has been selected to provide psychological support at a distance through different communication networks and platforms (Eisma et al., 2020). These interventions can be applied if the pandemic continues for longer periods. During the last decades, an increase in the implementation of online interventions has been observed due to the advantages that this entails, such as having greater flexibility and anonymity, in addition to having demonstrated positive effects comparable to face-to-face therapy (Wagner et al., 2014; Hoffmann et al., 2018).

On other hand, self-applied interventions appear as an option to arrive at a great number of participants. To make a self-applied intervention effective, tools are included to communicate skills that help to externalize the problem and set realistic goals, as recommended by Malkinson (2010), with the cross-cutting objective of reducing anxiety symptoms and exploring emotions (Aoun et al., 2020; Morris et al., 2020). Along the same lines, previous research has shown the effectiveness of online tools in grief support that help improve the adaptive adjustment of people in grief (Dominick et al., 2010). There is evidence of the efficacy of online interventions applied to patients suffering from abnormal grief. For example, in studies where an online intervention was carried out in which the patient has to write a letter to the deceased person, the researchers concluded that this activity alone was efficient in reducing emotional loneliness and increasing the state of positive mood, as well as its effect on rumination; however, no effects were observed in terms of grief and depression symptoms (Van der Houwen et al., 2010), indicating that an online intervention aimed at this population should be multicomponent.

In the study by Kersting et al. (2013) a brief 5-week intervention based on CBT, was implemented for parents who lost a child during pregnancy. The contents of the intervention were delivered through a web platform focused on three central axes: (a) self-confrontation, (b) cognitive reappraisal, and (c) social sharing. This study had 228 participants divided into two groups (intervention and on the waiting list). The participants in the intervention group reduced the symptoms of post-traumatic stress, prolonged grief, depression, and anxiety, with statistically significant changes (Kersting et al., 2013).

Another study focused on relatives of patients who died from hematological cancer, in which the participants were similarly divided into two conditions, the intervention group and the control group. The intervention group received the contents of the intervention similar to the Kersting study: (a) self-confrontation (patients describe their experience of loss, with a special emphasis on emotional and cognitive processes), (b) cognitive reassessment (the purpose of this phase is to work on a change of perspective to help participants develop realistic and useful coping strategies), and (c) social sharing (in this phase patients have to write a letter for people affected by the death of a loved one, including themselves, and a letter to the person who passed away). The Internet-based grief therapy is assumed to have at least moderate effects regarding Prolonged Grief and other bereavement-related mental health outcomes (Hoffmann et al., 2018). Also, there is wide evidence of the effectiveness of psychological interventions in terms of maintaining the results on the follow-ups, such as 3 months for a self-help online intervention for suicidal thoughts (Van Spijker et al., 2015) and a Meta-Analysis of Cowpertwait and Clarke (2013), identified that web-based interventions for depression where the effects are maintained for 3–6 months, and even the results have been observed to maintain in a 12 months follow-up in a self-help intervention for parents of children on cancer treatment (Cernvall et al., 2017), to mention a few examples.

Along similar lines, online interventions for patients with abnormal grief are supported by studies that have demonstrated their efficacy. However, one of the main problems that have been observed in terms of online interventions aimed at treating depression and anxiety symptoms is the broad description of the theoretical content, and the poor description of the relevant characteristics of the human-computer interaction design (Søgaard and Wilson, 2019). For example, a study published in 2017, identified that there is a lack of research offering qualitative data about the subjective User Experience (UX) of young people using interventions for depression, such as social network based (Santesteban-Echarri et al., 2017). In this sense, in the intervention of this research we have to take this into account and assume that in some cases an impediment may be encountered, such as the user's lack of experience in the use of ICTs or the need for more human contact. It is also important to note that the duration of the entire intervention without time spaces in which to receive feedback on improvement or emotional stability may lead to abandoning of the therapy, or lack of adherence to treatment. It is hoped that results can be seen throughout each module, but there may always be someone with an urgent need for instant feedback on improvement.

Likewise, there is available evidence that online interventions have good adherence to treatment in weekly sessions of 50 min, and with work between sessions. However, this structure is not recommended for groups that are not clinical, for example, for prevention and/or for people with mild problems, since the time they dedicate to the interventions is reduced, or if they do it only once, or if it is unlikely that they will return and finish (Cavanagh, 2010). Also when it comes to interventions of longer periods, there is the risk of losing motivation to continue (Melville et al., 2010), therefore, it is proposed to use short-time videos and to have at least two sessions per week (every other day) in order to increase adherence and probability of completing the intervention.

Among the aspects of human-computer interaction design, the concept of universal design aims to design interactions with digital tools which are aesthetically pleasing, and at the same time ensures that the tool can be used by all participants, regardless of their age, ability, or status (Søgaard and Wilson, 2019). It is relevant to note that older adults are interested in using technology to take care of their mental health and this form of intervention is feasible and reliable for them (Figueroa and Aguilera, 2020). According to these same authors, these interventions are specifically aimed at this vulnerable group and are adapted to their specific needs. It includes easy-to-use design options and uses a vocabulary adapted to the general population. In addition, its infrastructure ensures confidentiality, without violation of privacy and minimizes the risk of data leaks.

Other online interventions are known to mitigate the impact of COVID-19 on health, in which psychological well-being is promoted in health professionals (Blake et al., 2020). It is particularly vital to stimulate the development and dissemination of Internet-based treatments for grief, and it is also a question to ask if they should implement this type of intervention in health care systems. Due to the current circumstances, it is relevant to provide an online intervention to aid the population suffering of Grief due to the loss of a loved one, due to COVID or during the most part of this year, where the measures are strict, and funerals are unrecommended.

The intervention protocol through the platform presented in this research is focused to contribute to the reduction of the development of Complicated Grief Disorder (CGD) after experiencing the traumatic situation of loss, in this case specifically from the contingency of COVID-19 with a self-applied intervention based on CBT, Mindfulness, Behavioral Activation Therapy (BAT), and Positive Psychology (PP) and an increase in the quality of life. Other aims are the reduction of anxiety/depression symptoms and the increase of sleep quality. In this way the survivors will be able to establish self-care measures in different areas of their life (physical, emotional, cognitive, and spiritual), and the risk of the appearance of complicated grief is diminished (Greenberg et al., 2008).

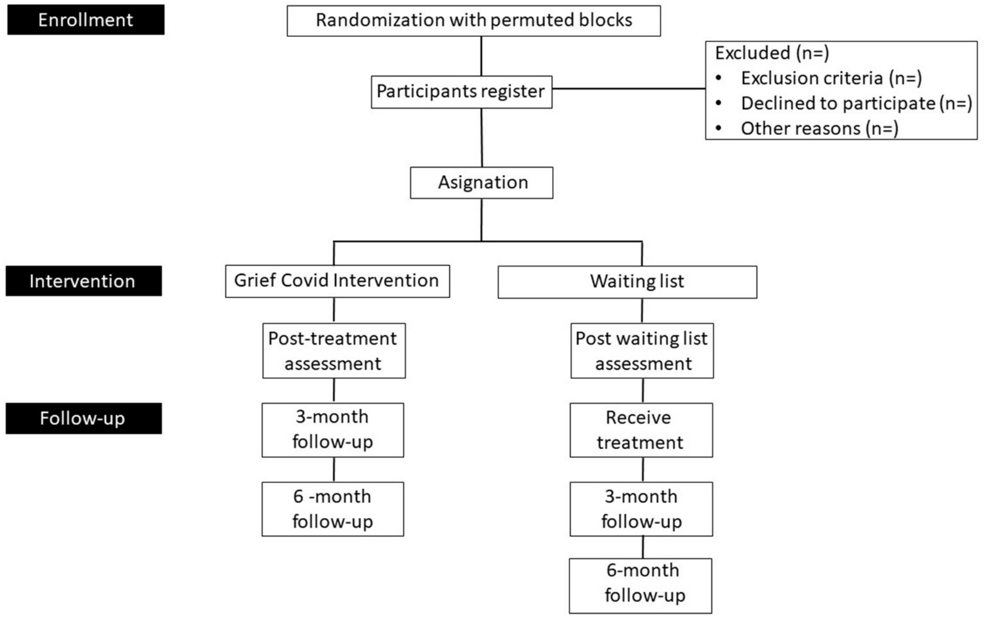


FIGURE 1 | Flow chart of the study design of the "Grief COVID" (Duelo COVID) intervention.

Aims

The online Intervention Grief COVID (Duelo COVID), aims to provide a self-applied intervention composed of 12 sessions based on CBT, Mindfulness, BAT, and PP, aimed at the decrease of the risk of developing Complicated Grief Disorder (CGD) specifically from the contingency of COVID-19, and increasing the quality of life. And as a secondary objective, to reduce the symptomatology of anxiety, depression, and to increase sleep quality. With the objective that the survivors are be able to establish self-care measures in different areas of their life (physical, emotional, cognitive, and spiritual).

HYPOTHESES

Primary Hypothesis

The self-applied multi-component psychological online intervention for the prevention of complicated grief disorder will show greater improvement in the quality of life and perception of the satisfaction of life than a waitlist control group.

Secondary Hypothesis

Participants in the self-applied multi-component psychological online intervention will report better indicators of change in reduction of symptoms of anxiety, depression, and greater sleep quality compared to the waiting list group; and the changes will be maintained for 3 and 6 months after completing the treatment.

METHODS AND ANALYSIS

Study Design

A randomized controlled clinical superiority trial with two independent groups will be used, with intrasubject measures at four evaluation periods: pretest, post-test, follow-up at 3 months, and follow-up at 6 months (Solomon et al., 2009). Participants will be randomly assigned to one of two groups:

(1) Grief COVID-19 intervention, participants in this group will receive 12 sessions of a multi-component psychological intervention focused on the decrease of the risk of developing CGD, increasing the life quality, reduction of symptoms of anxiety/depression and increase of sleep quality. Each session will be administered every third day to give time to do the tasks, and not too long to reduce the chance of abandoning the treatment.
(2) Waiting List group, the participants in this group will not receive the treatment immediately. They will be measured one time and then a second time 1.5–2 months later than the intervention group when it is calculated that the first group has carried out 12 sessions. The post-measures and follow up will be applied to all the participants to analyze the effectiveness of the intervention (see **Figure 1**).

Randomization Process

This will be a randomized controlled efficacy trial comparing an intervention for grief within control. The randomization procedure will use a permuted blocks algorithm via the Study Randomizer software (Study Randomizer, 2020), where a researcher in the team will obtain the location for the participants before they join the intervention. The process will consist on that once the participant creates an account on the platform, and fulfills the inclusion criteria, and does not fulfill any point of the exclusion criteria, he/she will be assigned to the corresponding condition (see **Figure 2**).

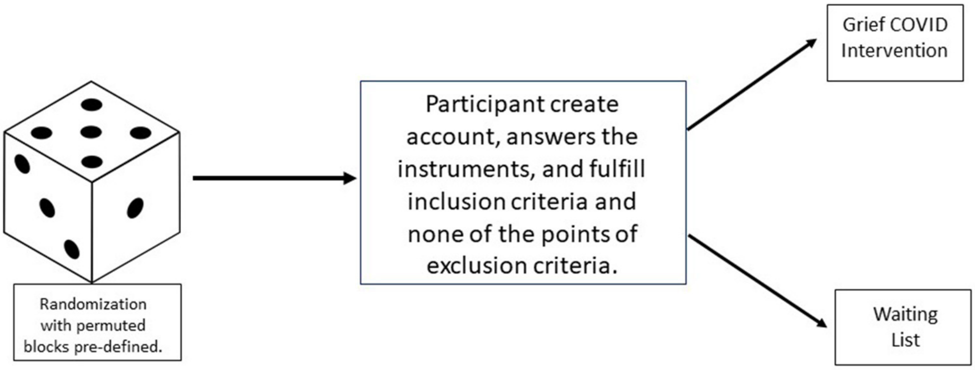


FIGURE 2 | Randomization process of the "Grief COVID" (Duelo COVID) intervention.

Sample

A total of 49 Spanish-speaking male and/or female users meeting the inclusion criteria are expected to be recruited via the online Grief COVID platform. The intervention is aimed at participants aged 18 or older.

Participant Criteria

Inclusion Criteria:

1. To have a communication device with access to the Internet (computer, tablet, or mobile).
2. To have a valid e-mail address.
3. To have basic digital skills in the use of an operational system and Internet browsing.
4. To be fluent in Spanish, since the complete intervention is in such language.
5. To have symptoms of Depression, State Anxiety and/or Acute Stress Disorder grief symptoms.

Exclusion Criteria:

1. To have a diagnosis of psychotic disorder.
2. To have more than 6 months passed since the death of the loved person.
3. To receive psychological and/or pharmacological treatment during the study.
4. To have a moderate to a high score in the suicide scale.
5. To have a recent attempt of suicide (3 months).
6. To have a diagnosis of Post-traumatic Stress Disorder.

The participants need to meet all the five points of the inclusion criteria to access the intervention and to not meet any of the six points of the exclusion criteria.

Psychological Measures

Center for Epidemiologic Studies Depression Scale (CES-D)

Depression levels will be assessed by the CESD-D, a self-report scale that assesses symptoms of depression in the past 2 weeks. This scale consists of 20 questions and contains four possible answers: rarely or never (<1 day), sometime or rarely (1–2 days), occasionally or a good part of the time (3–4 days) and most of the time (5–7 days). This instrument has been constantly used in health research and its psychometric properties prove to be a valid scale in Mexican population (Cronbach's alpha > 0.90), according to González-Forteza et al. (2011), and among different populations, such as young people and adults (Cuijpers et al., 2007).

Depression Anxiety Stress Scale (DASS-21)

The DASS-21 is a self-report scale that assesses the depression, anxiety, and stress subscales during the past week. Each subscale contains seven questions with four possible answers (0–3) as follows: does not apply to me (0), it applies to me to some degree, or sometimes (1), they applied to me to a considerable degree or a good part of the time (2), they applied to me a lot or most of the time (3). All scores must be multiplied by two to obtain the final score, where each subscale has a cut-off score for each severity condition (normal, moderate, and severe), the cut-off point for moderate levels is 14–20 for depression, 10–14 for anxiety, and 19–25 for stress, where any previous score is considered severe or extremely severe (Lovibond and Lovibond, 1995). This scale has been validated in the Mexican population obtaining a reliability for global ($\alpha = 0.86$) and for each subscale; depression ($\alpha = 0.81$), anxiety ($\alpha = 0.76$), and stress ($\alpha = 0.79$) (Gurrola et al., 2006).

The Pittsburgh Sleep Quality Index

The quality of sleep scores will be evaluated using the Pittsburgh Sleep Quality Index. This instrument assesses sleep quality patterns, differentiating people who have poor sleep quality from those who have good sleep quality. For this, seven areas are evaluated, where the response ranges go from 0 to 3 with a total sum that goes from 0 to 60, where the cut-off point is a score of 5, which indicates a poor quality of sleep (Buysse et al., 1989). The evaluation in the Mexican population has shown solid criteria of reliability ($\alpha = 0.78$) (Jiménez-Genchi et al., 2008).

Post-traumatic Stress Disorder Symptom Scale

It is a 17-item structured interview. The severity over the last 2 weeks of each item on the PSS is rated by the interviewer using a 4-point scale: 0 = not at all, 1 = a little bit, 2 = somewhat, and 3 = very much. The maximum possible score is 51 (severely affected) and the minimum possible score is 0 (total absence of the symptoms). The total severity score is calculated as the sum of the severity ratings for the 17 items. The diagnosis is made when one symptom of re-experience, three of avoidance and two of activation are observed (Foa et al., 1997). For this study, the validated version in Spanish will be used (Novy et al., 2001).

Satisfaction With Life Scale

This instrument consists of five items in which the participants must indicate how much they agree with each question, with an answer option in Likert format from 1 (totally disagree) to 7 (totally agree), the scores range from a minimum or 5 to a maximum of 35, where the highest scores indicate greater satisfaction with life (Vázquez et al., 2013). This scale has been validated in the Mexican population, obtaining good results of internal consistency ($\alpha = 0.74$) (López-Ortega et al., 2016).

Beck's Hopelessness Scale

This scale is composed of 20 items with a false or true answer option, the score ranges from 0 to 20 with higher scores indicating a higher level of hopelessness (Beck et al., 1974). It is a widely validated and used scale, and for this study the version validated in the Mexican population will be applied (Osnaya and Pérez, 2012).

Generalized Anxiety Disorder 7-Item (GAD-7)

The Generalized Anxiety Disorder 7-Item (GAD-7) scale. This is a brief scale consisting of 7 items designed to measure the severity of symptoms of generalized anxiety disorder. The answers are based on the symptoms perceived during the last week. The questions in this scale are answered in a Likert format with scores from 0 to 3, where the maximum total score is 21. A score between 0 and 4 points indicates that anxiety is not perceived, and a score between 15 and 21 is an indicator of perceived severe anxiety (Spitzer et al., 2006). The version in Spanish by García-Campayo et al. (2010), will be used for this study.

Inventory of Complicated Grief

It is composed of 19 items, with a five Likert-type scale ranging from 0 to 4, where: 0 "never," 1 "rarely," 2 "sometimes," 3 "often," and 4 "always." The items assess the frequency of the explored symptoms type (emotional, cognitive, or behavioral). For its evaluation, the points of each item are added, and the scores fluctuate between 0 and 76 points. Scores above 25 are an indicator of complicated grief. The properties of the adaptation of the scale to Spanish have good results of internal consistency ($\alpha = 0.88$). The version of Limonero et al. (2009), will be used for this study.

World Health Organization Quality of Life (WHOQoL)-BREF Spanish Version

This instrument is composed of 26 items, two global questions (global quality of life and general health), and 24 questions that provide a profile on the responders' life quality in four dimensions: (1) Physical health, (2) Psychological health, (3) Social relationships, and (4) Environment. It focuses on the degree of satisfaction that the person has with various situations in their daily life. Each item has 5 Likert-type response options (1–5). The scale was validated in the Mexican population showing wide validity in clinical settings (Acosta-Quiroz et al., 2013).

Plutchik Suicide Risk Scale

This questionnaire assesses the risk of suicide through questions posed in a dichotomous way (yes/no), where the history of suicide attempts, suicidal ideation and suicide are considered plans. This scale establishes a cut-off point of >6 that differentiates people at risk from those who are not at risk of suicide (Plutchik and Van Praag, 1994). The properties of this scale have shown good reliability ($\alpha = 0.74$), based on these findings, it is established that it is an appropriate questionnaire to assess the risk of suicide. This scale has been used in previous studies with the Mexican population (Alderete-Aguilar et al., 2017).

SECONDARY MEASURES

Acceptance/Satisfaction/Usability Measures

Opinion on the Treatment

This questionnaire is made up of four questions that report the level of satisfaction with the treatment, if the users would recommend the treatment to a friend or relative, if the patient considers the treatment useful, and if they think the treatment was difficult to handle or was aversive. The items are answered on a scale from 1 (not at all) to 10 (a lot) (Botella et al., 2009).

System Usability Scale

It is an instrument designed to validate the usability of a system, it is composed of 10 items, which are answered on a 5-point Likert-type scale with respect to the degree of conformity of the product (1 = totally disagree to 5 = completely agree). To obtain the global score of this scale, all the values obtained must be added and multiplied by 2.5, and this will result in a number between 0 and 100, which will be the global value of this scale (Brooke, 1996).

Study Period

Pre-intervention screening and the intervention process itself shall start on December 22nd and it is expected to conclude by June 1st. By then, the targeted sample is expected to be recruited. Prospective 3- and 6-month follow up assessments on outcome variables will be conducted to ascertain the intervention's effectiveness. The detailed description of the plan of the steps and instruments that will follow this study can be found on **Table 1**.

Outcomes

- Improved perceived satisfaction with life and quality of life is expected upon completion of the intervention.
- A reduction of anxiety and depression symptoms, as well as an increase of sleep quality are expected upon completion of the intervention. Such changes are expected to be maintained 3 and 6 months after the end of the intervention process.

TABLE 1 | SPIRIT figure to display the study's schedule of enrolment, interventions, and assessments.

	Study period					
	Enrolment	**Allocation**	**Post-allocation**			
Timepoint	**t0**	**0**	**t1: PRE**	**t2: Post**	**t3: Follow-up 1**	**t4: Follow-up 2**
ENROLMENT						
Eligibility criteria	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS						
1) Grief COVID-19 intervention						
2) Waiting List group						
ASSESSMENTS						
Primary outcome measure						
Center for Epidemiologic Studies Depression Scale (CES-D)	X			X	X	X
Depression Anxiety Stress Scale (DASS-21)	X			X	X	X
The Pittsburgh Sleep Quality Index	X			X	X	X
Satisfaction with Life Scale	X			X	X	X
Beck's Hopelessness Scale	X			X	X	X
Inventory of Complicated Grief	X			X	X	X
World Health Organization Quality of Life (WHOQoL)-BREF	X			X	X	X
Plutchik Suicide Risk Scale	X					
Post-Traumatic Stress Disorder Symptom Scale	X					
Generalized Anxiety Disorder 7-item (GAD-7)	X					
Secondary further outcome measures						
Opinion treatment				X		
System Usability Scale				X		

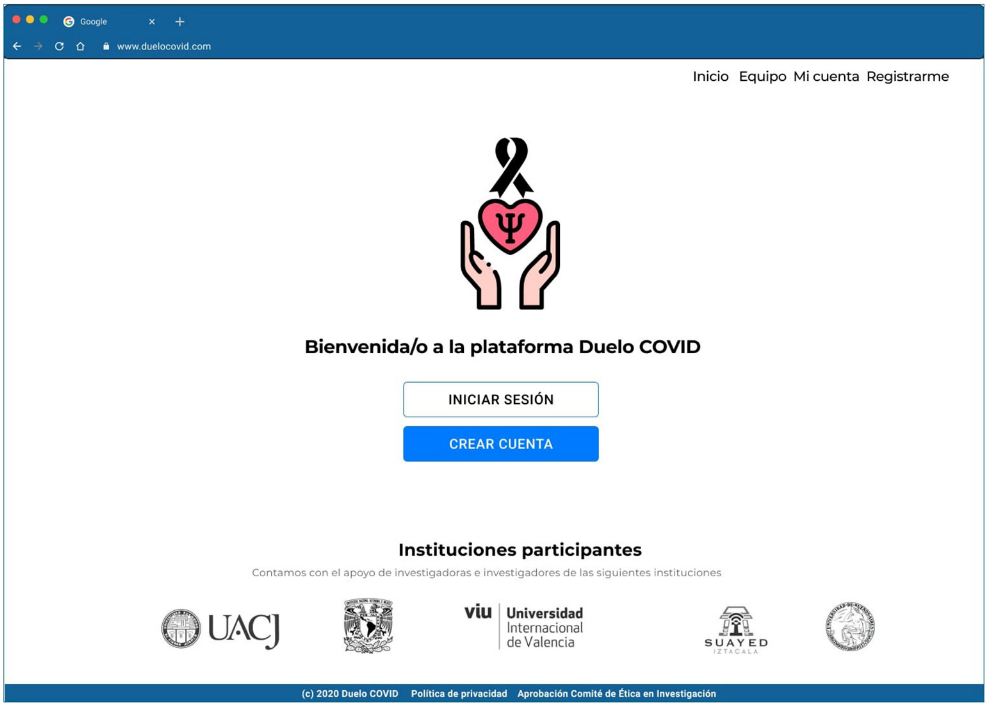
Description of the UX Process for the Design of the Grief COVID Platform

This intervention was created following the principles of UX, ensuring that the design characteristics of the tool will meet the desirable requirements to be perceived as easy to use, attractive and useful by the participants. The UX approach refers to the experience that a user has with a product, with special emphasis on human-product interaction (Hassenzahl, 2008; Tullis and Albert, 2013). The UX process was conducted by the main author who is a certified UX designer.

The first step was to review similar interventions, but there was none found that fulfilled the goals of the COVID Grief intervention. Afterwards, six interviews were conducted through Zoom with six objective users (persons that lost someone due to COVID or during the COVID outbreak) through interviews with a duration of 30–40 min where they shared what contents they would like on the platform. The interviews were recorded with the informed signed consent of the participants in order to evaluate with more details the information of the intervention.

After analyzing the recordings of the interviews, affinity mappings were conducted to find similar requests, needs or suggestions from the participants toward the intervention. From the results User Personas were created, these are fictional characters based on the overall results of the participants interviews (Adlin et al., 2006). Afterwards User Journey Maps and User Flows were also created, along with a site map proposal with four main sections: (1) Sessions, (2) Talk with a Psychologist, (3) Technical Support, and (4) My Profile.

Furthermore, a card sorting test was distributed online through Optimal Workshop (2020), and 13 participants completed the task. Also, the site map was redefined to three sections where the options "Talk with a Psychologist" and "Technical Support" were fitted into the "Help center" section. Afterwards, wireframes with the first proposal of the platform were drawn, followed by the creation of a low-fidelity prototype in Balsamiq (2020), followed by the creation of a mid-fidelity prototype in Figma (2020), a collaborative web design tool based in a web browser. The mid-fidelity prototype was validated with five objective participants individually through remote testing through zoom, they were also recorded, consent of the participants was obtained, and the usability of the platform was measured with a subjective scale reported by the scale from 0 not usable at all, to 10, totally usable without complications. The evaluated sections were: (1) create an account, (2) the onboarding process, (3) Section where the sessions of the treatment are and to navigate through the first section, (4) Help Center, and (5) My profile. While analyzing the recordings with the results obtained, another affinity map was conducted: The Observations, Positive Quotes, Negative Quotes, Errors, Suggestions and Metrics. Following the Jakob Nielsen Scale (Nielsen, 1994), where: 0 = I don't agree that this is a usability problem at all, 1 = Cosmetic problem only: need not be fixed unless extra time is available



Bienvenida/o a la plataforma Duelo COVID

Instituciones participantes

Contamos con el apoyo de investigadoras e investigadores de las siguientes instituciones

FIGURE 3 | High Fidelity Prototype in Figma of the main page of the "Grief COVID" (Duelo COVID) intervention.

on project, 2 = Minor usability problem: fixing this should be given low priority, 3 = Major usability problem: important to fix, so should be given high priority and 4 = Usability catastrophe: imperative to fix this before the product can be released. All the sections with scores from 4 to 1 were modified in that order of priority.

Also, the logo is important to feel connected to the intervention, therefore three options were offered in an online A/B testing distributed thorough Usability Hub (2020), 25 persons participated and 12 chose the logo on **Figure 3**.

Finally, a high-fidelity clickable prototype was designed in Figma with the previous design inputs by the users. This prototype and their archives were delivered to the Engineer for the development of the platform. The full detail on each step can be found on Domínguez-Rodríguez (2020). The contents of this intervention will be implemented through a responsive web application. The characteristics of this type of system can adapt to different screen sizes and resolutions, from the largest to the smallest screen sizes, such as computers, tablets, and cellphones. This type of tool adapts the page design, resizes images or cuts them proportionally (Baturay and Birtane, 2013). The intervention can be accessed on www.duelocovid.com.

Structure of the COVID Grief Platform

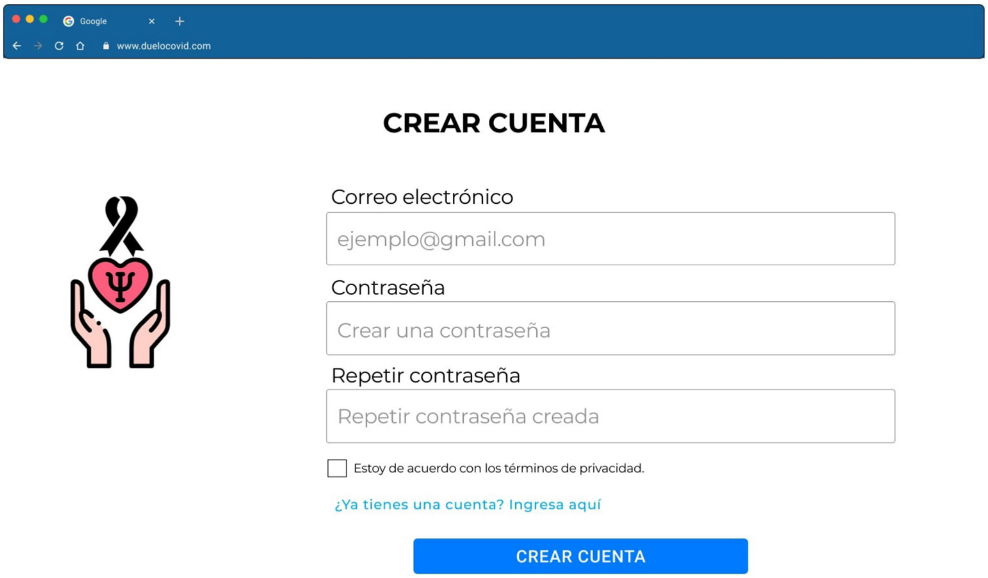
The platform is designed to be the most usable and simplest possible by every type of user, with or without a wide ability and experience with web platforms or cell phone applications (see **Figure 3**).

To create an account on the web page, the participant needs to read and accept the informed consent. Afterwards, the platform just requests an email and password. In order to protect the most possible information of the participant, non-sensible data is requested, such as their name (see **Figure 4**).

Once the participant has created an account, he/she will need to answer the psychometrics, and once finished, he/she can start to use the platform that will begin with an onboarding process, where the platform will explain how it is composed and the sections that are included. Once the onboarding process is finished the participant can find the main menu with the options from left to right: (1) Interventions sessions, (2) Help center, and (3) My profile (**Figure 5**).

The topics of the sessions are presented to the participants from the onboarding process, and then they are explained. To go from one session to the next the participant needs to see the contents, then wait from one session to the next for at least 3 days in order to process the received contents, do the requested tasks, and answer a quiz of five multiple-answer questions (see **Figure 6**). Once this is done the system will activate the following session.

The process for the design of the contents of the platform was the following: a group of expert clinicians designed the sessions and then they were provided to the coordinator of these projects. After the evaluation, and correcting when necessary, these sessions were provided to a narrator that audio recorded the sessions, and to a team of seven designers that created the draft, illustrations, and animation of the videos, editing the audios and introducing them into the videos.



CREAR CUENTA

Correo electrónico

ejemplo@gmail.com

Contraseña

Crear una contraseña

Repetir contraseña

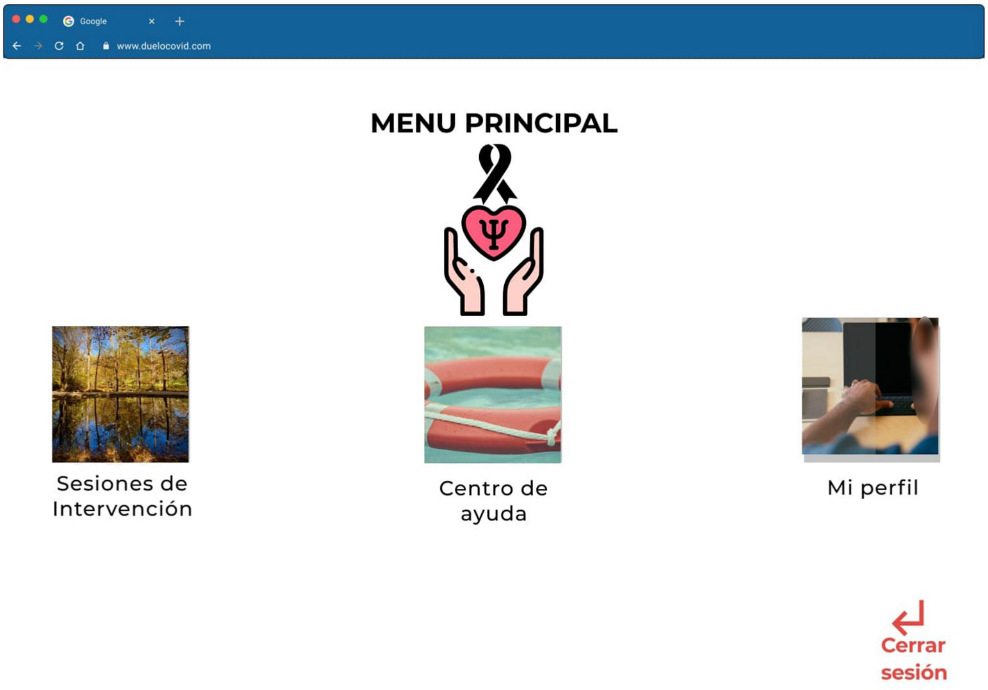
Repetir contraseña creada

☐ Estoy de acuerdo con los términos de privacidad.

¿Ya tienes una cuenta? Ingresa aquí

CREAR CUENTA

FIGURE 4 | High Fidelity Prototype in Figma of the login/create an account page of the “Grief COVID” (Duelo COVID) intervention.



MENU PRINCIPAL

Sesiones de Intervención

Centro de ayuda

Mi perfil

Cerrar sesión

FIGURE 5 | High Fidelity Prototype in Figma of the main menu page of the “Grief COVID” (Duelo COVID) intervention.

The platform will be delivered considering the principles of responsive design, in order to see the intervention in any device, such as a desktop, or a mobile device (Nebeling and Norrie, 2013).

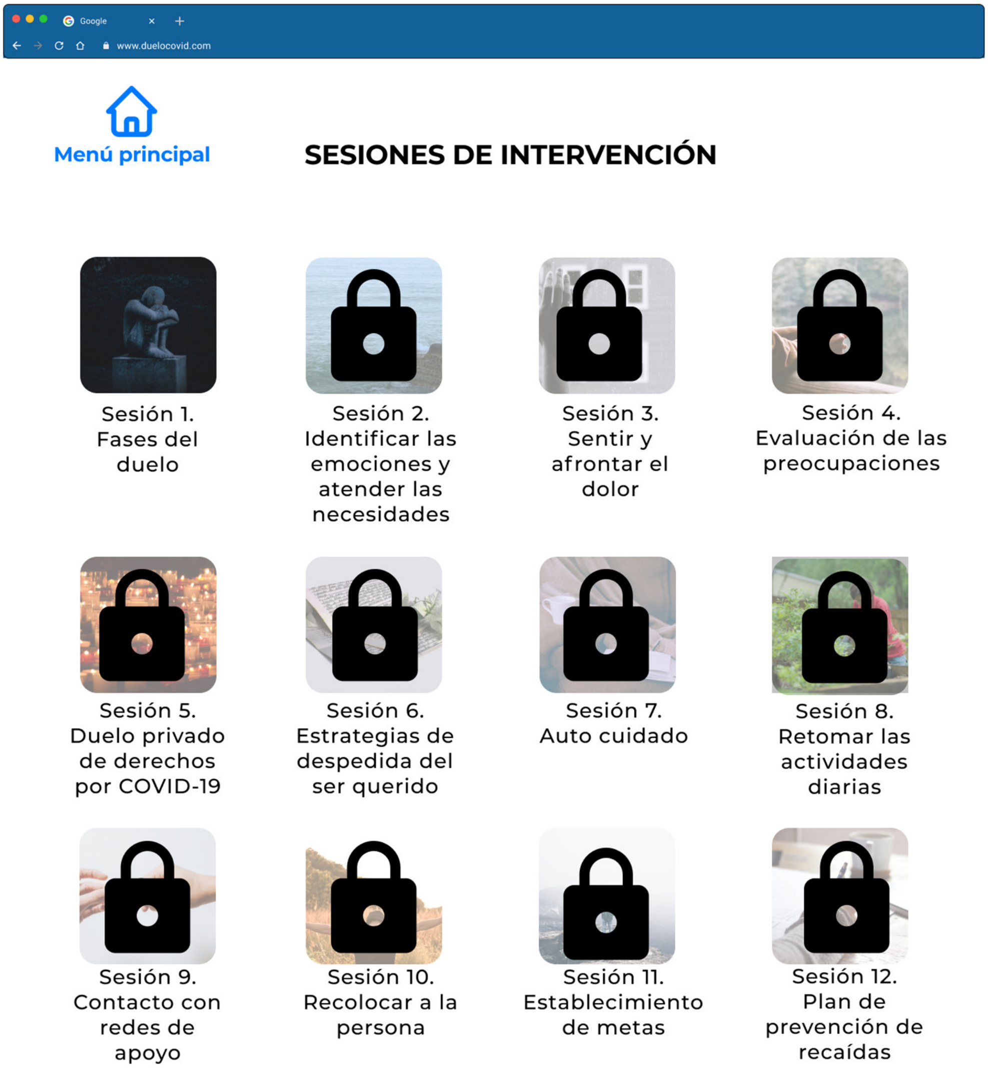


FIGURE 6 | High Fidelity Prototype in Figma of the available and pending sessions page of the "Grief COVID" (Duelo COVID) intervention.

In order to increase the adherence to the intervention the platform will send email reminders, a tool that has shown to be effective for this purpose (Horsch et al., 2017). Therefore, an email will be sent to the participant to notify them when the new session is open, and if the participant is absent from the platform for more than 4 days.

Description of the Intervention

The current protocol article describes the proposal and development of a UX-based self-administered online intervention for the prevention of complicated grief disorder with Mexican population who have lost someone due to or during the COVID-19 pandemic. This intervention will consist of 12 sessions; the purpose is to identify and resolve conflicts that contribute to the risk of developing CGD, like anxiety disorders, which are an exclusion criterion, and to improve well-being in different areas of their life (physical, emotional, cognitive and spiritual). The intervention is based on CBT, BAT, Mindfulness, and PP. Through this intervention, is expected that the quality of life and perception of life satisfaction will get improve. As well, it will be looked at as a reduction of anxiety and depression symptoms and the increase of sleep quality.

Through 12 sessions, it is expected to guide the participant to continue their own process of natural adaptation to the loss with their own coping strategies, by obtaining greater knowledge about the expected manifestations, while preventing the appearance of symptoms that lead to the complication of the grief process.

Session 1, psychoeducation, will be carried out regarding the manifestations of normal grief and its phases, with the objective that participants are able to work on the emotions experienced from the loss and that they begin to adapt to the situation.

Sessions 2–4 will mainly focus on the search for emotional relief, that is, helping the person to manage the pain of loss,

TABLE 2 | Detailed description of the main objective and the theoretical model of each of the sessions of the COVID grief self-applied intervention.

Module	Theory	Principal objective
Grief phases	Cognitive behavioral therapy	To carry out psychoeducation about the grief process and manifestations (Neimeyer, 2014). To explain myths about grief and grief phases (Klüber-Ross, 1969; Klüber-Ross and David, 2005).
To identify emotions and attend needs	Cognitive behavioral therapy and mindfulness	To accept negative impacts and search for emotional consequences to approach them. To identify needs, difficulties, preoccupations, and emotions (Neimeyer, 2014).
To feel and face the pain	Cognitive behavioral therapy and mindfulness and positive psychology	To normalize positive emotions, expressions, and to exculpate for experimenting them (Neimeyer, 2014).
Evaluation of pre-occupations	Cognitive behavioral therapy and mindfulness	To explore resources and possibilities of coping with difficulties. To recognize signs of each emotion (Neimeyer, 2014).
Rights deprived grief for COVID-19	Cognitive behavioral therapy	To orientate on how to identify characteristics of rights deprived deaths. To evaluate the emotional impact of deaths during the pandemic (Worden, 2008; Payás, 2010; Kokou-Kpolou et al., 2020).
Parting strategies	Cognitive behavioral therapy	To guide in alternative parting rituals application when it is not possible to say goodbye. To allow for emotional expression during parting rituals (World Health Organization, 2016; Osiris et al., 2020).
Self-care	Cognitive behavioral therapy and behavioral activation	To promote actions of self-care in the different spheres of life (physical, emotional, cognitive, and spiritual) (Díaz et al., 2014; Neimeyer, 2014).
Take back daily activities	Behavioral activation	To help a person gradually come back to his/her daily activities from the simpler to the increasingly difficult ones (Díaz et al., 2014; Osiris et al., 2020). To stimulate facing the new reality, resulting from loss, and to promote developing the necessary practice tasks (Barreto and Soler, 2007).
Contact with a support network	Cognitive behavioral therapy	To highlight the importance of having a social support network to express the emotional, as well as the consequences of avoiding isolation, and recognizing the importance of having lonely moments (World Health Organization, 2016; Osiris et al., 2020).
Relocate to the deceased person	Cognitive behavioral therapy	To guide the person to continue with their life without an unbearable pain related to memories of their loved one.
Establishment of goals	Behavioral activation	To take back to short and medium lapse, which get adjusted to personal needs, considering the scope and possible obstacles (World Health Organization, 2016; Osiris et al., 2020).
Relapse prevention plan	Cognitive behavioral therapy and behavioral activation	To elaborate a personalized relapse prevention plan.

recognizing, and accepting the pain experienced, therefore, it is expected that they learn to elaborate and regulate their emotions to feel them, and finally, to face the duel. The person will develop the ability to name their emotions, which will allow them to stop perceiving them as something threatening, likewise, they will enhance personal resources, as well as strengths and virtues. Finally, the participants will receive resources to detect those current situations that are being difficult to handle, and they will learn how to handle the emergence of emotions and thoughts that are unpleasant in the face of such events.

Sessions 5 and 6 are focused on how losses are experienced during the COVID-19 outbreak, it will help to identify the characteristics of deaths deprived of rights, what is the emotional impact that losses have during the pandemic, and it will allow survivors to find a way to say goodbye to their loved one when they were not able to do so. In addition, it will allow the experience of pain to normalize, by recognizing thoughts that accompany their emotions, generating alternative thoughts that reduce emotional discomfort and make it more tolerable.

Sessions 7–9 are aimed at acceptance and adaptation to loss, through these, the establishment of self-care measures is promoted in the different areas of people's lives, in order to influence their gradual recovery of daily activities and to reconnect with support networks. To achieve this, they will learn to prioritize their activities and carry them out depending on the degree of difficulty that these imply for the bereaved, going from the simplest to the most complex.

Finally, sessions 10–12 are designed to work on the readjustment and recovery, that is, helping the bereaved to reposition the deceased in their life without causing suffering, encouraging him or her to resume his or her life project and life goals at the person's own pace and to establish a plan relapse prevention based on the knowledge acquired through the sessions. On **Table 2**, it is located the description of the main objective and the theoretical model of each of the sessions that make up the platform.

This intervention contains communication skills tools to help externalize the problem and set realistic goals (Malkinson, 2010). Among them, guiding and reassuring the person to reduce anxiety symptoms and explore emotions (Aoun et al., 2020; Morris et al., 2020); transmitting therapeutic support to process information and recognize emotion (Neimeyer, 2014); paying attention to self-care; maintenance of social relationships through the internet, mobile, etc.; help to restructure thinking; expressing and identifying emotions; recognizing positive emotions (Lyubomirsky, 2008).

Each of the 12 sessions is composed by the following structure: first, a mindfulness exercise is presented so that users are located in the present moment and participate with full awareness of the session and the experiential activities; Subsequently, a series of short psychoeducational videos are shown, of ∼5 min, through which an explanation of the topics addressed in each of the sessions is given (see **Table 2**). In turn, it contains 2–3 experiential activities that participants are proposed to carry out based on what has been explained, using relaxation techniques, visualization, mindfulness, and/or orientation, as well as strategies to learn to name and recognize emotions, solution of problems, setting short, medium, and long-term goals, self-care, scheduling activities, activating a support network, tolerance to discomfort and prevention of relapses, depending on the content of each session. It is advisable to take 3 days between each session so that the participant can process what was addressed in each one. At the end of the session again, a mindfulness exercise is presented to the participant to close what was worked on during it. Similarly, the information contained in the sessions is available in written format for those who prefer to read the content instead of watching the videos.

Possible Negative Effects and Strategies to Reduce the Risk or Damage for the Participants

The main objective of this study is to aid the persons that lost someone due to COVID-19 or during the pandemic, therefore producing a benefit, and not a harm. However, it has been recorded that in previous studies, negative effects had been found on internet-based interventions. For example, on the study of Boettcher et al. (2014), it was identified that from 133 participants receiving a 11-week guided treatment for Social Anxiety Treatment, that out of 19 participants, in detail from the total of participants, 5% reported the emergence of new symptoms, 4% noted a deterioration of targeted symptoms. Other side effects, less frequent, were negative well-being lack of clear treatment results, non-compliance with the treatment followed by changes in the work situation, and fear of being stigmatized. In the same line, Rozental et al. (2015) in a review from four clinical trials with a total sample of 558 participants identified that 9.3% of the participants indicated a negative effect. Among the main ones are deterioration of the targeted conditions, and new symptoms.

Due to this data, and in order to protect at all times the participants of the COVID grief self-applied intervention, the implemented controls will start from the moment they answer the questionnaires, and with how the inclusion and exclusion criteria are established, where, with strict filters, the participants need to fulfill 5 inclusion criteria points and not fulfill none of the six points of the exclusion criteria. With this, ensuring that the participants with a more serious condition would not have access to the self-applied intervention and would be directed to specialized phone numbers and email addresses where they could contact a therapist of one of the institutions in México that is offering free of charge psychological treatment via phone or video call.

Also, it will be added on the platform an option to indicate if the participants that identify that they would need more support, or for whom the self-applied intervention is not sufficient, a special email address will be indicated where the participants can write an email and they will be contacted and redirected to the same phone numbers that the excluded participants would have access to. In this sense all the participants will be protected at all times from the possible negative effects that could be related directly or indirectly to the intervention. The participants that use this option will be removed from the intervention and the data will not be included in the statistical analysis.

Finally, an open question will be added on the post-evaluation, where the participant can indicate if, even though he or she did not contact the special email address, but felt that at some point during the intervention the symptomatology worsened, and in which sense. This will provide qualitative data that could increase the knowledge about the possible negative effects related to a self-applied online interventions.

Proposed Analyses

To test hypotheses, the Statistical Package for Social Sciences (SPSS) will be used. To examine whether a telepsychology intervention will improve quality of life and perception of the satisfaction of life, and also reduce adverse mental health indicators previously associated to grief/bereavement (e.g., depressive and anxiety symptoms), multiple (4) mixed between-within subjects ANOVA tests (Howell, 1999) will be conducted (within group comparisons; Time 1 [T1]—Pre-test, Time 2 [T2]—Post-intervention, Time 3 [T3]−3-month follow-up, Time 4 [T4]−6-month follow-up) with planned *post-hoc* tests (Tukey HSD, Gravetter and Wallnau, 2013) and between-group comparisons with experimental and control groups carried out from Time 1 to Time 4. Only complete questionnaire submissions from T1 to T4 will be considered for the proposed statistical analyses. Incomplete questionnaire submissions will not be considered for statistical analyses due to risk of bias and power reduction associated with multiple imputation methods (Field, 2009).

One-tailed analysis in this experiment means the strength of the effect is expected to be higher between T1 and T2 than between T1 and T4. That is, we expect a stronger effect during the intervention compared to the post-intervention follow-up phase. It also means the experimental group is expected to outperform the control group in terms of experiencing lower levels of adverse mental health related to bereavement, and higher levels of well-being from T2 to T4.

Power Size Calculation

A total of 49 participants will be recruited online for this study. The number of participants and expected power size needed is based on previous internet-based interventions focused on grief and associated adverse mental health (e.g., Kersting et al., 2013), and an a priori power analysis using G*Power software (Mixed between-within groups ANOVA tests, $1 - \beta = 0.95$, $\alpha = 0.05$, Cohen's $d = 0.8$) (Cohen, 1973), which revealed that the study would require a total sample size of $N = 36$. According to Cohen (1988), a value of 0.80 is considered a large effect size. An additional 13 participants have been added to this estimated sample size to account for an assumed 36% dropout rate, considering Linardon and Fuller-Tyszkiewicz's (2019) mean meta-analytic attrition rate found at longer-term follow up assessments in randomized controlled trials for smartphone-delivered interventions.

DISCUSSION

Due to the COVID-19 pandemic, a large number of deaths have occurred throughout the world and in Mexico, which has generated multiple consequences at a psychological level related to the suffering caused by the mandatory physical separation of relatives infected with COVID-19 (Singer et al., 2020). Among the main side effects of the confinement are anxiety, post-traumatic stress, depression, suicidal behavior, addictions, and domestic violence (Mengin et al., 2020). In addition to this, due to the constant losses that people face, such as not being able to say goodbye to their loved ones or being limited to performing traditional social and cultural rituals (Goveas and Shear, 2020; Morris et al., 2020), this can lead to a complicated grief, characterized by intense emotional discomfort, which in turn could generate a disability in people's daily functioning, compromising their health with an undefined duration (Barreto et al., 2012). In this way, the need arises to give timely attention to the psychological consequences due to the COVID-19 pandemic, however, we are facing a reduction in the availability to carry out these interventions in person, so it has been opted to provide psychological support at a distance through different communication platforms (Eisma et al., 2020), that help to mitigate the impact of the COVID-19 pandemic on the mental health of the population (Blake et al., 2020).

In order to respond to the needs of the Mexican population, the objective of this study is to prevent complicated grief through a self-applied online intervention to influence the early stages of the grief process (Litz et al., 2014). Related to this, Zhang et al. (2006), proposed that clinical interventions should focus on differentiating between expected grief reactions and complicated grief reactions, detecting the risk factors that make people more vulnerable to develop grief complications and establish measures to anticipate loss-maladjustment behavior. For this reason, this work proposes the design, development and validation of a self-applied intervention based on Cognitive Behavioral Therapy, Behavioral Activation Therapy, Positive Psychology and Mindfulness.

The online modality is chosen based on the advantages that some authors have found, such as greater flexibility and anonymity compared to face-to-face therapy (Wagner et al., 2014; Hoffmann et al., 2018). Another advantage of the implementation of online interventions has to do with reaching the vulnerable and low-income population, who find it difficult to have access to a psychotherapeutic service, which is why these types of interventions are profitable and accessible (Barak and Grohol, 2011). Another self-applied intervention has been designed and implemented by the authors of this manuscript for the Mexican population in order to reduce the symptoms of anxiety and depression, and increase positive emotions and sleep quality, during and after the COVID-19 outbreak (Dominguez-Rodriguez et al., 2020).

Another advantage of the proposed intervention is the novelty of designing it following the principles of UX design, similar to the industry where tools, such as Figma (2020) and Usability Hub (2020) are applied. The UX methodology has the potential to increase the adherence of the users of the interventions, due to its design in terms of how they would want to receive this intervention. In spite of the relevance of the UX steps in order to improve online interventions, this has not been widely reported. However, few exceptions, such as the study of Wozney et al. (2015), where five clinicians and four adolescents aged <20 years old evaluated the platform before identifying learnability, technical errors and efficiency, user satisfaction, site aesthetics, among other contents, but stating the importance of evaluating the UX of the participants objective in order to determine if their program was easy to understand, efficient with relevant content, and satisfactory. However, we went a step ahead, and we evaluated the proposal of the idea of the Covid Grief platform before it existed, from when it was an idea until it became a prototype of the product. With this we reduced greatly the costs of modifying a platform with the input of the users. In low and middle-income countries where usual care for mental health problems is scarce (Fu et al., 2020), the UX approach is cost wise. Also, along with the study of Wozney et al. (2015), considering the UX can help to create a positive experience toward using the platform, therefore increasing the probability of meeting the objectives in our study, and decreasing the probability of developing Complicated Grief Disorder.

Regarding the limitations of this study, the first limitation is that a wait list control group is proposed, instead of another intervention, or instead of providing the treatment directly to all the participants that meet the inclusion criteria and that do not have any points of the exclusion criteria. With respect to these points, other options, such as face to face treatment, would not be recommended due to the safety measures needed to avoid more infections of COVID-19. Neither therapist assisted intervention would be possible due to the broad amount of participants that we would like to offer an online open intervention without any cost to all the Mexican population. Due to this, and since this intervention is an exploratory study, due to the fact that we do not have knowledge that there is another freely available, completely self-applied intervention, based on UX principles, for the prevention of complicated grief disorder, before or during the COVID-19 pandemic. Therefore, we have set a control group comparison of this randomized controlled trial, that 36 days after completing the initial evaluation, will receive the intervention and also preventive measures considered to prevent damage to the participants and previously provide explanations. Finally, regarding this limitation, articles with well-designed studies were also considered, as well as recent articles published in prestigious journals that included a wait list control group for Online or presential Psychological Interventions (Eckert et al., 2018; Hjemdal et al., 2019; Stächele et al., 2020).

The following limitation is related to the self-report instruments, where it would be of higher reliability when the measures are applied by a trained clinician. However, due to the reach of this self-applied intervention, this would not be possible with the current resources and with not having a sufficient number of therapists to apply all the measures to the participants. Therefore, this study is supported on the benefits that it provides a self-applied intervention where the participants can answer the instruments whenever they want. Regarding this limitation, the participants will answer very similar instruments before starting the intervention and after receiving the intervention, that could affect the response on the second time they answer the instruments, as previously indicated, once the participants finish the intervention they will also be requested to fill the scales Opinion on the treatment (Botella et al., 2009), and the System Usability Scale (Brooke, 1996). However, in order to fulfill the reliability of this study it would be needed to perform the evaluation with the same instruments. A solution in future studies could be to count with a controlled number of participants and with the necessary budget to be able to have an in person or an online evaluation done by a trained psychologist.

Regarding the confounding variables that could influence the results, among the main ones is the gender. As widely studied, in general, men are more reticent to search for psychological support compared to women (Liddon et al., 2018; Seidler et al., 2018), and also when they are receiving online treatment, there is a bigger dropout of men than women, however the results are still inconclusive and further research needs to be conducted (Melville et al., 2010). Therefore, it is probable that in our study most of the participants could also be women, and that the results cannot be generalized for both genders. However, in order to reduce the probability that this could happen, we will actively work on the advertisement of the intervention for everyone, and that men could also get benefits out of this intervention, making emphasis on the anonymity that the intervention provides, since it is not necessary to provide name, telephone number, address or economic status. The participant can feel safe that his or her identity will not be identified. Also, the proper statistical analysis would be applied in case that the participants are considerably more women than men, to try to reduce the impact of this difference. Another confounding variable that could influence on the results is the educational level of the participants, where participants with a higher educational level engage more with online interventions and have lower drop-out rates compared to lower educated persons. The reasons could be related to the fact that lower educated people tend to use more written health information, invest less time online seeking health information, and it is possible that they lose interest in the intervention sooner (Reinwand et al., 2015). In order to solve this, on the section "Description of the UX process for the design of the Grief COVID Platform" it was described that the platform has been designed with the highest standards of usability testing, giving as a result a platform easy to use, and therefore making it more attractive and without a struggle platform to be used. The results of the intervention would provide information regarding UX as a methodology that could be implemented to improve adherence, and attractiveness to the interventions. Also, email reminders will be sent for the open sessions and to try to "rescue" when the participants disconnect from the intervention for more than 5 days.

With respect to the unintended effects that could appear due to this treatment, they are considered and tried to be controlled on the possible side effects and controls to reduce the risk or damage for the participants section of this manuscript. Where it is explained that the platform will have several filters to grant access to the treatment, and if any of these filters is not fulfilled the participant will be directed to a list of free of charge psychological services offered by diverse institutions in México due to the pandemic. Also, in case that the participant crosses these filters but he or she feels that the intervention is not helping him or her and is feeling worse, an emergency email will be included inside the platform to reach the researchers in this project, and also the same list of institutions will be provided as excluded participants received. Once it is registered by the contact of the participant to the clinical team, the participant data will be automatically removed from the platform and will be indicated on the following reports of articles with the results of the intervention.

This intervention design is expected to improve quality of life and perception of life satisfaction, depression, anxiety, hopelessness and stress symptoms, among others, and greater sleep quality, thus coinciding with the studies by Lotzin et al. (2020) and Riva et al. (2020). The contents of Grief COVID intervention will be implemented through a responsive web application. At the time of writing this manuscript, the participants have not been evaluated nor assigned to any group (intervention or control), but the evaluation of the first proposal of the platform and the usability test have been conducted with a sample of a representative of the participants. If this research shows evidence of effectiveness, then it could be implemented in other Latin American countries with the respective cultural adaptation.

ETHICS STATEMENT

This study will be carried out protecting the participants integrity and information. The protocol was approved by the Research Ethics Committee of the Autonomous University of Ciudad Juárez, México. All the participants will have access to the written informed consent in accordance with the Declaration of Helsinki.

AUTHOR CONTRIBUTIONS

AD-R conceived the original idea, did the User Experience process, and supervised the graphic designers' team and all the project steps. AD-R, SM-L, MH, AD, PA-L, EE, CA-S, and AS designed the study and the original protocol. SM-L and MH wrote the scripts for the 12 intervention sessions. JA and AD-R developed the COVID Grief platform. AD-R, SM-L, MH, AD, PA-L, EE, CA-S, AS, RV, and FR-M wrote the paper. AC narrated and audio recorded the 12 sessions. FR-M obtained the funding for the platform. All the authors contributed to the article and approved the submitted version.

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REVIEW
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Innovating Technology-Enhanced Interventions for Youth Suicide: Insights for Measuring Implementation Outcomes

Hannah S. Szlyk[1]**, *Jia Tan*[2] *and Rebecca Lengnick-Hall*[2]

[1] *School of Social Work, Rutgers, The State University of New Jersey, New Brunswick, NJ, United States,* [2] *Brown School of Social Work, Washington University in St. Louis, St. Louis, MO, United States*

Edited by:
Cristina Costescu,
Babeş-Bolyai University, Romania

Reviewed by:
Patti Ranahan,
Concordia University, Canada
Emma Motrico,
Loyola Andalusia University, Spain

***Correspondence:**
Hannah S. Szlyk
hannah.szlyk@rutgers.edu
orcid.org/0000-0001-7337-8475

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Technology is one medium to increase youth engagement, especially among underserved and minority groups, in suicide preventive interventions. Technology can be used to supplement or adjunct an in-person intervention, guide an in-person intervention, or be the stand-alone (automated) component of the intervention. This range in technological use is now called the continuum of behavioral intervention technologies (BITs). Overall, suicide intervention researchers do not use this terminology to categorize how the role of technology differs across technology-enhanced youth interventions. There is growing recognition that technology-enhanced interventions will not create substantial public health impact without an understanding of the individual (youth, families, and providers), mezzo (clinics and health systems of care), and contextual factors (society, culture, community) that are associated with their implementation. Implementation science is the study of methods to promote uptake of evidence-based practices and policies into the broader health care system. In this review, we incorporate work from implementation science and BIT implementation to illustrate how the study of technology-enhanced interventions for youth suicide can be advanced by specifying the role of technology and measuring implementation outcomes.

Keywords: youth, suicidality, technology, psychosocial intervention, implementation science

INTRODUCTION

Globally, suicide is a leading cause of death among youth (Centers for Disease Control and Prevention, National Center for Injury, Prevention and Control, 2020; World Health Organization, 2019). Suicidality, which includes suicidal ideation, plans of a suicide attempt, and actual suicide attempts (Posner et al., 2007) is also a pervasive problem that burdens young lives (Kokkevi et al., 2012; Page et al., 2013; Kann et al., 2018). Yet, many youth exhibiting suicidal thoughts and behaviors do not have contact with a mental health specialist over the course of a year, especially youth who identify as male, or as a racial or ethnic minority (Husky et al., 2012). Attitudinal (e.g., concerns about stigma, preference for self-management) and structural (e.g., limited time, transportation, and insurance) barriers may impact youth initiation of mental health services (Arria et al., 2011; Czyz et al., 2013). Untreated suicidality may lead to future psychological distress, as the presence of suicidal ideation during adolescence increases the odds of a suicide attempt in adulthood (Cha et al., 2017). Therefore, it is crucial that at risk individuals and those presenting symptoms of suicidality are engaged in appropriate mental health services as soon as possible (Cho et al., 2013).

As internet and smart-phone use is prominent among youth world-wide (Anderson and Jiang, 2018; Taylor and Silver, 2019), interventions that integrate technology may address barriers to engagement in in-person mental health services, such as access, reach, and stigma (Kreuze et al., 2017; Berrouiguet et al., 2018). Within suicidology, there has been a recent focus on the development of evidence-based technology-enhanced interventions and tools that integrate various technologies ranging from telephones and text messaging to videos and online platforms (Kreuze et al., 2017). Technology may be used to supplement or adjunct an in-person intervention or may be the stand-alone component of the intervention (i.e., an automated intervention with no provider interaction) (Hermes et al., 2019). Hermes et al. (2019) call this range in technological use the "continuum of behavioral intervention technologies (BITs)." In contrast to other mental and behavioral health fields (Nguyen et al., 2013; Glover et al., 2019), suicidology, overall, does not currently use the BIT terminology to categorize how the role of technology differs across the delivery of technology-enhanced youth interventions.

While randomized controlled trials (RCTs) are often the gold standard for testing the efficacy of interventions (Hariton and Locascio, 2018), there is minimal knowledge on if and/or how trials incorporate implementation outcomes regarding youth suicide interventions. Implementation science is the study of methods to promote uptake of evidence-based practices and policies into the broader health care system (National Cancer Institute, 2020), and implementation is a critical element to understanding how and why technology-enhanced interventions work (or need adjustments) in the real world (Wozney et al., 2018). The implementation of health and mental health services is often measured by 8 defined outcomes: acceptability, adoption, appropriateness, feasibility, fidelity, implementation, penetration, and sustainability (Proctor et al., 2011). Without detailed measurement and assessment of these outcomes, pitfalls are not identified, and the implementation of technology-enhanced interventions in larger mental health care systems may fail (Graham et al., 2019). For example, concerns regarding user privacy and confidentiality, and the commercialization of mobile health tools may impact youth usage and the sustainability of interventions (Struik et al., 2017; Lustgarten et al., 2020). To address the limitations of RCTs, scholars now recommend the use of effectiveness-implementation hybrid designs, which integrate the testing or observation of the intervention's clinical impact and implementation processes (Curran et al., 2012).

Objectives

In this review, we incorporate work from implementation science (Proctor et al., 2010, 2011) and BIT implementation (Wozney et al., 2018; Hermes et al., 2019) to illustrate how the study of technology-enhanced interventions for youth suicide can be advanced by specifying the role of technology and measuring diverse outcomes that take into account the unique features of this implementation context. Examples are drawn from 12 RCTs that were identified as part of a larger systematic review focused on the efficacy and effectiveness outcomes of technology-enhanced suicide interventions for youth (Szlyk and Tan, 2020). The 12 international studies represent interventions conducted over the last 19 years that span common place-based settings for youth (e.g., schools, hospital, clinics) and include online platforms as the treatment setting. The variety of selected studies demonstrate opportunities for innovation in measuring implementation outcomes and exemplify the heterogeneous use of technology in interventions.

In the following sections, we discuss how (1) how technology-enhanced interventions for youth suicide can be classified using the BIT continuum, and (2) how implementation outcomes can be measured in future effectiveness trials of these interventions. Our overall intent is to illuminate how technology-enhanced interventions for youth suicide can benefit from the explicit measurement of implementation outcomes.

REDEFINING IMPLEMENTATION OUTCOMES FOR TECHNOLOGY-ENHANCED INTERVENTIONS FOR YOUTH SUICIDE

Proctor et al. (2011) taxonomy provided an invaluable foundation for measuring implementation outcomes in the behavioral health sciences. Currently, researchers suggest that the traditional implementation outcomes be redefined to account for the growing use of technology in behavioral and mental health interventions (Wozney et al., 2018; Hermes et al., 2019). For example, the meaning of traditional implementation outcomes may be different within the context of technology. Perceived usability and usefulness are considered other terms for feasibility and appropriateness; yet, in this context, they may be a better fit for measuring the acceptability of a technology-enhanced intervention (Brooke, 1996; Hermes et al., 2019). Also, since provider and organizational interaction can vary with technology-enhanced interventions, the level of analysis of implementation outcomes may be different as compared to face-to-face interventions. For instance, a fully-automated intervention will not measure implementation outcomes at the provider level, since interaction is between the youth consumer and tool or platform.

Now is an ideal moment for suicidologists to learn from colleagues who specialize in implementation science and BITs: researchers are rapidly developing new technology-enhanced interventions, there is a need for youth suicide interventions that are engaging and accessible, and researchers must also identify how current interventions can be improved and implemented into real-world practice settings. Keeping these three points in mind, we examined 12 RCT studies that included prominent youth suicide interventions that incorporated technology. The selected studies were the only RCTs identified through a large systematic review of the technology-enhanced interventions for youth suicide. The systematic review adhered to PRISMA guidelines (Moher et al., 2009) (please see flow diagram, search terms, and checklist in **Supplementary Materials**). Even though the large systematic review allowed for interesting insights about the technology-enhanced interventions, we felt that only an examination of the cumulative 26 studies (of varying study design) was a missed opportunity to understand the nuances of study subsamples (e.g., RCTs). We considered the identified RCTs to be an appropriate sample to examine how established and prominent youth suicide preventive interventions could be categorized along the BIT continuum and could measure implementation outcomes in future hybrid trials.

The interventions represented were: Signs of Suicide (SOS), a universal prevention program for high school (Aseltine and Demartino, 2004) and middle school students (Schilling et al., 2014); Brief Intervention and Contact (BIC; Bertolote et al., 2010); MI-SafeCope (Czyz et al., 2019), a motivational interview-enhanced safety planning intervention; ProHelp (Han et al., 2018), a brief psychoeducational online program; ReFrame-IT (Hetrick et al., 2017), an internet-based CBT program; Electronic Bridge to Mental Health Services (eBridge; King et al., 2015), which provided personalized feedback and optional online counseling for university students; the Youth Nominated Support Team Version Two (YST-II; King et al., 2009), a psycho-education and follow-up intervention following psychiatric hospitalization; Dialectical Behavior Therapy for Adolescents (DBT-A; Mehlum et al., 2014); the Family Intervention for Suicide Prevention (FISP; Rosenbaum et al., 2011), an adaptation of an emergency room intervention; Sources of Strength (Wyman et al., 2010), a school-based suicide prevention program; Coping Long-Term with Active Suicide Program for Adolescents (CLASP-A; Yen et al., 2019), an adapted program for the post-discharge transition period. **Table 1** provides additional study characteristics.

BIT Continuum and Potential Data Streams

Hermes et al. (2019) posit that the measurement of implementation outcomes needs to take into account the data streams of a BIT (how data is recorded and collected) and the continuum of provider and technology-based support (adjunct, guided, or fully-automated intervention). This contrasts the usual practice in suicidology, of categorizing and grouping interventions by tier of prevention: universal, selective, and indicated. For example, from this review: Sources of Strength (Wyman et al., 2010) is a universal preventive intervention that is offered to all students; eBridge (King et al., 2015) is a selective preventive intervention used to identify university students at elevated risk of suicide; DBT-A (Mehlum et al., 2014) is an indicated preventive intervention that treats youth experiencing severe suicidality. Prior to identifying implementation outcomes, we categorized the 12 studies as adjunctive, guided, or fully-automated (Hermes et al., 2019) and the use of technology (the data stream) was documented (see **Table 2**).

Nine studies described interventions that could be categorized as adjunctive technology-enhanced interventions (Aseltine and Demartino, 2004; King et al., 2009; Bertolote et al., 2010; Wyman et al., 2010; Rosenbaum et al., 2011; Mehlum et al., 2014; Schilling et al., 2014; Czyz et al., 2019; Yen et al., 2019). This means that these studies featured a technological component to supplement an intervention delivered by a provider (Hermes et al., 2019). For example, the SOS program for high school students included a video to enhance a psychoeducational presentation about youth suicide risk (Aseltine and Demartino, 2004). Two studies described interventions that could be categorized as guided technology-enhanced interventions (King et al., 2015; Hetrick et al., 2017). Therefore, important aspects of the intervention were delivered by a technological component with some provider support. For instance, college students engaged the eBridge platform remotely, and mental health providers responded accordingly to students' completed suicide risk assessments and digital messages (King et al., 2015). Finally, one study described an intervention that could be categorized as a fully-automated technology-enhanced intervention (Han et al., 2018); college students accessed ProHelp, a brief psychoeducational online program, with minimal to no provider support. Technology used ranged from phones (either for calls or text messaging), videos, to online platforms, which suggests a potential variety of data streams.

Measurement of Implementation Outcomes

We examined how the eight implementation outcomes from Proctor's taxonomy, with adjustments based on the work of Hermes et al. (2019) and Wozney et al. (2018) and colleagues, could be identified and measured among our sample (see **Table 3**). Feasibility was conceptualized as "trialability" and informed by recruitment, retention, and youth participation rates (Proctor et al., 2011). Feasibility was measured by the number or proportion of youth participants recruited, enrolled, and retained in the study or lost to dropout. Eight studies measured adoption of the intervention (Aseltine and Demartino, 2004; King et al., 2009, 2015; Wyman et al., 2010; Mehlum et al., 2014; Hetrick et al., 2017; Czyz et al., 2019; Yen et al., 2019), and, overall, studies recorded session attendance and participant engagement with online intervention tools and modules. Five studies measured intervention fidelity by using adherence rating scales for session evaluation (King et al., 2009; Mehlum et al., 2014; Czyz et al., 2019; Yen et al., 2019), interrater reliability of psychometric outcomes and session checklists (King et al., 2009) and verification of completion of intervention components by additional sources (Wyman et al., 2010).

Four studies measured acceptability of the intervention and its components by using participant ratings or responses to open-ended questions about intervention satisfaction (Aseltine, 2003; Han et al., 2018; Czyz et al., 2019; Yen et al., 2019). One study also measured acceptability by using the Internet Evaluation and Utility Questionnaire (IEUQ; Ritterband et al., 2008; Thorndike et al., 2008), which assesses usability, likeability, and usefulness of an online intervention (Han et al., 2018). Four studies measured appropriateness of the intervention by assessments of participants' help-seeking behaviors (Schilling et al., 2014) and beliefs and attitudes about help-seeking (Han et al., 2018), perceptions of intervention helpfulness and

TABLE 1 | Study characteristics.

	Country	Setting	Sample size	Mean age (years)	Majority gender of sample	Majority ethnicity of sample	Intervention name
Aseltine and Demartino (2004)	USA	High School	2,100	Not Available	Female	Hispanic-non White	SOS
Bertolote et al. (2010)	Brazil; India; Sri Lanka; Iran, China	Emergency Department	1,867	23	Female	Indian	BIC
Czyz et al. (2019)	USA	Hospital	36	15.42	Female	White/ Caucasian	MI-SafeCope
Han et al. (2018)	Australia; China	University; online	257	19.32	Female	Chinese	ProHelp
Hetrick et al. (2017)	Australia	High School; online	50	14.7	Female	Not available	Reframe-IT
King et al. (2015)	USA	University; online	76	22.9	Female	White/ Caucasian	*e*Bridge
King et al. (2009)	USA	Hospital	448	15.59	Female	White/ Caucasian	YST-II
Mehlum et al. (2014)	Norway	Psychiatric Outpatient	77	15.6	Female	Norwegian	DBT-A
Rosenbaum et al. (2011)	USA	Emergency department	181	14.7	Female	Hispanic-non White	FISP
Schilling et al. (2014)	USA	Middle school	386	Not available	Female	White/ Caucasian	SOS-Middle School
Wyman et al. (2010)	USA	High school	2,675	Not available	Female	White/ Caucasian	Sources of Strength
Yen et al. (2019)	USA	Psychiatry inpatient unit	50	15.74	Female	White/ Caucasian	CLASP-A

practicability (Aseltine, 2003), and ratings of perceived need for help and readiness to access help (King et al., 2015). We included measures of help-seeking as a proxy for appropriateness since this key behavior influences the intervention's fit and relevance for youth participants struggling with suicidality.

Examples of implementation cost, penetration, and sustainability were not identified among our sample. It is logical that these three outcomes were not identified among the RCTs, as they are outcomes that are observed or that occur in later stages of implementation (Proctor et al., 2011). Suggestions for future research are outlined in the discussion section.

DISCUSSION

This review sought to discuss and demonstrate how technology-enhanced interventions for youth suicide can adopt the terminology of the BIT continuum and begin to measure implementation outcomes in future hybrid trials. Based on the first exercise, technology-enhanced interventions for youth greatly varied in terms of provider and technology support. Therefore, the conceptualization of implementation outcomes and how they can be measured or observed should be specific to the category of the BIT continuum. For instance, the SOS program (Aseltine and Demartino, 2004; Schilling et al., 2014), an adjunctive BIT, would measure implementation outcomes differently than ProHelp (Han et al., 2018), a fully-automated BIT. The SOS program could measure implementation outcomes by different levels of analysis—provider (teacher or mental health professional), consumer (student), and administrator (principal), while ProHelp may only report consumer-based outcomes (the youth who are accessing the intervention).

Additionally, we discovered that data stream sources range across the BIT continuum and within BIT categories. Using the same example, the SOS program's psychoeducation video cannot be used as a source of implementation data collection, while ProHelp's online platform automatically records youth intervention engagement and use (i.e., youth clicks on an online advertisement, participant entry into the platform). Yet, MI-SafeCope (Czyz et al., 2019), another adjunctive BIT, had a different data stream than the SOS program by using phone calls and text messages for participant follow-up. Therefore, technology-enhanced suicide interventions for youth are incredibly heterogeneous, and suicidologists should consider an intervention's stage in the BIT continuum and data stream when measuring both effectiveness and implementation outcomes. These observations may inform how specifically technology-enhanced interventions should be matched when comparing outcomes, since comparison by common characteristics (e.g., sample population, study design) overlooks that the interventions' mechanisms are extremely varied.

TABLE 2 | The Continuum of Behavioral Intervention Technology (BIT) and use of technology.

	Adjunctive BIT	**Technology use**	**Guided BIT**	**Technology use**	**Fully automated BIT**	**Technology use**
	BIT supplements or enhances provider-delivered intervention		Key aspects of intervention delivered by BIT with provider support		BIT delivered intervention directly to consumer; minimal provider support	
Aseltine and Demartino (2004)	X	Psychoeduc-ational elements taught using video				
Bertolote et al. (2010)	X	Follow-up contacts included phone calls				
Czyz et al. (2019)	X	Check-in using phone call and text messages during follow up period				
Han et al. (2018)					X	Self-directed, online psychoeducat-ional program
Hetrick et al. (2017)			X	Online CBT modules delivered and supported by school well-being staff		
King et al. (2015)			X	Online screening program with counselor interaction		
King et al. (2009)	X	Phone consultation for the adult support persons post-discharge				
Mehlum et al. (2014)	X	Telephone coaching to support in-person DBT sessions				
Rosenbaum et al. (2011)	X	Telephone contacts for supporting outpatient treatment attendance post ED-discharge				
Schilling et al. (2014)	X	Psycho-education taught via DVD				
Wyman et al. (2010)	X	Use of videos, social networking sites, and text-messages to engage youth				
Yen et al. (2019)	X	Weekly telephone booster calls and daily text messages to enhance treatment engagement				

Definition of BIT categories from Hermes et al. (2019).

TABLE 3 | Implementation outcomes reported and how they were measured.

	Acceptability	**Adoption**	**Appropriateness**	**Cost**	**Feasibility**	**Fidelity**	**Penetration**	**Sustainability**
	Satisfaction with aspects of the intervention	Uptake; intention to use	Perceived fit, relevance or compatibility of the intervention	Cost of develop-ment and implement-tation effort	Extent to which the intervention can be carried out	Adherence to original intervention as intended	Integration of intervention within system	Extent to which the intervention is maintained within the system
Aseltine and Demartino (2004)	*Earlier publication reported school staff's perception of the satisfaction of intervention components and materials to students	*Reported teachers' summary of student participation at video screenings	*School staff rated perceived helpfulness and practicability of intervention components and materials		Sample number engaged in study and lost to dropout			
Bertolote et al. (2010)					Number of participants lost to follow-up			
Czyz et al. (2019)	Youth and parents rated general satisfaction with the intervention and if they would recommend it to others	Youth's daily engagement in coping skills and safety planning skills acquired during intervention			Percentage of participants enrolled, completion of components and participation in follow-up	Adherence measure, by intervention counselor during or after sessions		
Han et al. (2018)	Internet Evaluation and Utility Question-naire (IEUQ)[a] used to assess youth's usability, likeability, and usefulness; also questions about ease of use and clarity of information provided.		Youth's professional help-seeking beliefs items based on General Help-Seeking Question-naire[b] Youth's professional help-seeking attitudes were measured by the Attitudes Toward Seeking ProfessionalPsychological Help Scale[c]		Counted clicks on Facebook advertisement and number of students invited from the SONA platform. Number of participants recruited, eligible, and engaged in study. Completion rates for post-test and 1-month follow-up surveys.			
Hetrick et al. (2017)		Metrics of how many modules and how much of each module was completed by youth, how many activities were completed, and how often the message board was used.			Sample number engaged in study, lost to dropout, and completion of follow-up assessments			

(Continued)

TABLE 3 | Continued

	Acceptability	Adoption	Appropriateness	Cost	Feasibility	Fidelity	Penetration	Sustainability
King et al. (2015)		Number of participants who sent messages to the counselor (i.e., never, once, etc.); number of participants who viewed feedback from counselor	Need for help, assessed if in the previous 2 months the youth thought they needed help for emotional, mental health or problems related to substance abuse. Readiness to access help was assessed, with responses: "Sometimes I think about doing this"; "I have taken steps toward doing this"; and "I already did this."		Number of participants enrolled and number of participants retained at follow-up assessment.			
King et al. (2009)		Number of sessions attended by parent/adult support person; number of calls and face to face interactions; percentage of participants using treatment method at stages of study			Retention of sample at each time point in the study.	Intervention sessions were audiotaped and specialists completed checklists after sessions. Interrater reliability was established on psycho-metric outcomes and session categories.		
Mehlum et al. (2014)		Mean scores of all participant completion of sessions by modality (i.e., individual or family therapy)			Number of participants enrolled and number lost to dropout; *more than 3 dropped individual therapy sessions is considered dropout in DBT-A.	Adherence was assessed by an independent rater using the DBT Global Rating Scale[d]. For each patient-therapist dyad individual therapy, 5 sessions were videotaped. One randomly selected videotaped skills training session per group was rated per month.		

(Continued)

TABLE 3 | Continued

	Acceptability	**Adoption**	**Appropriateness**	**Cost**	**Feasibility**	**Fidelity**	**Penetration**	**Sustainability**
Rosenbaum et al. (2011)					Number of participants enrolled and lost to dropout			
Schilling et al. (2014)			Eight questions were used to assess participants' help-seeking behavior.		Number of schools approached for study and number enrolled; number of participants who returned consent forms; number of participants enrolled.			
Wyman et al. (2010)		Peer leaders completion of the messaging steps of the intervention			Number of participants enrolled and number who completed pre and post-tests.	Staff members were interviewed after the messaging phase to verify peer leaders' compliance.		
Yen et al. (2019)	Participants and parents provided intervention approval ratings on a Likert scale; open-ended comments recorded.	Number of sessions completed by participant and parents			Number of participants enrolled, retainment at study stages, and number lost to dropout.	A blind independent evaluator (pre-doctoral fellow) rated session tapes for adherence and competency.		

**See Aseltine (2003).*

[a] *IEUQ Information: 15 items with 2 open-ended questions (Ritterband et al., 2008; Thorndike et al., 2008).*

[b] *General Help-Seeking Questionnaire (GHSQ; Wilson et al., 2005).*

[c] *Attitudes Toward Seeking Professional Psychological Help Scale (ATSPPHS-SF; Fischer and Farina, 1995).*

[d] *DBT Global Rating Scale Information: (Linehan, 2003), a 64-item instrument scored from 0 to 5, with higher scores reflecting higher adherence.*

It is important to note that the majority of our sample were adjunctive technology-enhanced interventions. This is likely the result of the elongated time frame it takes to pilot, adapt, and then perform an RCT using a then considered "cutting edge technology" (e.g., text-messaging, DVDs). We believe more RCTs will be conducted for guided and automated interventions, as technology progresses, and researchers and funders become more adept at expediting the experimental process for technology-enhanced interventions.

The second exercise demonstrated how implementation outcomes can be potentially measured in RCTs of technology-enhanced interventions for youth suicide. Of the constructs present, outcomes were measured via observations or counts, questionnaires and/or rating. Future studies may benefit from including case audits, analyses of administrative data, qualitative methods (focus groups and semi-structured interviews), and the leveraging of data that platforms automatically collect (Proctor et al., 2011; Hermes et al., 2019) and balance outcomes reported by youth consumers and parents/guardians, non-clinical actors (such as peer leaders and school staff), clinical providers, and organizational administrators (Wozney et al., 2018). The practice of collecting implementation outcomes from various sources may also help to ensure that new interventions adequately respect youth privacy and confidentiality, and that user data is managed accordingly.

Researchers should consider measuring and reporting implementation cost, penetration, and sustainability, as these outcomes are also dependent on a study's stage in the BIT continuum, source of data stream, setting, and stage in the implementation process. Implementation cost is an outcome that is relevant to all stages of implementation (Proctor et al., 2011), and increased reporting of cost can inform colleagues and funding sources of the financial realities of developing, disseminating, and sustaining a technology-enhanced intervention for youth suicide. For instance, interventions that have more provider-driven components (such as DBT-A; Mehlum et al., 2014) would require substantial funding for ongoing clinician trainings, while interventions with more automated components (such as Reframe-IT; Hetrick et al., 2017) would require funding for launching, monitoring, and maintaining an online platform. Researchers must also consider the potential financial cost for the youth user (e.g., payment for internet access or cellphone coverage, payment to access mobile app).

Guided or fully-automated interventions broaden the possibilities for measuring penetration, since interventions can be disseminated or accessed by many people at a faster rate than interventions that are mainly face to face. This also suggests that the level of analysis may now include a virtual setting that is part of a larger education or medical institution or under the auspice of a private technological software company. For example, the school-based SOS program (Aseltine and Demartino, 2004) (an adjunctive BIT) would measure penetration by including school personnel and student peers who are trained and who implement the intervention (level of analysis at the school or school district); eBridge (King et al., 2015) (a guided BIT) may measure penetration based on the online platform's capacity to screen a certain number of students by the number of students who access the platform (level of analysis at the university counseling center's platform). Lastly, measurement of sustainability may now include the technological evolution of a youth suicide intervention. For instance, a fully-automated intervention would track updates (e.g., version 2.0 of a mobile application), and report adjustments to account for new technology and consumer preferences (e.g., switching from having the intervention developed for a mobile application specific to Android phones to one featured on IPhones).

Conclusion

Overall, this review emphasizes the diversity within the sub-field of technology-enhanced interventions for youth suicide. Therefore, it is important that suicidologists be specific of how their intervention uses technology, varies in provider and technology-based support, and measures implementation outcomes. As youth suicide and suicidality continues to increase in the U.S., especially among youth with minority identities, the measurement of implementation outcomes may help to understand why an intervention fails or underperforms among a certain youth population, and how successful interventions can be disseminated more broadly. This review also illustrates that implementation outcomes can be measured as early as the RCT phase and raises considerations for how outcomes could be integrated in more implementation-focused studies.

The ever increasing integration of technology in interventions provides opportunities to innovate youth engagement and access. Yet, it also provides opportunities for further stigmatization of underserved populations and misallocated efforts if interventions do not take into account the needs of youth and providers, and the realities of implementing interventions beyond controlled settings. As demonstrated by colleagues specializing in implementation science and BIT, the development and testing of technology-enhanced interventions for youth suicide allow for recharacterization of implementation outcome measurement and, thus, heighten chances of achieving public health impact (Graham et al., 2019). We hope that this review honors the work of youth suicide researchers who have integrated technology into interventions and inspires future suicidologists to understand the nuances of technology-enhanced interventions, and how both provider and technologically-based components translate to implementation in real-world settings.

AUTHOR CONTRIBUTIONS

HS and JT identified the subsample of articles and extracted examples based on implementation and Behavioral Intervention Technology (BIT) frameworks. RL-H provided expertise in implementation science to evaluate examples identified from selected studies. HS wrote body of manuscript. JT and RL-H edited final versions of manuscript. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

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A Randomised Controlled Trial of Clinician-Guided Internet-Based Cognitive Behavioural Therapy for Depressed Patients in Singapore

Sharon H. X. Lu[1]*, Hanita A. Assudani[1], Tammie R. R. Kwek[1], Shaun W. H. Ng[1], Trisha E. L. Teoh[1] and Geoffrey C. Y. Tan[2,3,4]

[1] Department of Psychology, Institute of Mental Health, Singapore, Singapore, [2] Department of Mood and Anxiety, Institute of Mental Health, Singapore, Singapore, [3] Singapore Institute of Clinical Sciences, Agency for Science Technology and Research (A∗STAR), Singapore, Singapore, [4] Clinical Imaging Research Centre, Yong Loo Lin Medical School, National University of Singapore, Singapore, Singapore

This study examined the efficacy and acceptability of a hybrid, clinician-guided internet-based Cognitive Behavioural Therapy (iCBT) programme for outpatients with depression in a psychiatric hospital in Singapore. Fifty three participants were randomly assigned to a treatment or wait-list control group before they underwent a cross-over of conditions. Treatment consisted of a 4-week iCBT with three face-to-face sessions. 60.9% of participants who received treatment completed all six modules. Intention-to-treat analysis showed treatment was associated with significant reductions in symptoms of depression, anxiety and psychological distress but not in functional impairment, while the control condition was not associated with changes in any measures. These reductions had moderate to large effect sizes (ESs) for symptoms of depression and anxiety, and moderate ES for psychological distress. The between-group difference in depression score had a moderate ES. There was a significant between-group treatment effect in depressive symptoms, but not in the other measures. Treatment gains were maintained at 3-month follow-up. Most of the participants were highly satisfied with the programme, with 90 percent stating they would recommend it. This is the first RCT to provide preliminary evidence for the efficacy and acceptability of iCBT for depression in Singapore.

Keywords: internet treatments, cognitive behavioural therapy, depression, Asians, randomised control trial

Edited by:
Alexandra Voinescu,
University of Bath, United Kingdom

Reviewed by:
Caterina Adele Viganò,
University of Milan, Italy
Costina Ruxandra Păsărelu,
Babeş-Bolyai University, Romania

***Correspondence:**
Sharon H. X. Lu
sharon_hx_lu@imh.com.sg

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INTRODUCTION

Depression is the leading cause of disability globally (Kessler et al., 2003, 2006). Depression is highly comorbid with other mental and physical conditions and its presence exacerbates dysfunction, and burden on health services (Angst et al., 1999). It is estimated that 6.3% of Singaporeans will have depression and 1.6% will have anxiety at some point, with 3.5% suffering from at least two mental health disorders in their life (Subramaniam et al., 2020).

Cognitive Behavioural Therapy (CBT) is a mainstay in evidence-based treatments for depression and anxiety. However, 59.6% of Singaporeans with depression do not access professional help (Chong et al., 2012). Previous studies have shown that the barriers to accessing treatment in Asian populations include stigma, concerns about treatment costs, transportation difficulties and a shortage of culturally appropriate services (Lu et al., 2013). Furthermore, access to psychotherapy may also be limited during periods of emergency, as witnessed during the ongoing COVID-19 pandemic where multiple countries have gone into lockdown and healthcare services have been restricted (Yang et al., 2020).

One strategy that has been shown to increase access to treatments is internet-delivered CBT (iCBT) (Abbott et al., 2008; Barak et al., 2009; Ryan et al., 2010). iCBT involves the delivery of skills and information based on the CBT approach, *via* the internet. Clinician guidance in the form of telephone and/or email coaching is often provided concurrently and has been shown to improve effect sizes and adherence (Andersson and Cuijpers, 2009; Talbot, 2012). iCBT is a cost-effective and efficacious treatment for depression and anxiety as singular disorders (Spek et al., 2007; Andrews et al., 2010) or for comorbid depression and anxiety (Titov et al., 2010, 2011, 2012; Dear et al., 2011; Johnston et al., 2011).

While iCBT has shown efficacy in Western populations, limited evidence exists for Asian populations. Ooi et al. (2016) reported web-based CBT programmes to be efficacious in decreasing the severity of selective mutism among affected Singaporean children. Choi et al. (2012) reported a culturally adapted version of iCBT to be efficacious in treating depression among Chinese-speaking immigrants in Australia. However, to our knowledge, no studies have yet examined the efficacy of iCBT for treating depression in an Asian setting.

As such, the present study would be the first of its kind to explore the feasibility of delivering iCBT to depressed patients in Singapore. Given that the introduction of delivering CBT *via* the internet is relatively new to the population in Singapore, the authors aimed to scaffold the delivery of iCBT with face-to-face support provided by a clinician, instead of relying solely on email or phone support. Feedback from users on the acceptability of a hybrid model of iCBT as a psychotherapeutic treatment option will also be obtained.

The present study aims to explore the efficacy and acceptability of a blended iCBT programme, with three face-to-face sessions conducted by a clinician, for patients with depression in Singapore.

METHOD

Design, Sample Size, and Hypotheses

The current study involves a cross-over, randomised controlled trial between a treatment group and a delayed waitlist control group. The control group underwent the same intervention with clinician support after waiting 4 weeks (**Figure 1**).

Power calculations for a cross-over randomised controlled trial determined that a total sample size of 32 was sufficient to detect an effect size of 0.5 (power at 80% and alpha at 0.05), which is the minimum expected based on a similar study (Choi et al., 2012).

It was hypothesised that compared to control, treatment would be associated with greater pre-post improvements in depressive symptoms. These gains would also be sustained at 3-month follow-up. Lastly, participants would find iCBT to be acceptable.

Participants and Recruitment

Outpatients from the Institute of Mental Health who presented with mild to moderate depressive symptoms were invited to participate in the current study from 2017 to 2018. The study had to be terminated prematurely due to the unexpected closure of the server which hosted the online programme, even though the recruitment target has not been met. The inclusion criteria were: (1) aged 21 to 65 yr old, (2) not currently seeing a therapist for any form of individual or group therapy, (3) presented with mild to moderate depressive symptoms, (4) if on medication for depression, to be on a stable dose for at least a month, (5) provided informed consent, (6) able to read and speak at least Primary 6 level English, and (7) adequate computer skills to operate the iCBT programme. All participants recruited had undergone formal psychiatric assessment with a psychiatrist in the hospital and presented with primarily depressive symptoms.

The exclusion criteria were: (1) severe depression (i.e., score $\geq$ 23 on PHQ-9), (2) strong suicidal ideation (i.e., score $>$ 2 on Question 9 of the PHQ-9), (3) current active suicidal intention or plan, (4) depression was not the presenting problem, (5) did not meet the minimum English language requirements, and (6) concurrently attending other forms of group/individual psychotherapy.

The study was approved by the ethics board, the National Healthcare Group Domain Specific Review Board (DSRB) in Singapore (Protocol Record 2015/00404) and registered with ClinicalTrials.gov as NCT04100785.

Primary Outcome Measure

Patient Health Questionnaire-9 (PHQ-9)

The PHQ-9 (Kroenke et al., 2001) is a nine-item self-report measure of symptoms and severity of major depressive disorder, based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV; American Psychiatric Association, 2000) criteria for Major Depressive Disorder. Scores on each item range from 0 (not at all) to 3 (nearly every day). An overall cut-off score of 10 or greater is sensitive to a DSM-IV diagnosis of depression (Kroenke et al., 2010). The PHQ-9 has an internal reliability of 0.86–0.89, a sensitivity of 88%, and a specificity of 88% for the clinical cut-off of 10. It also has an excellent test-retest reliability of 0.84 and correlates moderately ($r = 0.58$) with the SF-20 mental health scale (Kroenke et al., 2001). The PHQ-9 has also been found to be valid and reliable for screening depression in Singapore (Sung et al., 2013).

Secondary Outcome Measures

Generalised Anxiety Disorder-7 (GAD-7)

The GAD-7 (Spitzer et al., 2006) is a seven-item self-report measure of symptoms and severity of Generalised Anxiety Disorder (GAD), based on the DSM-IV criteria for GAD. Scores for each item range from 0 (not at all) to 3 (nearly every day). An overall cut-off score of 10 or greater is sensitive to DSM-IV diagnoses of GAD, social phobia, and panic disorders (Kroenke et al., 2007). The GAD-7 has an internal reliability of 0.92, test-retest reliability of 0.83, and criterion validity of 0.75 with the SF-20 mental

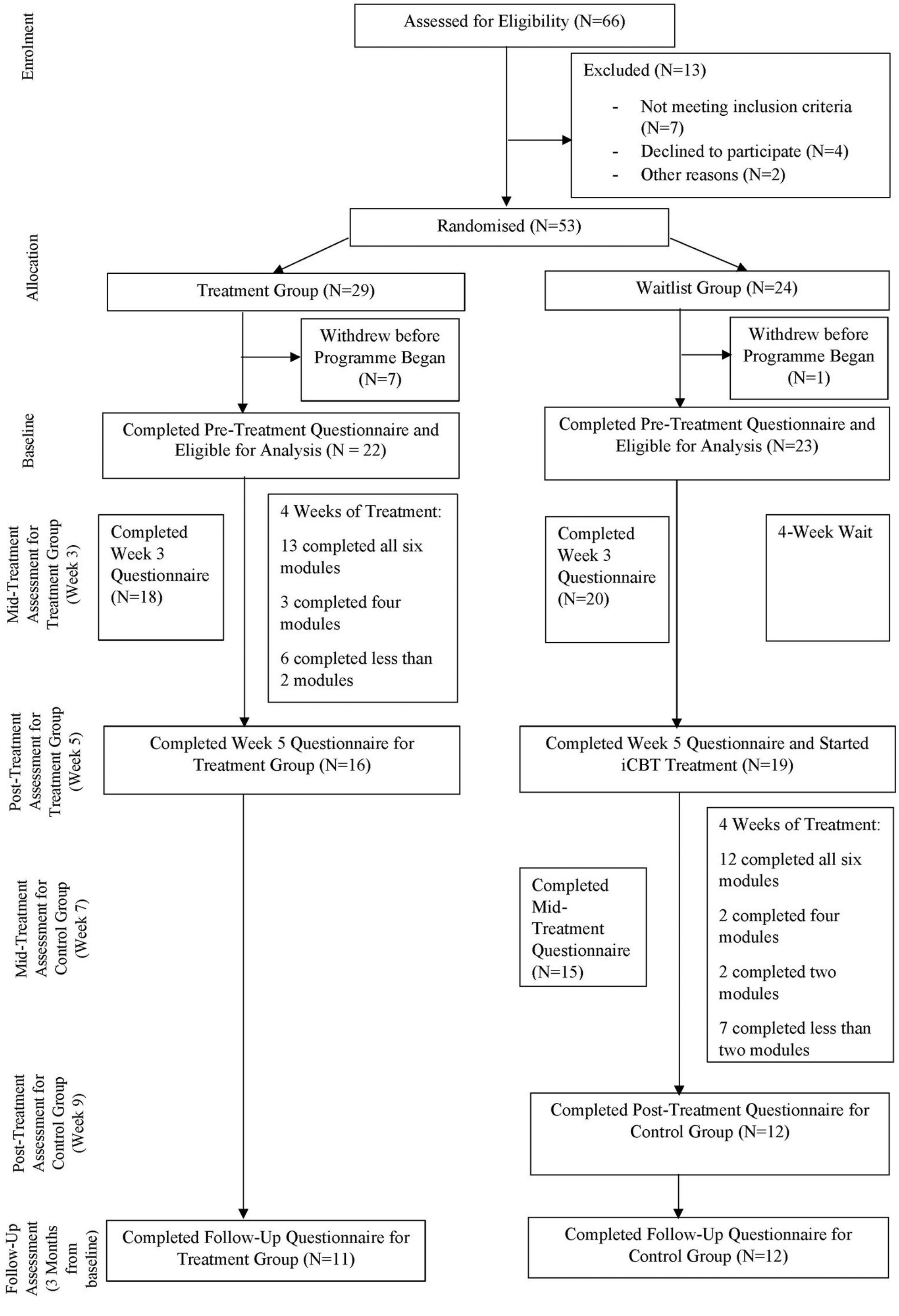

FIGURE 1 | Participants flow chat.

health scale (Spitzer et al., 2006). The GAD-7 is increasingly adopted in empirical studies and large-scale dissemination studies as a general measure of shifts in anxiety symptoms (Clark et al., 2009).

Kessler-10 Item (K-10)

The K-10 (Kessler et al., 2002) is a ten-item self-report measure of non-specific psychological distress and strong support has been found between the K-10 and its associations with diagnoses of anxiety and depression (Andrews and Slade, 2001). Scores for each item ranged from 0 (no distress) to 5 (highly distressed), with total scores spanning from 0 to 50. The scale possesses excellent internal consistency ($\alpha = 0.93$), even with ethnically diverse populations (Fassaert et al., 2009).

Work and Social Adjustment Scale (WSAS)

The WSAS (Mundt et al., 2002) is a five-item self-report measure of the extent of impairment in work and social functioning, with scores ranging from 0 to 40. An overall score of above 20 appears to suggest moderately severe or worse psychopathology. Scores between 10 and 20 are associated with significant functional impairment but less severe clinical symptomatology. The WSAS has an internal reliability of 0.70–0.94 and a test-retest reliability of 0.73. Its convergent validity compared with clinical interviews and severity of depression is 0.76–0.86.

Timepoints

Participants in the treatment group started the intervention after the first face-to-face meeting with a psychologist. On the other hand, participants in the delayed waitlist-control group received the intervention after 4 weeks.

The iCBT programme spanned over 4 weeks. The outcome measures were administered during the face-to-face session at Week 1 (before Module 1), Week 3 (mid-treatment), and Week 4 (after Module 6), as well as at three-month follow-up *via* email.

Intervention

The iCBT programme consisted of six online modules adapted from the THRIVE programme, which is a community mental health self-help programme locally developed by Khoo Teck Puat Hospital in Singapore. The outline for each module is as follows: (1) introduction to depression, (2) problem-solving, (3) understanding the influence of thoughts and beliefs in depression, (4) overcoming negative thoughts and beliefs, (5) planning meaningful activities (part 1), and (6) planning meaningful activities (part 2). Participants were instructed to complete Modules 1 and 2 in week 1; Modules 3 and 4 in week 2 and week 3; Modules 5 and 6 in week 4.

In addition to the online modules, there were three face-to-face 30-min sessions with a psychologist conducted at weeks 1, 3, and 4. The face-to-face sessions were recommended by the ethics board to ensure that patients presenting to an acute psychiatric hospital were able to receive a minimal standard of care—one component being face-to-face contact with a clinician. These sessions were for patients to discuss the application of the content of the modules in relation to their presenting problems. It should be noted that these face-to-face sessions were not therapy sessions, and the role of the psychologists in the present study was solely to provide support and encouragement, as well as to assist the participants in applying the content of the modules. These sessions were arranged to maintain contact so as to promote adherence to the online treatment and reduce dropout rates. Moreover, administrative matters could also be settled, such as resolving technical issues, completing questionnaires, and obtaining ongoing feedback.

Therapists

Two clinical psychologists with postgraduate training in clinical psychology provided all face-to-face contact (three sessions) with participants. The content of the face-to-face contact followed a specific structure, where opportunities for reinforcing participants, guidelines for answering frequently asked questions, and additional information were provided.

Procedure

Upon expressing their interest in the study, participants were contacted by the researchers to arrange for a first face-to-face meeting. During this meeting, the researchers explained the purpose of the study, the procedures involved, obtained informed consent from the participants to take part in the study and administered the baseline questionnaires. Participants were then randomised to either the intervention or the delayed waitlist control group *via* a random number generator. After being assigned to a group, participants were briefed on the procedures depending on the group they belonged to. Participants in the treatment group were also briefed on log-in details and given information about assessing the iCBT materials.

Following the first face-to-face meeting, participants from the treatment group underwent 1 week of online modules, followed by the second face-to-face meeting, where they completed the mid-treatment measures, followed by another week of online modules before the third face-to-face meeting, where the post-treatment measures were taken. Similarly, participants from the control group completed the mid-treatment and post-treatment measures on the third and fifth week *via* email following the first face-to-face meeting. After the completion of the post-treatment measures, participants from the delayed waitlist control group commenced their treatment within the same week. At the end of the study, participants were remunerated with a small inconvenience fee for their participation.

Analyses

The study employed a cross-over randomised design where each group underwent an initial comparison arm, followed by a cross-over arm. In the initial comparison arm, the group undergoing treatment initially was referred to as the "treatment group," while the waitlist group was designated as the "control group." Differences between treatment and control groups in demographic data and pre-treatment scores were analysed using two-sample *t*-tests and chi-square tests. Baseline differences between completers and non-completers were analysed using two-sample *t*-tests. In line with previous RCTs, univariate ANCOVAs were conducted to compare treatment and control groups in the initial comparison arm, analysing for differences at week 5 while controlling for baseline scores (Choi et al., 2012). Repeated measures General Linear Models (rmGLM) were used to analyse data collected at pre-treatment, post-treatment, post-cross-over, and follow-up. To reduce potential biases from attrition, rmGLM were used for longitudinal analysis of the cross-over design across both arms and per-protocol and intention-to-treat analyses were performed. Effect sizes (ESs; Cohen's d) were calculated to quantify the magnitude of change in symptoms for within and between groups, based on the pooled standard deviation. All analyses were performed in PASW version 25.0 (SPSS Inc., Chicago, IL).

Our primary outcome measure was the PHQ-9 as the intervention was designed to target depressive symptoms. Secondary outcome measures comprised the GAD-7, WSAS, and K-10. Regarding the cross-over design, there are two dependent variables: (i) control response, which is the response under the control condition, and (ii) treatment response, which is the response under the iCBT condition and both variables are deviations from each subject's baseline measurements including order of intervention as a between-subject factor. Longitudinal effects of treatment and control were further analysed in each arm. We conducted both per-protocol and intention-to-treat analyses.

Clinical significance was examined using remission and recovery rates. Remission is defined as the proportion of participants who initially scored at or above, but subsequently scored below the cut-off scores of 10 for the PHQ-9 total score (Kroenke et al., 2001, 2010; Gilbody et al., 2007) and 8 for the GAD-7 total score. Secondly, clinical recovery is estimated using the proportion of participants who showed a significant reduction of 50 percent of pre-treatment PHQ-9 and GAD-7 scores, as described in previous studies (Richards and Suckling, 2009; Titov et al., 2011).

Thematic analysis of the feedback obtained from open-ended questions ("Please elaborate on what you have found to be helpful and not helpful in this programme"; "Is there anything we can do to make the iCBT programme more useful?") was conducted to generate a list of preliminary themes that participants found useful about iCBT in this current study.

TABLE 1 | Demographic characteristics of the participants.

Variable	Treatment group		Control group		Total		Significance statistics
	n	%	*n*	%	*n*	%	
Gender							
Male	11	50	13	56.5	24	53.3	$x^2 = 0.19, p = 0.66$
Female	11	50	10	43.5	21	46.7	
Age							
Mean	36.1 (12.1)		30.3 (8.0)		33.1 (10.5)		$t(43) = 1.92, p = 0.06$
Range	21 to 58		20 to 48		20 to 58		
Marital status							
Single	12	54.5	17	73.9	29	64.4	$x^2 = 1.98, p = 0.37$
Married	6	27.3	3	13.0	9	20.0	
Divorced/widowed	4	18.2	3	13.0	7	15.6	
Highest educational level							
Secondary School	4	18.2	2	8.7	6	13.3	$x^2 = 0.90, p = 0.64$
Diploma/junior college	9	40.9	11	47.8	20	44.4	
Graduate/ post graduate	9	40.9	10	43.5	19	42.2	
Employment status							
Student	3	13.6	1	4.3	4	8.9	$x^2 = 2.19, p = 0.335$
Employed	13	59.1	18	78.3	32	68.9	
Unemployed	6	27.3	4	17.4	10	22.2	
Taking medication							
No	8	36.4	7	30.4	17	33.3	$x^2 = 1.27, p = 0.529$
Depression	9	40.9	13	56.5	22	48.9	
Depression and Anxiety	5	22.7	3	13.0	8	17.8	
Previously had therapy							
Yes	15	68.2	13	56.5	28	62.2	$x^2 = 0.65, p = 0.420$
No	7	31.8	10	43.5	17	37.8	
Previously done CBT							
Yes	6	27.3	4	17.4	10	22.2	$x^2 = 0.64, p = 0.425$
No	16	72.7	19	82.6	35	77.8	
Internet use per week							
<10 h	5	22.7	3	13.0	8	17.8	$x^2 = 0.81, p = 0.668$
10 to 35 h	11	50.0	12	52.2	23	51.1	
More than 35 h	6	27.3	8	34.8	14	31.1	

RESULTS

Demographic Characteristics of Participants

The mean age of participants was 33.1 years ($SD = 10.5$), and 24 (53.3%) of them were males. Other relevant demographic characteristics of the participants are included in **Table 1**. Chi-squared tests revealed no significant differences between groups on all the demographic characteristics of the participants ($p > 0.05$). There was no significant difference in pre-treatment PHQ-9 scores between the treatment group and the control group, $t_{(44)} = 0.08$, $p = 0.94$.

Adherence and Attrition

Out of the 29 participants who were assigned to the treatment group, seven (24.1%) did not attend the first face-to-face session. 22 people completed the pre-treatment questionnaires and were eligible for analysis. Out of the 22 participants in the treatment group who started treatment, 13 (59.1%) completed all six modules within the 4 weeks of the intervention, three (13.6%) completed four modules, and six (27.3%) completed less than two modules. The average number of complete modules was 4.09 ($SD = 2.65$). 11 (50%) completed the three-month follow-up questionnaire.

Out of the 24 participants who were in the control group, one (4.2%) did not complete the pre-treatment questionnaire. 23 people (95.8%) completed at least the pre-treatment questionnaire and were included in the analyses. Out of the 23 participants, 19 started the iCBT intervention at Week 5.12 (63.2%) completed all six modules, two (10.5%) completed four modules, two (10.5%) completed two modules, and seven (36.8%) completed less than two modules. In total, 25 out of 41 (60.9%) of participants who received the intervention completed all six modules. The average number of completed modules was 3.73 ($SD = 2.78$). 12 (52.2%) completed the post-treatment questionnaire and 12 (52.2%) completed the three-month follow-up questionnaire.

Pre-treatment symptom scores were analysed using independent 2-sample t-tests to compare those who completed the post-treatment questionnaire and those who did not. From a total of 45 participants, there were 35 completers and 10 non-completers. As compared to non-completers, completers did not have significant differences in their baseline scores for PHQ-9 (mean difference = 1.93, $SE = 1.94$, $t = 0.992$, $p = 0.33$), GAD-7 (mean difference = 1.69, $SE = 2.15$, $t = 0.78$, $p = 0.44$), WSAS (mean difference 6.50, $SE = 3.23$, $t = 2.01$, $p = 0.051$) and K10 (mean difference = 5.25, $SE = 3.15$, $t = 1.67$, $p = 0.10$) .

Treatment Outcomes

The initial comparison arm was analysed for between-group differences in post-treatment scores, controlling for pretreatment scores, between the treatment group and the control group.

Treatment vs. Control in the Initial Comparison Arm

In the per-protocol analyses, the between-group difference in post-treatment PHQ-9 scores was significant in the initial comparison arm, ($F_{1,34} = 4.96$, $p = 0.033$). The between-group difference was not significant for the GAD-7 ($F_{1,34} = 2.45$, $p = 0.13$), WSAS ($F_{1,34} = 1.54$, $p = 0.22$), and K-10 ($F_{1,34} = 0.68$, $p = 0.42$).

In the intention-to-treat analyses of the between-group difference in post-treatment scores there were no significant differences for the PHQ-9, ($F_{1,44} = 1.29$, $p = 0.26$), GAD-7, ($F_{1,44} = 0.52$, $p = 0.47$), WSAS ($F_{1,44} = 0.96$, $p = 0.33$) and K-10 ($F_{1,44} = 0.073$, $p = 0.79$).

Treatment Response Across Both Arms

Treatment response across initial comparison and cross-over arms was analysed with rmGLMs from pre-treatment to post-treatment for both arms, with order as a between-subject factor.

Per-protocol analysis revealed a significant treatment response for the PHQ-9 ($F_{1,26} = 9.96$, $p = 0.004$) and GAD-7 ($F_{1,26} = 11.54$, $p = 0.002$). There was no significant treatment response observed for the WSAS ($F_{1,26} = 1.99$, $p = 0.171$). There was a marginally significant treatment response observed for the K-10 ($F_{1,26} = 3.86$, $p = 0.060$).

Intention-to-treat analyses revealed a significant treatment response for the PHQ-9 was significant ($F_{1,43} = 7.06$, $p = 0.011$), GAD-7 ($F_{1,43} = 7.19$, $p = 0.010$) and K-10 ($F_{1,43} = 4.71$, $p = 0.036$). The treatment response for the WSAS was marginally significant ($F_{1,43} = 3.84$, $p = 0.057$).

Control Response Across Both Arms

Control response across initial comparison and cross-over arms was analysed with rmGLMs from pre-control to post-control for both arms, with order as a between-subject factor.

In the per-protocol analyses, there were no significant control responses for the PHQ-9 ($F_{1,25} = 0.44$, $p = 0.51$), GAD-7 ($F_{1,25} = 0.36$, $p = 0.55$), WSAS ($F_{1,25} = 0.0004$, $p = 0.98$) and K-10 ($F_{1,25} = 0.11$, $p = 0.74$).

In the intention-to-treat analyses, there were no significant control responses for the PHQ-9 ($F_{1,43} = 1.54$, $p = 0.22$), GAD-7 ($F_{1,43} = 0.35$, $p = 0.56$), WSAS ($F_{1,43} = 0.0004$, $p = 0.99$) and K-10 ($F_{1,43} = 0.76$, $p = 0.39$).

Comparison Between Treatment and Control Responses in Both Arms

In the per-protocol analyses, there were no significant differences in the within-individual comparison between treatment and control responses in the PHQ-9 ($F_{1,21} = 0.63$, $p = 0.44$), GAD-7 ($F_{1,21} = 1.98$, $p = 0.17$), WSAS ($F_{1,21} = 0.037$, $p = 0.85$) and K-10 ($F_{1,21} = 0.069$, $p = 0.80$).

In the intention-to-treat analyses, there were no significant differences in the within-individual comparison between treatment and control responses in the PHQ-9 ($F_{1,43} = 1.59$, $p = 0.21$), GAD-7 ($F_{1,43} = 1.90$, $p = 0.18$), WSAS ($F_{1,43} = 1.76$, $p = 0.19$), and K-10 ($F_{1,43} = 0.87$, $p = 0.36$).

Follow-Up After Treatment Across Both Arms

The follow-up time-point was analysed by rmGLMs to determine whether treatment gains were maintained from baseline to follow-up and whether there were any changes from the post-intervention time point (week 5 for the initial treatment group

TABLE 2 | Observed and estimated means, standard deviations, ESs (Cohen's d) for outcome measures.

	Observed means			ESs		Treatment vs. control ESs
	Pre	**Post**	**Follow-up (3 months from week 1)**	**Pre to post**	**Pre to follow-up**	**Pre to post**
PHQ-9						
Treatment	11.95 (6.03)	7.63 (6.05)	6.73 (3.55)	0.72*	1.30*	0.78*
Control	12.78 (6.76)	11.84 (6.30)	NA	0.14	NA	NA
Control (cross-over)	11.84 (6.30)	7.83 (7.27)	6.83 (7.42)	0.59	0.73	NA
Treatment response	12.20 (5.66)	7.71 (6.47)	NA	0.74*	0.95*	0.51
Control response	10.62 (6.33)	9.97 (5.94)	NA	0.11	NA	NA
GAD-7						
Treatment	8.50 (5.20)	5.31 (4.53)	4.27 (4.05)	0.65	0.91*	0.27
Control	11.47 (6.74)	10.53 (5.76)	NA	0.15	NA	NA
Control (cross-over)	10.53 (5.76)	5.83 (5.02)	5.78 (4.47)	0.87*	1.05*	NA
Treatment response	9.44 (5.49)	5.54 (4.66)	NA	0.77*	0.97*	0.33
Control response	8.56 (6.36)	8.23 (5.97)	NA	0.05	NA	NA
WSAS						
Treatment	15.32 (10.20)	9.31 (8.75)	9.00 (8.81)	0.63	0.66	0.36
Control	17.37 (8.91)	17.15 (10.26)	NA	0.02	NA	NA
Control (cross-over)	17.15 (10.26)	13.42 (10.24)	12.38 (11.78)	0.37	0.54	NA
Treatment Response	16.17 (10.14)	11.07 (9.46)	NA	0.52	0.59	0.23
Control Response	13.69 (9.31)	14.17 (10.40)	NA	−0.05	NA	NA
K10						
Treatment	23.91 (8.04)	19.44 (8.86)	18.27 (6.48)	0.53	0.77*	0.66
Control	27.37 (9.96)	25.68 (10.03)	NA	0.17	NA	NA
Control (cross-over)	25.68 (10.03)	20.80 (11.24)	16.80 (11.22)	0.46*	0.73*	NA
Treatment Response	24.73 (8.95)	20.10 (9.93)	NA	0.49*	0.74*	0.30
Control Response	24.15 (10.03)	23.96 (9.42)	NA	0.02	NA	NA

*Standard deviations are shown in parentheses. Pre, Pre-treatment; Post, Post-treatment; Follow-up, Three-month follow-up; PHQ-9, Patient Health Questionnaire 9-item; GAD-7, Generalised Anxiety Disorder 7-item. *indicates statistically significant results.*

and week 9 for the delayed wait-list group) to the 3-month follow-up timepoint.

In the per-protocol analyses, treatment gains were maintained from baseline to follow-up on the PHQ-9 ($F_{1,21} = 13.2$, $p = 0.002$), GAD-7 ($F_{1,21} = 8.14$, $p = 0.010$) and K-10 ($F_{1,21} = 5.20$, $p = 0.033$), while there was no significant change from baseline to follow-up in the WSAS ($F_{1,21} = 2.69$, $p = 0.12$). This was supported by the lack of any significant changes between post-treatment and follow-up on the PHQ-9 ($F_{1,10} = 0.74$, $p = 0.41$), GAD-7($F_{1,10} = 0.011$, $p = 0.92$), WSAS ($F_{1,10} = 0.035$, $p = 0.86$) and K-10 ($F_{1,10} = 0.12$, $p = 0.73$).

In the intention-to-treat analyses, treatment gains were maintained from baseline to follow-up on the PHQ-9 ($F_{1,43} = 9.71$, $p = 0.003$), GAD-7 ($F_{1,43} = 7.71$, $p = 0.008$), and K-10 ($F_{1,43} = 4.67$, $p = 0.036$), while there was a marginally significant change from baseline to follow-up in the WSAS ($F_{1,43} = 3.82$, $p = 0.057$). This was supported by the lack of any significant changes between post-treatment and follow-up on the PHQ-9 ($F_{1,43} = 1.38$, $p = 0.25$), GAD-7 ($F_{1,43} = 1.76$, $p = 0.19$), WSAS ($F_{1,43} = 0.38$, $p = 0.54$) and K-10 ($F_{1,43} = 0.41$, $p = 0.52$).

Effect Size

The ESs of the intervention in the treatment group on the change in PHQ-9 scores from baseline to week 5 and follow-up were 0.72 and 1.05, respectively (**Table 2**). For the wait-list control group, the ES of the change from baseline to week 5 was 0.14. The between-group effect size at post-treatment was 0.78. After the control group received the intervention, the ES post-intervention was 0.59. Across both groups, the intervention had an ES of 0.51 as compared to 0.08 for non-intervention periods. The response to treatment as compared to the response to non-intervention had an ES of 0.51.

The ESs of the intervention in the treatment group on the change in GAD-7 scores from baseline to week 5 and follow-up were 0.65 and 0.91, respectively. For the wait-list control group, the ES of the change from baseline to week 5 was 0.15. The between-group ES at week 5 is 0.27. After the control group received the intervention, the ES post-intervention was 0.87. Across both groups, the intervention had an ES of 0.50 as compared to 0.04 for non-intervention periods. The response to treatment as compared to the response to non-intervention had an effect size of 0.33.

TABLE 3 | Proportion of participants above and below cut-off scores of clinical significance (remission) and proportion demonstrating at least 50% reduction in pre-treatment scores (recovery).

	Treatment group		Control group		Control group (cross-over)	
Measure	**Proportion (Number of cases/total)**	**%**	**Proportion**	**%**	**Proportion**	**%**
PHQ-9						
Baseline not meeting clinical significance (score < 10)	8/22	36.4	7/23	30.4		
Post-treatment score ≥ 10 (remission)	10/16	62.5	7/19	26.8	8/12	66.6
Post-treatment score $\leq 50\%$ pre-treatment score (Recovery)	7/16	43.8	4/19	21.1	6/12	50
Follow-up score ≥ 10 (Remission)	8/11	72.7	NA	NA	10/12	83.3
Follow-up score $\leq 50\%$ pre-treatment score (Recovery)	6/11	54.5	NA	NA	7/12	58.3
GAD-7						
Baseline score < 8	10/22	45.5	9/23	39.1		
Post-treatment score < 8 (Remission)	12/16	75	5/19	26.3	9/12	75
Post-treatment score $\leq 50\%$ pre-treatment score (Recovery)	8/16	50	4/19	21.1	7/12	58.3
Follow-up score < 8 (Remission)	9/11	81.8	NA	NA	9/12	75
Follow-up score $\leq 50\%$ pre-treatment score (Recovery)	5/11	45.5	NA	NA	7/12	58.3

The ESs of the intervention in the treatment group on the change in WSAS scores from baseline to week 5 and follow-up were 0.63 and 0.66, respectively. For the wait-list control group, the ES of the change from baseline to week 5 was 0.02. The between-group ES at post-treatment is 0.36. After the control group received the intervention, the effect at post-intervention was 0.37. Across both groups, the intervention had an ES of 0.52 as compared to -0.05 for non-intervention periods. The response to treatment as compared to the response to non-intervention had an ES of 0.23.

The ESs of the intervention in the treatment group on the change in K-10 scores from baseline to week 5 and follow-up were 0.53 and 0.77, respectively. For the wait-list control group, the ES of the change from baseline to week 5 was 0.17. The between-group ES at post-treatment is 0.66. After the control group received the intervention, the effect at post-intervention was 0.46. Across both groups, the intervention had an ES of 0.49 as compared to 0.02 for non-intervention periods. The response to treatment as compared to the response to non-intervention had an ES of 0.30.

Proportion Showing Clinically Significant Change

Chi-squared analyses indicated significant differences in remission between treatment and control groups at week 5 on the PHQ-9 (Chi-squared = 4.38, $p = 0.036$) and GAD-7 (Chi-squared = 8.01, $p = 0.0046$) (**Table 3**). However, significant differences were not observed in recovery at post-treatment on the PHQ-9 (Chi-squared = 2.02, $p = 0.16$) and GAD-7 (Chi-squared = 3.13, $p = 0.08$).

Therapist Time

The mean total time spent per treatment group participant was 176.32 min (*SD* = 49.62) and this included the telephone screening interview, sending of encouragement emails as well as face-to-face sessions. The total time spent for the control group participants included the telephone screening interview, sending of reminder emails to complete questionnaires, as well as telephone calls to remind participants to complete questionnaires if they did not complete said questionnaires post-email reminders The mean total time spent per Control group was 26.15 min (*SD* = 3.70).

Treatment Satisfaction

The treatment group participants who completed the post-treatment feedback questionnaire reported a good level of satisfaction with the programme (refer to **Table 4**). When they were asked to provide a rating from 1 to 5, where 5 indicates the highest level of agreement. The treatment group participants rated that they were satisfied with the programme (*M* = 4.0, *SD* = 0.74), that the programme had helped with their low mood (M = 3.58, *SD* = 0.79), and that they were likely to use the skills that they learnt from this programme if they were to encounter depressive symptoms again (M = 4.33, *SD* = 0.89). 10 out of 12 (91.7%) of the treatment participants who completed the post-treatment feedback questionnaire reported that they felt confident in recommending this programme to a friend.

Qualitative Feedback

Three main themes on improvements to the programme were identified: (1) Therapist contact, (2) module content, and (3) module delivery.

Therapist Contact

Several participants cited a desire for more therapist contact for various reasons such as:

a) Having greater assistance in applying the skills taught from the modules, "…having more face to face sessions to support clients so that they can use the skills…effectively, as a result, the program would be more relevant and meet the clients' needs.";

TABLE 4 | Treatment satisfaction with the programme.

Measure	Very poor		Poor		Fair		Good		Very good	
	N	%	*N*	%	*N*	%	*N*	%	*N*	%
Module content	0	0	0	0	2	20	5	50	3	30
Duration of programme	0	0	0	0	5	50	3	30	2	20
Number of face-to-face sessions	0	0	1	10	3	30	2	20	4	40
Length of each face-to-face session (i.e., approximately 50 min)	0	0	0	0	3	30	3	30	4	40
Time intervals in between face-to-face sessions (i.e., meet once every 2 weeks)	0	0	0	0	2	20	5	50	3	30
Homework materials	0	0	0	0	3	30	5	50	2	20
Ease of use for online materials	0	0	0	0	1	10	2	20	7	70

b) To increase motivation for change, "…I think personally I need to be motivated/reminded/pressured more to do things, e.g., reading the online modules and putting the things into practise.";
c) Having the space to talk about their conditions and difficulties, "…sometimes, they (patients) are just too embarrassed or stressed out to talk, but maybe by asking them this (what is really bothering them), they are willing to share."
d) Allowing for customisation of CBT to their issues, "…more sessions with psychologists and some specific CBT techniques to practise".

Module Content

Several participants provided feedback or suggestions for module content:

a) Illness-specific content to include other mental illness, "…more different modules for those suffering from other mental illness such as BPD (Borderline Personality Disorder)..and anxiety".
b) Other patients' testimonies, "…include some videos testimonies or articles of people who have managed to pull through depression. In this way, participants (can) relate and be inspired to take the first step towards self-improvement".
c) Reducing homework requirements from the modules.
d) Supplementary resources, "…provide more tips and reading recommendations for further read-ups".·

Module Delivery

There was also feedback on module delivery:

a) More visual aids to improve engagement, "…use of graphics is much better than words"; "…by having more visual aid and materials, making the session more interactive").
b) Increasing the programme duration with longer intervals between face-to-face sessions, to allow for more time to complete the modules and apply the skills learned.
c) Customisable and flexible programme schedule, "…the duration of the whole programme and the time intervals in between face-to-face sessions can be adjusted according to each individual's needs or mental health condition, so that he or she can complete the iCBT programme adequately."

DISCUSSION

The present study examined the efficacy and acceptability of a hybrid iCBT programme with three face-to-face sessions for patients presenting with mild to moderate depressive symptoms in Singapore. There were significant reductions in symptoms of depression (moderate to large ESs), anxiety (moderate to large ESs), and psychological distress (moderate ESs) in response to treatment, and no significant reductions in control conditions in both per-protocol and intention-to-treat analyses. However, the between-group analysis between treatment and control groups in the initial comparison arm was only significant for the PHQ-9 (moderate ES) for the intention-to-treat analysis and comparisons between treatment and control responses were not significant.

Examining the means and individual data revealed a few contributors to the lack of significance in the comparison between treatment and controls. The between-group analysis was relatively underpowered as it did not include data from the cross-over arm. In the initial treatment group, the post-treatment follow-up was used as a control condition. However, it appeared that participants continued to improve in their symptoms during the post-treatment period. Finally, the nature of the cross-over analysis meant that participants who dropped out even in the follow-up period were not included in the per-protocol analyses and diluted effects seen in the intention-to-treat analysis. The improvements in symptoms of depression (moderate to large ESs), anxiety (large ESs), and psychological distress (moderate ESs) observed at post-treatment were sustained at follow-up. The ESs are generally consistent with the results from similar iCBT studies (Choi et al., 2012; Titov et al., 2013) and other transdiagnostic face-to-face programs (McEvoy et al., 2009).

A majority of the participants who completed the post-treatment questionnaires were satisfied with the programme. Specifically, 90 percent of participants were willing to recommend it to others, stating they were most pleased with the convenience, teaching skills, and ability to revisit the materials at their convenience. The unfamiliarity with iCBT might partly account for anecdotal reports by some participants in our study, whereby they found face-to-face sessions beneficial and preferred more of such sessions. Talking to a clinician allowed them to express their feelings and receive guidance on applying their learned techniques. This is supported by a previous survey conducted on Chinese-speaking international students in Australia which found that more respondents reported a preference for face-to-face treatments over internet treatments (Lu et al., 2013). As such, a hybrid iCBT model which includes regular face-to-face sessions may be more acceptable for certain Asian populations than solely offering only phone or email support.

The completion rates in our study were slightly lower (60.9 vs. 68%) than a similar study conducted among Chinese participants (Choi et al., 2012). One difference between the two studies is Choi's et al. (2012) study recruited volunteers from the community, whereas participants from our study were patients referred by their clinicians at a tertiary, acute mental health hospital. In addition, in terms of demographics, our sample was younger, had a smaller proportion of married individuals and was less educated than Choi's et al. (2012) participants. It has been shown that younger age, being single and lower education are associated with higher drop-out rates from psychotherapy (Fenger et al., 2011).

In light of the potential benefits of internet treatments and the general acceptability of such treatments amongst this population, the low recruitment rate (i.e., only 66 people were referred over 2 years) in this study is surprising. Given the limited application of internet treatments to Asian populations, depressed individuals in Singapore might be hesitant to participate in iCBT programs due to their unfamiliarity with what such programs entail. This finding is supported by Mitchell and Gordon (2007) study which indicates that people who do not have prior exposure to computer-based CBT, including iCBT, generally do not possess favourable attitudes towards such approaches.

LIMITATIONS

The results of the present study need to be interpreted in light of the limitations of the study, which include a relatively small sample size and high attrition rates in the completion of outcome measures over time. Additionally, the study did not conduct formal diagnostic assessments but relied on the diagnoses provided by the patients' psychiatrists and used thresholds from self-reported measures as a surrogate for clinical remission.

Nonetheless, improvements on the primary and secondary outcome measures occurred in the clinically expected direction and the analyses suggested that our findings could not be explained by biases in participants who dropped out. The treatment group and cross-over arms showed consistency in their ESs in response to treatment, providing further support for the reliability of our findings.

CONCLUSION

This current study is the first of its kind to provide preliminary evidence for the efficacy and acceptability of iCBT for depression in Singapore. In light of the ongoing Covid-19 global crisis, iCBT has assumed increasing importance as it can allow for the continual provision of mental health services when access to traditional services are disrupted (Liu et al., 2020). As other programmes have shown wider adoption across the community in other countries (Richards et al., 2015), this study provides valuable information for further development of local internet-based programmes and early groundwork for their broader adoption in Asian cultures.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation, upon request.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by National Healthcare Group, Domain-Specific Review Board ethics committee (Protocol Record 2015/00404). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

SL contributed to the design of the trial, recruitment, provision of interventions, and write-up of manuscript. HA contributed to recruitment and provision of interventions. TK contributed to recruitment, data collection and cleaning, write-up of parts of methodology, and preliminary review of manuscript. SN contributed to data cleaning and preliminary review of manuscript. TT contributed to data cleaning and review of manuscript. GT contributed to the statistical analysis and write-up of manuscript.

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SUPPLEMENTARY MATERIAL

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MINI REVIEW
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Access to Nature *via* Virtual Reality: A Mini-Review

Hansen Li[1], Xing Zhang[2], Hongying Wang[3], Zongqian Yang[1], Haowei Liu[1], Yang Cao[4,5]* and Guodong Zhang[1]*

[1] Key Laboratory of Physical Fitness Evaluation and Motor Function Monitoring of General Administration of Sports of China, Institute of Sports Science, College of Physical Education, Southwest University, Chongqing, China, [2] Department of Basketball and Volleyball, Chengdu Sport University, Chengdu, China, [3] College of Physical Education, JiMei University, Xiamen, China, [4] Clinical Epidemiology and Biostatistics, School of Medical Sciences, Örebro University, Örebro, Sweden, [5] Unit of Integrative Epidemiology, Institute of Environmental Medicine, Karolinska Institutet, Stockholm, Sweden

Nature exposure is known to promote physical and mental health. However, actual nature exposure may be difficult to achieve for the population of people with physical disabilities or chronic conditions. Therefore, many attempts have been made to duplicate nature exposure *via* media devices, and virtual reality (VR) is deemed as a promising technology due to its advantage in creating a sense of immersion. Generally, current studies suggest that being exposed to virtual nature may contribute to psychological and physiological relaxation. Besides, some pieces of evidence indicate that virtual nature may improve attentional resources, cognitive performance, and pain experience. Although VR is deemed as an advanced media, insufficient evidence was found concerning the advantages of VR over traditional two-dimensional media when it comes to simulated nature exposure. On the other hand, computer-generated (CG) scenarios were found to be more beneficial than 360° videos, and mini-games may be useful in creating an interactive VR format for simulated nature exposure. Further research is needed because of the limited relevant studies.

Keywords: nature exposure, virtual reality, mood, stress, health benefit, virtual environment

Edited by:
Cristina Costescu,
Babeş-Bolyai University, Romania

Reviewed by:
Alexis Buatois,
Pontifical Catholic University of Rio Grande do Sul, Brazil
Tomasz Maciej Rutkowski,
RIKEN Center for Advanced Intelligence Project (AIP), Japan

***Correspondence:**
Guodong Zhang
lygd777@swu.edu.cn
Yang Cao
yang.cao@oru.se

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INTRODUCTION

Being exposed to nature, including blue and green natural environments, is known to elicit a range of physical and mental health benefits (e.g., improve emotional states, reduce the risk of mental health issues, and benefit cardiovascular functions) (Gascon et al., 2015; White et al., 2021). Nowadays, various natural environments provide urban dwellers with important health resources to mitigate harmful exposures and their effects on urban living, such as pollution, attention depletion, and stressful short-term experiences (Ilies et al., 2007; Li H. et al., 2020). However, while human–nature interaction is encouraged, there is a considerable amount of people who have difficulties accessing ideal natural environments due to limited residential areas and physical conditions, especially for the elderly and patients with disabilities or chronic conditions (Browning et al., 2019). Therefore, there has been a growing interest in using virtual environments that depict nature to enhance public health (Reddon and Durante, 2018). In response, several studies aimed to duplicate nature exposure *via* traditional media, such as photos and videos (Jo et al., 2019). However, in many cases, only subtle benefits were obtained in indoor experiments, which might be due to the limited visual contact *via* traditional media (Jo et al., 2019).

On the other hand, virtual reality (VR) is an advanced media that can simulate highly realistic virtual environments, which offers a chance to deliver health benefits *via* virtual nature (Bohil et al., 2011; Mattila et al., 2020). Additionally, VR can help duplicate a sense of immersion, which is hardly realized *via* traditional two-dimensional (2D) media. According to the findings on actual nature exposure, immersing in natural surroundings may be crucial to receive environmental benefits (Antonelli et al., 2019). Therefore, VR has been deemed as a promising technology when it comes to virtual nature. However, limited studies compared VR with traditional 2D media in simulated nature exposure, which needs extra investigation.

With lower prices and being more portable than before, VR technology has become a practical method for healthcare and rehabilitation (Maggio et al., 2018; Verhoef et al., 2021; Wren et al., 2021). The main types of simulation for virtual environments are real-scene-based 360°videos and computer-generated (CG) scenarios (Yeo et al., 2020). The former can provide a more realistic view, while the latter allows for more interaction with virtual environments. Additionally, many interactive designs have been embedded in virtual environments, such as games and physical activities, which may also enhance the experience of virtual nature. However, it is yet to be concluded whether the benefits of virtual nature may vary with the simulation types and modes of VR. Therefore, we carried out the current review based on published literature to address the following questions:

1. What benefits can be derived from virtual nature?
2. Is VR a better medium than traditional media for simulated nature exposure?
3. Can virtual nature be equivalent to real nature?
4. Is there a difference between the simulation types and modes of virtual nature?

CURRENT VIRTUAL REALITY DEVICES FOR VIRTUAL NATURE

Empirically, VR is typically defined in terms of its technological hardware, including computers, head-mounted displays, headphones, and motion-sensing gloves (Steuer, 2010), which offer accessible ways to enable immersion with pleasant virtual environments (Riches et al., 2021). Currently, although multisensory VR has been developed, a head-mounted display (HMD) is still the most common device due to its convenience and affordability. Relevant studies concerning our research questions also only used HMDs to deliver visual and auditory stimuli of nature. In these studies, the virtual environments were displayed *via* 360° videos based on real scenes (360-VR) or CG images generated by computer game engines (CG-VR).

GENERAL EFFECTS OF VIRTUAL NATURE

Relaxation is the key function of virtual nature, which includes both psychological and physiological relaxation (Riches et al., 2021). These relaxation effects are usually detected via physiological indices (e.g., heart rate variability, electrodermal activity, and saliva cortisol) and self-reported questionnaires (e.g., the Positive and Negative Affect Schedule and the State-Trait Inventory) (Annerstedt et al., 2013; Anderson et al., 2017; Blum et al., 2019; Browning et al., 2019; **Figure 1**). Additionally, some studies found that virtual nature may promote restorativeness, which deals with the restoration from attention fatigue (Browning et al., 2019; Mattila et al., 2020). Such a benefit on attention restoration has been traditionally considered as a function of actual nature, especially when it comes to visual stimulation (Ratcliffe et al., 2013; Ohly et al., 2016). However, virtual nature has also been effective, which could be due to its vivid and fascinating views (Mattila et al., 2020). Moreover, there is also evidence for cognition and pain experience. Specifically, a study reported the positive effect of virtual nature on cognitive performance (Mostajeran et al., 2021), which could be related to its restorativeness (Shin, 2011). Tanja-Dijkstra et al. (2018) reported that virtual nature reduced both experienced and recollected pain during simulated pain, which is broadly in line with the recent findings on pain relief and actual nature exposure (Stanhope et al., 2020; Li et al., 2021a). Drawing from previous studies, pain relief could result from both the distraction of VR itself and the audiovisual stimuli of nature (Kline, 2009; Sil et al., 2014; Guo et al., 2015). According to the author, restorative natural stimuli could be more critical.

These benefits from virtual nature are generally consistent with those from actual nature. According to previous studies, visual and audio factors play important roles in obtaining benefits from nature exposure (Kline, 2009; Akers et al., 2012; Wooller et al., 2018; Briki and Majed, 2019). Current VR devices can deliver vivid audiovisual stimuli, and thus, create the illusion of being transported into a virtual world and facilitate presence in a restorative natural environment with the consequent psychological benefits (Smyth et al., 2015). The benefits of nature, such as restorativeness and relaxation, are also regulated by the characteristics of the environment, including environmental quality and structure (Pretty et al., 2005; Gatersleben and Andrews, 2013; Lopez-Pousa et al., 2015). The virtual environments for virtual nature are usually created based on high-quality and pleasant landscapes; thus, they may offer viewers optimized experiences and improve psychological and physiological outcomes (Mattila et al., 2020).

VIRTUAL REALITY VS. TRADITIONAL 2D MEDIA

Virtual reality is deemed as a better media than traditional 2D media in delivering audiovisual stimuli. However, there still exist some controversies on the advantages of VR technology (**Figure 1**). Specifically, two studies found that ocean views being displayed by VR resulted in a higher positive affect than their 2D counterparts (Liszio et al., 2018; Yeo et al., 2020). In contrast, Mostajeran et al. (2021) argued that exposure to a forest in VR is not as effective in reducing stress when compared with photos. Palanica et al. (2019) also reported the similar effects of

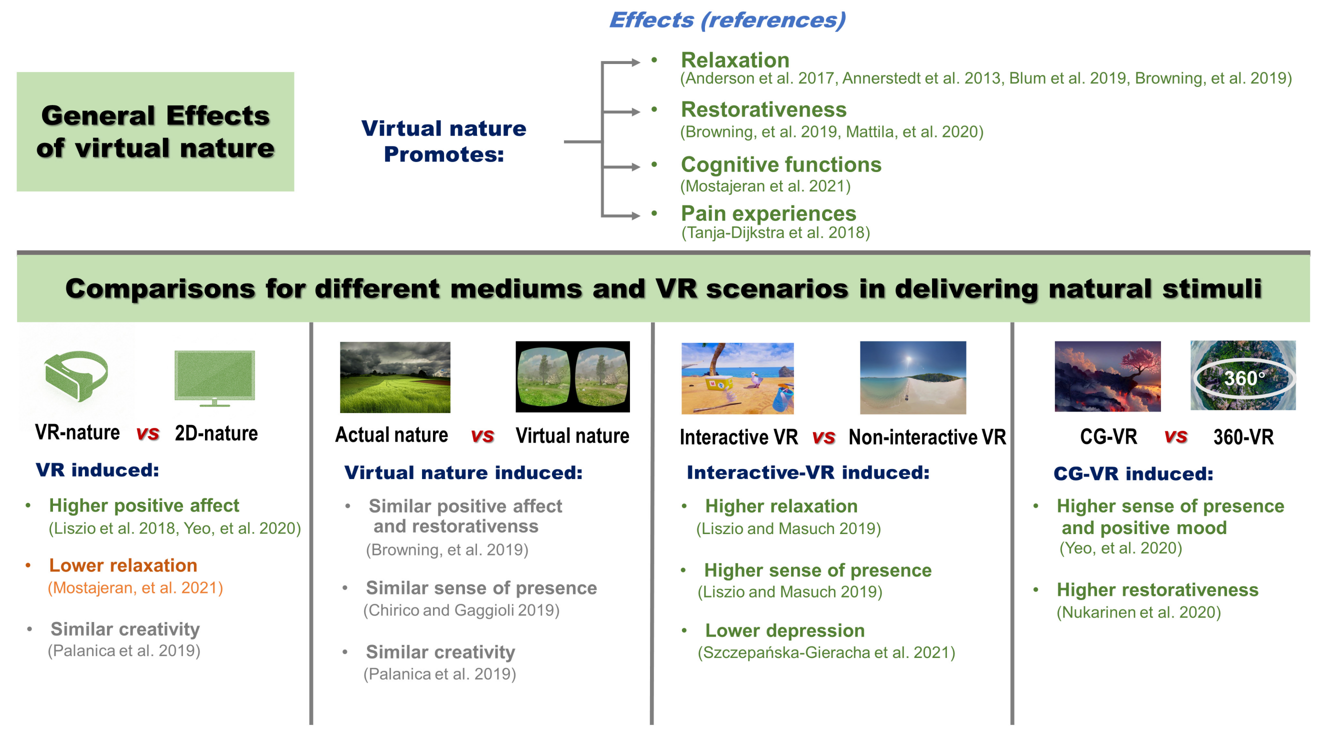

FIGURE 1 | The effects of virtual nature and comparisons for the different mediums and scenarios.

2D and VR in enhancing creativity. The inconsistent findings do not support the previous hypothesis that VR may be more effective and beneficial than traditional 2D mediums. Mostajeran et al. (2021) explained that VR may induce an intensive sense of presence, which may be positively correlated with physiological arousal, thus buffering the physiological relaxation of natural stimuli. On the other hand, such psychological and physiological responses may be associated with the properties of virtual nature. For instance, the higher stability of VR videos is found to improve the effect profile of participants and reduce fatigue (Litleskare and Calogiuri, 2019), and the brightness of VR videos may also cause impacts on stress levels during an intervention (Li C. et al., 2020). Besides, the effects may also vary with the demonstrated natural views and the corresponding audio, which may regulate the effectiveness of simulated nature exposure (Annerstedt et al., 2013; Hedblom et al., 2019b; Wang et al., 2019; Lindquist et al., 2020). Therefore, there is still a need to identify beneficial stimuli to optimize the experience of virtual nature.

VIRTUAL NATURE VS. ACTUAL NATURE

Relevant studies generally suggested that VR induced nearly equivalent psychological and physiological benefits as real nature (**Figure 1**). Browning et al. (2019) reported that both virtual nature and actual nature induced similar positive affect and restorativeness. The two other studies further supplemented that a sense of presence and creative thinking were not significantly different between actual and virtual nature (Chirico and Gaggioli, 2019; Palanica et al., 2019). These studies indicate the comparable benefits of exposure to virtual nature and actual nature, which could be due to the vivid audiovisual stimuli discussed above. However, it is not clear why other known beneficial environmental factors did not cause potential differences. For instance, exposure to sunlight, environmental microbiomes, and negative air ions generated by plants were reported to improve emotional outcomes, but these factors are absent in virtual nature (Stanhope et al., 2020). According to Mattila et al. (2020), the absence of other sensory stimuli may make the participants focus on the content of the application, and thus improve psychological outcomes. Additionally, due to the lack of physical engagement, such as walking and contact with things in nature, the brain may process information differently from reality, resulting in some environmental factors being masked or ignored (Taube et al., 2013). Given the limited number of studies that made direct comparisons between the virtual and actual, the differences between the two types of nature exposure still need to be re-examined in the future.

INTERACTIVE VIRTUAL REALITY VS. NON-INTERACTIVE VIRTUAL REALITY

Interactive VR is deemed as a more interesting and motivating tool to promote the engagement of subjects in rehabilitation therapy (Choi and Paik, 2018). Liszio and Masuch (2019) designed two mini-games (throwing a coconut and flower watering) at a virtual beach and found that interactive VR elicited a higher sense of spatial presence and led to a higher heart rate variability level, indicating better physiological relaxation. Likewise, Szczepańska-Gieracha et al. (2021) designed a 4-week VR treatment containing interactive games (simulated plant watering and a coloring task) and observed reduced depression in an elderly population, which brings a practical indication of using virtual nature to improve the health of this special population. However, another study using an active VR intervention failed to identify its advantage over a normal VR experience (Tanja-Dijkstra et al., 2018). This might be due to the different designs of interactivity, for the former two studies used mini-games, while Tanja-Dijkstra et al. (2018) used a controller for participants to manipulate the virtual environment, which might demand less attention, and thus, less engagement. According to existing evidence, the game design could be relevant to the health benefits of interactive VR.

360-VR VS. CG-VR

Two formats were used to express virtual nature in the relevant studies, namely, 360° videos and CG scenarios. However, only two studies investigated the difference between the two forms (**Figure 1**). Yeo et al. (2020) reported that CG-VR induced a significantly greater sense of presence and positive mood than 360-VR, but boredom remained similar in the two conditions. However, although Yeo et al. (2020) have demonstrated similar views on the marine world in both conditions, the images are not completely consistent. To make a fair comparison, Nukarinen et al. (2020) constructed a CG scenario and made a 360-VR based on the same view of actual nature. Nukarinen et al. (2020) reported that the CG-VR was more emotionally restorative than the 360-VR, which showed the advantage of CG-VR over 360-VR in simulated nature exposure.

LIMITATIONS OF VIRTUAL NATURE

Though VR is an advanced form of media to access nature, the general VR applications rely on audiovisual stimuli and do not exploit the addition of other sensory stimuli (Melo et al., 2020). Recent evidence indicates that VR with multisensory stimuli may elicit a positive impact on users (Melo et al., 2020). However, only a few studies employed multisensory VR to focus on the effects of virtual nature, and only the olfactory stimulus was considered, while other popular sensory stimuli such as haptics were not included (Hedblom et al., 2019a; Sabiniewicz et al., 2021). According to Hedblom et al. (2019a), the olfactory stimuli of nature may be better at decreasing stress than visual stimuli, which could be related to the odor of trees (Ikei et al., 2015). However, due to limited devices (HMD only), none of the multisensory VR applications has been adopted in the studies concerning our research questions.

On the other hand, cybersickness is a known problem of VR experience, but it received insufficient concern (Martirosov et al., 2021). Only two studies concerning our research questions investigated the conditions of cybersickness (Liszio and Masuch, 2019; Mostajeran et al., 2021), but no method was adopted to avoid this issue, and the effects of cybersickness were not investigated either. Therefore, it is still unclear whether the benefits of virtual nature can be reduced by negative symptoms and the extent of their effect. Also, it cannot be determined whether the different levels of immersion or types of environments play a role in inducing cybersickness. These uncertainties will bring difficulties in generalizing the known benefits of virtual nature to the public (Mostajeran et al., 2021). According to Litleskare and Calogiuri (2019), increasing the stability of the camera may reduce the symptoms of cybersickness in virtual nature, which should be considered in future studies.

DIRECTION FOR FUTURE STUDY

Application of Virtual Nature

Virtual nature is deemed as a potential method for relaxation (Riches et al., 2021). Theoretically, patients and the elderly are most likely to benefit from the technology due to the inconvenience of physical activity. However, the current studies mainly aimed to explore the effects of virtual nature, without paying much attention to special populations. For instance, only two studies concerning our research questions focused on patients and the elderly (Lakhani et al., 2020; Szczepańska-Gieracha et al., 2021). Therefore, future studies need to involve more special populations, such as people who are quarantined due to COVID-19, to explore more practical and useful interventions. Additionally, as most studies are concentrated on the acute effects of simulated nature exposure, long-term interventions are needed to check if virtual nature can be beneficial without the sense of novelty (Riches et al., 2021).

Simulated Green Exercise

Green exercise is a concept of nature-based exercise referring to exercises carried out in natural environments, which aims for the combined health benefits of nature exposure and physical activities (Mnich et al., 2019). Due to the known health and training benefits of green exercise, many attempts have been made to replicate green exercise *via* media, and evidence indicates that a simulated natural environment may help reduce perceived exertion and provide a smooth exercise experience (Akers et al., 2012; Li et al., 2021b). As a technology that creates a better sense of immersion, VR is reported to have positive effects on the presence and perceived environmental restorativeness during a simulated nature walk, which is equivalent to the actual nature walk counterpart (Calogiuri et al., 2017). However, no benefit in mood was found during high-intensity interval cycling while viewing a virtual natural scene, indicating that the benefits of simulated green exercise may vary with the measured dimension and the type of exercise (Alkahtani et al., 2019). Some studies have revealed the effects of VR on enhancing exercise experience and training outcomes (Cho et al., 2016; Wender et al., 2019; Qian et al., 2020). However, the role of the demonstrated virtual environment received less attention, and the benefits of simulated green exercise need to be investigated further.

Blue vs. Green Virtual Environment

The virtual natural environments demonstrated in the relevant studies contained both blue and green environments (see **Supplementary Table 1**). A recent study has implied the difference between actual green and blue environments (White et al., 2021). According to Wang et al. (2019), the corresponding responses may also vary with the type of virtual environment. Although considerable studies have focused on the differences between virtual nature and a virtual urban environment (Valtchanov and Ellard, 2010; Yu et al., 2018; Palanica et al., 2019; Mostajeran et al., 2021), there is a lack of understanding of the difference between green and blue virtual natural environments, which remains a topic for future studies.

CONCLUSION

The current review summarized the benefits and effectiveness of nature exposure *via* VR technology. The existing evidence generally supports that virtual nature may induce a relaxation effect and also benefit attentional resources, cognitive performance, and pain experience. Game designs may be useful in creating interactive VR scenarios that may improve the virtual experience. Additionally, CG scenarios may be more effective than 360° videos in inducing the psychological benefits of virtual nature. These findings indicate the potential role of simulating nature exposure in health promotion in urban and certain special populations. According to the interests of relevant research fields, the application of virtual nature, simulated green exercise, and diverse virtual natural environments may be topics for further study.

AUTHOR CONTRIBUTIONS

HSL wrote the manuscript. ZY, XZ, HW, and HWL revised the manuscript. YC and GZ supervised the project and amended the final version of the manuscript. All authors contributed to the article and approved the submitted version.

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BRIEF RESEARCH REPORT
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Investigating the Persuasive Effects of Testimonials on the Acceptance of Digital Stress Management Trainings Among University Students and Underlying Mechanisms: A Randomized Controlled Trial

Jennifer Apolinário-Hagen[1]*, Lara Fritsche[2], Jeannette Wopperer[3], Frank Wals[3], Mathias Harrer[4], Dirk Lehr[5], David D. Ebert[6] and Christel Salewski[2]

[1]Institute of Occupational, Social and Environmental Medicine, Centre of Health and Society, Faculty of Medicine, Heinrich Heine University Düsseldorf, Düsseldorf, Germany, [2]Department of Health Psychology, Faculty of Psychology, University of Hagen, Hagen, Germany, [3]Faculty of Psychology, University of Hagen, Hagen, Germany, [4]Department of Clinical Psychology and Psychotherapy, Friedrich-Alexander-University Erlangen-Nuremberg, Erlangen, Germany, [5]Department of Health Psychology and Applied Biological Psychology, Institute of Psychology, Leuphana University Lueneburg, Lueneburg, Germany, [6]Department of Sport and Health Sciences, Technical University of Munich, Munich, Germany

Objective: This experiment aims to investigate the influence of narrative information varying in the degree of perceived similarity and source credibility in supplemented testimonials on the acceptance of digital mental health services (digi-MHSs).

Methods: In fall 2020, $n = 231$ university students were randomly assigned to an active control group (aCG, $n = 55$, "information only") or one of three intervention groups (IGs) receiving information plus different testimonials being presented either by nonacademic staff (IG1, $n = 60$), university students (IG2, $n = 58$) or experts (IG3, $n = 58$). We assessed mediation effects of similarity and credibility on acceptance in terms of attitudes and usage intentions.

Results: Exposure to testimonials was associated with higher usage intentions ($d = 0.50$) and more positive attitudes toward digi-MHSs ($d = 0.32$) compared to mere information (aCG). Regarding source-related effects, one-way ANOVA showed group differences in intentions ($\eta_p^2 = 0.13$) that were significantly higher after exposure to testimonials targeted at students than in the other groups after adjusting for baseline intentions ($\eta_p^2 = 0.24$). Concerning underlying mechanisms, there were full mediation effects of similarity (IG1 versus IG2) on attitudes [95%CI (0.030, 0.441)] and intentions to use digi-MHSs [95%CI (0.100, 0.528)] and of credibility on attitudes [IG2 versus IG3; 95%CI (−0.217, −0.004)], all favoring students' testimonials.

Conclusion: Overall, this study indicates that the acceptance of digi-MHSs can be substantially increased by providing a simple, context-sensitive information intervention, including testimonials by university students. Since we identified mediating effects of

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Christine Rummel-Kluge,
Leipzig University,
Germany
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Heidelberg University Hospital,
Germany

****Correspondence:***
Jennifer Apolinário-Hagen
jennifer.apolinario.hagen@hhu.de

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credibility on cognitive attitudes and similarity on affect-driven intentions, a future trial could vary these features using narrative versus statistic information on digi-MHSs.

Keywords: eHealth, mental health, stress, attitude, intention, students, personal narratives

INTRODUCTION

Mental health promotion for college and university students has become a central topic on the international research and health policy agenda in recent years, given the increasing prevalence for psychological problems in this population (Cuijpers et al., 2019). Still, there is an immense discrepancy between the supposed need and actual uptake of mental health services by students worldwide (Auerbach et al., 2018). Moreover, since the onset of the Covid-19 pandemic, university students have been found to experience further psychosocial strain and help-seeking barriers (Benjet, 2020; Davenport et al., 2020; Kohls et al., 2021). Digital mental health services (digi-MHSs) provide additional options to increase the availability of health promotion and treatment offers (van Daele et al., 2020). In general, digi-MHSs include a broad range of interventions differing in theory base [e.g., internet-delivered cognitive behavioral therapy (iCBT)], application fields (e.g., stepped care), guidance (e.g., asynchronous feedback), and technical implementation (e.g., virtual reality; Ebert et al., 2019). To date, solid evidence exists for the efficacy of digi-MHSs for improving subjective wellbeing or coping with stress, anxiety, and depression across student populations (Harrer et al., 2018; Lattie et al., 2019). As an example, online stress management trainings have been demonstrated to be efficacious for distressed to moderately depressed traditional and nontraditional university students facing multiple challenges, like study-work-family-conflicts (Harrer et al., 2021).

Interestingly, research indicated a higher acceptance of digi-MHSs among university students with personal use experience, but the utilization rates of existing digital interventions remain very low (Dunbar et al., 2018; Hadler et al., 2021; Lavergne and Kennedy, 2021). Potentially, suitable digi-MHSs are yet not well known and thus seldom used by university students despite overall positive attitudes (Mayer et al., 2019; Apolinário-Hagen et al., 2021). Although many university students appear ready to use digital health solutions, they still report difficulties in finding reliable information online (Machleid et al., 2020; Dadaczynski et al., 2021). Accordingly, the willingness to use digital media for mental health purposes depends on appropriate, easy accessible information regarding core requirements, like data security (Montagni et al., 2020). Uncertainties grounded on limited or conflicting information, besides unmet preferences, may thus impede the adoption of evidence-based psychological services (Cunningham et al., 2014, 2017).

Recent research suggests that tailored fact-based psychoeducational information can help increase intentions to use mental health services among university students (Ebert et al., 2018). Under "real world" conditions, consumer choices are oftentimes based on the opinions, anecdotes, or recommendations from trustworthy sources. Hence, a commonly applied practice is to make use of the supposed impact of user reviews, including star ratings, quality claims, and expert statements, especially in order to advertise commercial mental health apps (Apolinário-Hagen et al., 2018a; Larsen et al., 2019). Narrative messages can facilitate experience-based heuristic decisions, based on rules of thumb or practical examples. Simple heuristics are particularly useful in pragmatic decisions in new situations in daily life (e.g., reducing complexity, dealing with limited information; Gigerenzer and Gaissmaier, 2011).

Consequently, dual-processing models, like the *Elaboration Likelihood Model* (Petty et al., 2009) and the *Heuristic-Systematic Model* (Chaiken, 1980), propose two main pathways of persuasion or attitude change (analytical versus heuristic) that depend on the individual ability and motivation to process health messages as well as various contextual factors. To date, though, knowledge on the specific influence of different features of mental health information, especially of those being related to the context (e.g., expert heuristics, reputation) instead of the content (e.g., facts like duration, themes), is limited and inconclusive. Most research on health-related testimonials has dealt with prevention and treatment choices regarding somatic disorders and yielded mixed findings on the benefits of statistical over narrative information, like testimonials (e.g., Zebregs et al., 2015; Perrier and Martin Ginis, 2017). Among message recipients without own experience with mental health interventions, testimonials by past users may be more influential on hypothetical treatment choices than among recipients with first-hand treatment experience (Pruitt et al., 2012). In addition, it may be possible that educational material combining fact-based statistical information with testimonials can improve attitudes toward digi-MHSs such as iCBT among both concerned and unconcerned people (Soucy et al., 2016).

Regarding variables related to attitude change, perceived similarity between testimonial sources and oneself as well as source credibility have been identified as persuasive factors across various health communication fields (Green and Clark, 2013; Shen et al., 2015; Shaffer et al., 2018). Medical students, for instance, have been shown to prefer digital interventions that are tailored to students and approved by trustworthy academic sources (Dederichs et al., 2021). Accordingly, testimonials on digi-MHSs may represent a simple way to facilitate their acceptance among university students as they are seldom familiar with such offers and may thus likely be affected by heuristics based on perceived similarity or source credibility (Quintero Johnson et al., 2017, 2021).

Abbreviations: aCG, active control group (information only); APOI, attitudes toward psychological online interventions (questionnaire); digi-MHSs, digital mental health services; ETAM, e-therapy attitude measure; IG, intervention group (receiving information plus testimonials); PSS, perceived stress scale; PU, perceived usefulness (attitude short scale); RQ, research question; TPB, theory of planned behavior; UTAUT, unified theory of acceptance and use of technology.

Taken together, little is known about the usefulness of testimonials as a widely applied marketing tool to promote the acceptance of digi-MHSs among university students as well as mechanisms underlying testimonial effects, which could help tailor health messages.

Objectives

This study aimed to investigate the influence of information varying in the degree of supposed similarity of narrators with oneself and source credibility of testimonials compared to mere information on the acceptance of digi-MHSs (in terms of attitudes and intentions) among university students. Another purpose was to explore whether perceived similarity and source credibility mediate the influence of testimonials on the acceptance of digi-MHSs, like digital stress management trainings. In view of the inconclusive evidence of testimonials effects, we postulate three research questions (RQs).

> **RQ1:** *Is there an added value of testimonials as a supplement to neutral information compared to mere information regarding the acceptance of digi-MHSs among university students?*

We assumed positive influences on (RQ1a) attitudes and (RQ1b) intentions to use digi-MHSs among university students after the exposure to information augmented with testimonials compared to information only.

> **RQ2:** *Are there differences in students' acceptance of digi-MHSs following information varying in source credibility and perceived similarity?*

We explored differences in (RQ2a) attitudes and (RQ2b) intentions based on the exposure to testimonials from different sources (i.e., employees working outside of academia versus university students versus qualified academic experts). We supposed a higher influence of university students' and experts' testimonials compared to nonacademic staff testimonials and information only.

> **RQ3:** *Do perceived similarity and source credibility mediate the effects of different testimonial sources on students' acceptance of digi-MHSs?*

Concerning mechanisms underlying testimonial effects, we explored mediation effects of (RQ3a) perceived similarity with oneself and (RQ3b) source credibility on students' attitudes and intentions.

MATERIALS AND METHODS

Study Design and Interventions

In a randomized controlled trial with four parallel information groups (study arms), we assessed differentiated effects of brief, written testimonials in addition to text-based information on attitudes and intentions to use digi-MHSs, as shown in **Figure 1**.

The anonymously conducted survey-based online experiment was designed based on previous work (Apolinário-Hagen et al., 2018a, 2021). Using a computer-based algorithm (balanced, 1:1:1:1) implemented in the online survey tool *Unipark* (Questback), participants were randomly assigned to an active control condition (aCG = "information only") or to one of three narrative intervention groups (IGs). The IGs involved information differing in supplemented fictitious testimonials that were either presented by staff outside of academia (IG1), university students (IG2), or academic experts (IG3) in order to vary similarity to students (IG2 versus IG1 and IG3) and credibility (IG3 versus IG2 and IG1). All participants received the same general information on digi-MHSs, while the IGs additionally received three text-based testimonials that were constructed in orientation to real-world examples, theoretical considerations and pretested stimulus material. The complete contents of the interventions are shown in **Supplementary Material 1**. In contrast to the pilot studies (e.g., Apolinário-Hagen et al., 2021), we did not include brands of existing digi-MHSs, albeit the described service was based on an evidence-based, guided digital stress management training (Ebert et al., 2016; Harrer et al., 2021). Moreover, the revised study material was designed more consistently and less detailed (e.g., exclusively scoping on stress prevention, missing age of testimonial sources) while trying to achieve external validity (e.g., emulating existing testimonials, experts as additional source).

The valence of testimonials was positive, focused on advantages (personal experience in IG1 and IG2, third-party: IG3), and the intended effect was persuasion (c.f., Shaffer and Zikmund-Fisher, 2013). All testimonials were fictional in order to control for contextual factors related to varying knowledge and popularity of experts. The online survey was pretested with $n = 10$ university students. The average completion time was between 12 and 17 min. This study was approved by the ethic committee of the University of Hagen, Faculty of Psychology, Germany (EA_278_2020).

Sample and Recruitment

Inclusion criteria were self-reported student status, age of at least 18 years, and provided consent (click-to-agree). Data were collected online between September 3, 2020 and October 3, 2020 using *Unipark*. German-speaking participants were recruited using the *virtual lab* and *Moodle* groups of the University of Hagen as Germany's only state distance-learning university, social media (e.g., *Facebook*), flyers with QR code distributed across different German universities and emails (e.g., student representatives). Psychology undergraduate students could receive study credits, while all completers had the chance to win book vouchers. Regarding the required sample size, *a priori* power analyses using G*Power (Faul et al., 2007) indicated $n = 170$ for RQ1 [two-tailed independent-sample t-test, unequal group ratio 3:1, moderate effect size ($d = 0.5$), power = 0.8] and $n = 180$ for RQ2 [one-way ANOVA, power = 0.80, alpha = 0.05, moderate effect ($f^2 = 0.0.25$)], respectively.

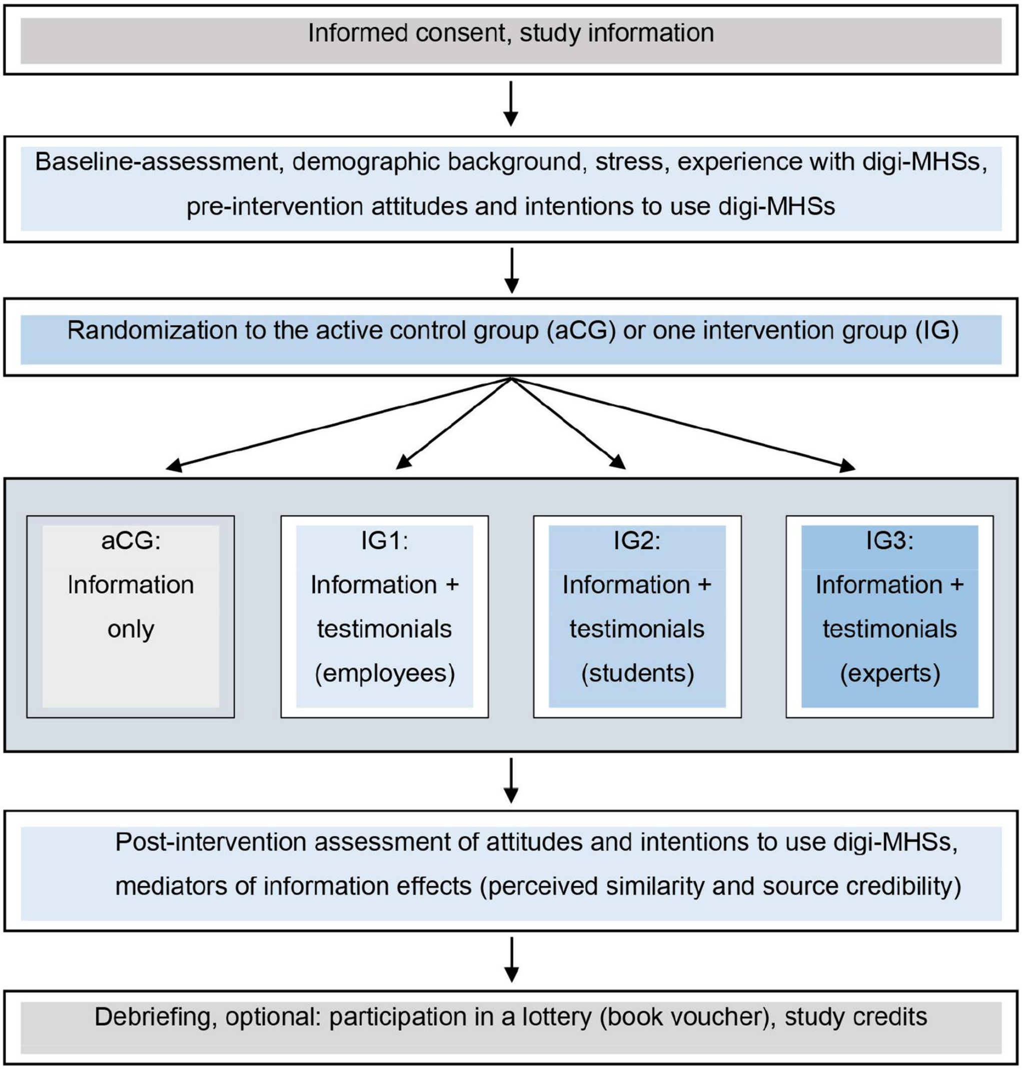

FIGURE 1 | Study flow chart. Procedure of the online experiment comparing attitudes and intentions to use digital mental health interventions (digi-MHSs) between three narrative intervention groups (IGs) receiving information plus various testimonials and the active control group (aCG) receiving information only.

Measures and Procedure

The survey consisted of three main parts: (1) baseline, (2) intervention, and (3) post-intervention assessment. Different validated and pre-tested self-constructed scales were used for assessing information effects on the acceptance of digi-MHSs, as illustrated in **Table 1**.

At baseline, participants were asked to answer few background questions (e.g., age, gender, study model, and experience with digi-MHSs). Next, baseline attitudes and intentions regarding digi-MHSs were measured using three items each on a response scale ranging from 1 ("fully disagree") to 7 ("fully agree"). Specifically, we assessed behavioral intentions based on the *Unified Theory of Acceptance and Use of Technology* (UTAUT; Venkatesh et al., 2003) using a German adaptation (Hennemann et al., 2016), while the attitude short scale emphasizing perceived usefulness (PU) was grounded on the *Theory of Planned Behavior* (TPB; Ajzen, 1991) and pretested in previous work (Apolinário-Hagen et al., 2021). Perceived stress in the past 2 weeks was measured with the validated 10-items German version of the *Perceived Stress Scale* (PSS-10; Klein et al., 2016) on a Likert scale ranging from 1 ("never") to 5 ("very often"; adapted scale sum range: 10–50).

Next, participants were automatically randomized to one of four information groups, either the aCG ("information only") or one of three IGs: IG1 (employees), IG2 (university students), or IG3 (experts), each receiving different additional testimonials on an online stress management training, as documented in **Supplementary Material 1**.

At post-intervention, we assessed the mediators perceived similarity (five items, IGs only) and source credibility (three items, all four groups) in line with a pilot trial (Apolinário-Hagen et al., 2021). Attitudes and intentions were measured again with the short scales described above. To extend the scope to further digi-MHS applications, attitudes toward

TABLE 1 | Constructs and psychometric data on the measured variables.

Construct/scale	Items	Min.	Max.	*Mean*	*SD*	Cronbach's α
Baseline/pre-intervention						
Intentions (UTAUT, pre)[a]	3	1.33	7.00	4.53	1.01	0.67
Attitude (PU, pre)[a]	3	2.00	7.00	5.23	0.91	0.85
Perceived stress (PSS-10), mean (sum score)[a]	10	1.10 (11)	4.60 (46)	2.75 (27.41)	0.68 (6.82)	0.89
Post-intervention						
Source credibility[a]	3	2.00	7.00	5.25	0.96	0.76
Perceived similarity[b]	5	1.00	7.00	4.21	1.19	0.88
Intentions (UTAUT, post)[a]	3	1.00	7.00	4.72	1.15	0.73
Attitude (PU, post)[a]	3	1.33	7.00	5.38	0.91	0.86
Attitude, clients (APOI)[a]	16	1.88	4.31	3.18	0.52	0.82
Attitude, public (ETAM)[a]	17	1.29	5.00	3.16	0.57	0.87

[a] *N = 231 (full sample, four groups).*

[b] *n = 176 (intervention groups only, three groups).*

Min., minimum; Max., maximum; SD, standard deviation; APOI, Attitudes toward Psychological Online Interventions (attitudes toward online interventions such as online therapies by clients; clinical context); ETAM, E-Therapy Measure (public attitudes toward online psychotherapy); post, post-intervention assessment; PSS-10, Perceived Stress Scale, 10 items (adapted scale range: 1–5); PU, perceived usefulness; UTAUT, Unified Theory of Acceptance and Use of Technology.

online psychotherapies were assessed on a Likert scale with 1 ("fully disagree") to 5 ("fully agree") using the scales *Attitudes to Psychological Online Interventions* (APOI; Schröder et al., 2015) with 16 items (eight inverted items) and the *E-Therapy Attitude Measure* (ETAM; Apolinário-Hagen et al., 2018b) with 17 items. Finally, all participants were debriefed.

Statistical Analyses

Collected data were extracted from *Unipark*, if marked as completed or screened out. Data handling was done in accordance with a pilot trial (Apolinário-Hagen et al., 2021), as documented in **Figure S1** in the **Supplementary Material 2**. Imputation by mean was performed in case of few missing values (e.g., one missing value in the ETAM). Research questions were tested on an alpha level of 0.05 (two-fold) using IBM-SPSS, version 26.

We conducted independent two-sample *t*-tests to compare the aCG with the IGs (RQ1) in attitudes and intentions at post-intervention (added value of testimonials, coding: aCG = 0, IGs = 1). Furthermore, we performed one-way ANOVA to determine differences in attitudes and intentions between the four study arms (RQ2; differentiated effects of testimonial sources) at post-intervention, including *post-hoc* tests (Bonferroni, multiple comparisons) and the adjustment of baseline values (ANCOVA for sensitivity analyses). Effect sizes were classified according to social sciences' conventions (Cohen, 1988).

Mediation analyses (RQ3) were performed using the *PROCESS* macro for SPSS by Hayes, version 3.4 (Hayes, 2018), with source credibility and perceived similarity as mediators, testimonial type [dummy-coding: IG1 versus IG2 (IG1 = 0, IG2 = 1), IG2 versus IG3 (IG2 = 0, IG3 = 1), IG1 versus IG3 (IG1 = 0, IG3 = 1)] as independent and attitudes as well as intentions as dependent variables (5,000 bootstrapping samples).

RESULTS

Participant Characteristics

Out of *n* = 231 included university students, *n* = 55 were randomly assigned to the aCG, while the other were additionally presented either with testimonials by employees (IG1, *n* = 60), university students (IG2, *n* = 58), or experts (IG3, *n* = 58). The median age was 29 years (*Mean* = 32.02, *SD* = 10.5, range 18–62 years). Most (85.3%) were women (14.3% men, 0.4% other). Recruitment sources were 58.9% the University of Hagen (e.g., *virtual lab*), 22.9% *via* Facebook and 18.2% *via* other options.

With 46.3%, the majority reported the general university entrance qualification as highest educational attainment, followed by 26.0% with a bachelor's degree, 15.6% with a master's degree, and 12.1% with other qualifications. Most (66.2%) indicated distance learning university as study model, while 26.9% were enrolled in a traditional university and 6.5% in both study models simultaneously (other: 0.4%). Sixty-one percent (*n* = 141) studied full-time and 39.0% (*n* = 90) in part-time.

Descriptive and Ancillary Analyses

Regarding awareness, 26.8% (*n* = 62) of the sample reported to have heard about digi-MHSs ["no": *n* = 155 (67.1%); "not sure": *n* = 14 (6.1%)], while 7.8% (*n* = 18) stated to have obtained more information on specific digi-MHSs and 4.8% (*n* = 11) indicated respective experience.

Table 1 shows psychometric data of the assessed scales. Descriptive data differentiated by experimental group and ancillary analyses can be found in the **Supplementary Material 2**. For instance, perceived stress was moderately high according the *PSS-10*, but only weakly correlated with intentions ($r = 0.159$, $p = 0.015$) and attitudes (*ETAM*; $r = 0.161$, $p = 0.014$) at post-intervention.

Main Outcomes on Group Differences

RQ1: Benefits of Adding Testimonials to Information

RQ1a: Regarding attitudes, as measured with the short scale, we found a significant difference [$t_{(229)} = -2.06$, $p = 0.041$], with less favorable attitudes in the aCG ($Mean = 5.16$, $SD = 0.99$, $n = 55$) compared to the IGs ($Mean = 5.45$, $SD = 0.87$, $n = 176$), $d = 0.32$. In contrast, we found no differences in attitudes toward online therapies according to the *APOI* [$t_{(229)} = 0.20$, $p = 0.839$] and *ETAM* [$t_{(229)} = -1.05$, $p = 0.296$].

RQ1b: Intentions to use digi-MHSs were significantly lower in the aCG ($Mean = 4.29$, $SD = 1.15$, $n = 55$) than in the IGs ($Mean = 4.86$, $SD = 1.12$, n = 176) at post-intervention, $t_{(229)} = -3.26$, $p = 0.001$, $d = 0.50$.

RQ2: Differences Between Information Sources

RQ2a: Regarding attitudes, we found no significant differences between the study arms, as measured by the short scale at post-intervention [one-way ANOVA, $F_{(3, 227)} = 2.23$, $p = 0.086$] regarding digi-MHSs for health promotion [after adjusting for baseline attitude: $F_{(3, 226)} = 1.27$, $p = 0.285$, $\eta_p^2 = 0.017$], and online therapies according to the *APOI* [$F_{(3, 227)} = 1.51$, $p = 0.213$] and *ETAM* [$F_{(3, 227)} = 1.29$, $p = 0.279$].

RQ2b: One-way ANOVA demonstrated differences in intentions to use digi-MHSs between the study arms before [$F_{(3,227)} = 11.48$, $p < 0.001$, $\eta_p^2 = 0.13$] and after adjusting for baseline intentions [ANCOVA, $F_{(3, 226)} = 23.92$, $p < 0.001$, $\eta_p^2 = 0.24$].

As shown in **Table 2**, Bonferroni-adjusted *post-hoc* tests of the ANCOVA revealed higher intentions to use digi-MHSs only after exposure to students' testimonials ($ps < 0.001$).

RQ3: Mediation Effects

RQ3a: Perceived Similarity

As shown in **Table 3**, perceived similarity fully mediated the effect of testimonials for students (IG1) versus employees (IG2) on intention to use [indirect effect = 0.289, 95% CI (0.100, 0.528)], as well as on attitudes toward digi-MHSs [indirect effect = 0.212, 95% CI (0.030, 0.441)].

In addition, there was a partial mediation for perceived similarity in IG3 versus IG2 [indirect effect = −0.364, 95% CI (−0.651, −0.101)], with higher intentions in case of greater similarity following the exposure to testimonials by students compared to experts.

RQ3b: Source Credibility

Source credibility fully mediated the influence of students' testimonials on attitudes in comparison to expert testimonials [IG2 versus IG3, indirect effect = −0.103, 95% CI (−0.217, −0.004)]. There was no mediation effect of source credibility, neither on attitudes in comparison of IG1 versus IG3 (staff versus expert) nor on intentions.

DISCUSSION

This study aimed to explore the influence of testimonials on the acceptance of digi-MHS among university students as well as mediation effects.

RQ1: Added Value of Testimonials

Concerning the efficacy of narrative interventions, our analyses showed that the exposure to testimonials in addition to written information was associated with higher intentions to use ($d = 0.50$) and more positive attitudes toward digi-MHSs for stress prevention ($d = 0.32$), compared to mere information.

TABLE 2 | Differences between the experimental groups in intentions to use digital mental health interventions at post-intervention after adjusting for baseline intentions (multiple comparisons).

					95% CI	
(I)	**(J)**	**Δ *M* (I-J)**	***SD***	***p***	***LL***	***UL***
aCG (control)	IG1	−0.143	0.124	1.00	−0.474	0.188
	IG2	−0.903***	0.124	<0.001	−1.233	−0.573
	IG3	−0.047	0.124	1.00	−0.377	0.282
IG1 (staff)	aCG	0.143	0.124	1.00	−0.188	0.474
	IG2	−0.760***	0.122	<0.001	−1.084	−0.436
	IG3	0.096	0.122	1.00	−0.230	0.422
IG2 (student)	aCG	0.903***	0.124	<0.001	0.573	1.233
	IG1	0.760***	0.122	<0.001	0.436	1.084
	IG3	0.856***	0.122	<0.001	0.530	1.181
IG3 (expert)	aCG	0.047	0.124	1.00	−0.282	0.377
	IG1	−0.096	0.122	1.00	−0.422	0.230
	IG2	−0.856***	0.122	<0.001	−1.181	−0.530

$^{***}p < 0.001$.

N = 231. Post-hoc tests with Bonferroni adjustment, dependent variable: intentions to use digital mental health services (digi-MHSs) for stress management purposes, independent variable: study group (information intervention), covariate: baseline intentions. Δ M, Mean difference; SD, Standard deviation; 95% CI, 95% confidence interval; LL, lower limits; UL, upper limits. Abbreviations (study arms): aCG, active control group ("information only"); IG, narrative intervention group (IG); IG1, information plus testimonials by unspecified staff; IG2, information plus testimonials by university students; IG3, information plus testimonials by experts.

TABLE 3 | Mediation analyses on the influence of narrative intervention type on acceptance.

IV	**DV**	**Mediator**	***a***	***b***	***ab***	**Indirect effect**		***c′***	**Direct effect**	
						95% CI$_{ab}$		***X-Y***	**95% CI$_{c'}$**	
X	***Y***	***M***	***X-M***	***M-Y***	***X-M-Y***	***LL***	***UL***		***LL***	***UL***
IG1-IG2	Intention	Similarity	0.933***	0.310***	0.289	0.100	0.528+	0.232	−0.0164	0.629
		Credibility	0.009	0.259*	0.002	−0.070	0.068	0.232	−0.164	0.629
	Attitude	Similarity	0.933***	0.205**	0.212	0.030	0.441+	−0.121	−0.439	0.197
		Credibility	0.009	0.392***	0.004	−0.131	0.135	−0.121	−0.439	0.197
IG1-IG3	Intention	Similarity	−0.164	0.353***	−0.058	−0.214	0.094	−0.304	−0.648	0.040
		Credibility	−0.330	0.280**	−0.070	−0.189	0.006	−0.304	−0.648	0.040
	Attitude	Similarity	−0.164	0.218**	−0.029	−0.113	0.055	−0.093	−0.401	0.215
		Credibility	−0.330	0.290***	−0.096	−0.225	0.007	−0.093	−0.401	0.215
IG3-IG2	Intention	Similarity	−1.10***	0.332**	−0.364	−0.651	−0.101+	−0.534	−0.956	−0.113
		Credibility	−0.340*	0.163	−0.055	−0.170	0.026	−0.534	−0.956	−0.113
	Attitude	Similarity	−1.10***	0.095	−0.104	−0.249	0.023	−0.223	−0.336	0.291
		Credibility	−0.340*	0.304***	−0.103	−0.217	−0.004+	−0.223	−0.336	0.291

**p < 0.05, **p < 0.01, ***p < 0.001.*

a = effect of X (IV, independent variable, intervention) on M (mediator), b = effect of the mediator M on Y (DV, dependent variable; attitude or intentions in terms of acceptance), ab = indirect effect via the mediator M, c′ = direct effect of X (IV) on Y (DV); 95% CI, 95% confidence interval; LL, lower limits; UL, upper limits; + means that the confidence interval of the ab-path does not include the number zero (i.e., significant indirect effect). Subsample: n = 116 (IG3 versus IG2), n = 118 (IG1 versus IG2). Abbreviations concerning the narrative information groups: IG, intervention group (i.e., information with added testimonials), IG1 = information plus testimonials by staff (i.e., employees with unspecified occupation, working outside of academia as work area), IG2 = information plus testimonials by university students, IG3 = information plus testimonials by experts.

Hence, this study indicated that the acceptance of digi-MHS for stress management can be improved to a meaningful extent by a simple testimonial intervention. This finding corresponds to prior work on acceptance-facilitating interventions involving multi-component information on digi-MHSs, like iCBT (Ebert et al., 2015; Soucy et al., 2016). In contrast, we found no testimonial effects on attitudes toward online therapies, which is potentially due to the scope on health promotion in the stimulus material. Overall, however, the evidence base for narrative interventions is indecisive (Shaffer et al., 2018) and particularly scarce for mental health services. Consequently, the identified testimonial effects in digital mental health promotion can be considered as one major contribution of this experiment.

RQ2: Differences in Acceptance

Another goal was to compare the influence of different information types on the acceptance of digi-MHSs. We identified higher intentions attributable only to students' testimonials compared to each other information group before and after adjusting for baseline intention values, with moderate-to-high effect size. While the influence of students' testimonials appears plausible, it was unexpected to identify no influence of expert statements. Potentially, expert testimonials were processed rather more analytically than first-person testimonials. Participants may have concluded that these testimonial sources intended to persuade them, which may have led to less trustworthiness and more reactance (Wang and Shen, 2019). Accordingly, a recent survey indicated that recipients of health advertisements were concerned regarding the inappropriate use of academic reputation (doctors as expert sources) and found that testimonials should be viewed more critically in healthcare compared to consumer contexts (Holden et al., 2021). To date, only few investigations on effects of expert versus lay people testimonials on digi-MHSs exist and yielded indecisive results (Healey et al., 2017). Here, we confirmed positive influences of first-person testimonials, which have been shown to be more persuasive than third-person narratives in other health promotion experiments (Chen and Bell, 2021).

In contrast to intentions, we found no group difference in attitudes toward online interventions for stress coping or therapy. Possibly, attitudes were easier biased by social desirability than intentions, making it more difficult to induce improvements with source-related differences. In addition, attitudes and intentions represent different stages of adoption in terms of intention as mediator of the effect of attitude on behavior in line with the TPB (Ajzen, 1991; MacKinnon et al., 2000). According to a meta-analysis, research showed that statistical evidence seems to be more suitable to improve attitudes and beliefs (cognitive elaboration) and that narrative messages rather influence affective responses, like behavioral intentions (Zebregs et al., 2015). However, none of the reviewed studies focused on mental health or eHealth. Therefore, more research is required to explore source-related effects of testimonials and related factors not only on the acceptance of digi-MHSs but also on the influence of acceptance on subsequent registration or uptake rates (Healey et al., 2017; Wopperer et al., 2019) as well as successful program completions (Fleming et al., 2018).

Recent research demonstrated an association between prior experience with digi-MHSs and higher acceptance among university students, but also little experience and low uptake rates at the same time (Lavergne and Kennedy, 2021). Additionally, previous experience appears not mandatory to form positive attitudes toward digi-MHSs (Mayer et al., 2019). Overall, the low experience rates regarding digi-MHSs in our sample (5%) correspond to earlier surveys from Germany (Webelhorst et al., 2020; Breil et al., 2021) and international findings across different populations (Toscos et al., 2018; Clough et al., 2019; Richardson et al., 2020). Although research has revealed positive attitudes and the readiness to try stand-alone digi-MHSs among university students (Hadler et al., 2021), in direct comparison face-to-face support, including blended care, have been shown to be preferred in surveys, including discrete choice experiments (Phillips et al., 2021). Future experiments on acceptance-facilitating interventions may therefore extend the scope to blended interventions.

RQ3: Mediation Effects

Another purpose was to identify mediators of attitudes and intentions. Consistent with prior work (Apolinário-Hagen et al., 2021), perceived similarity mediated the influence of exposure to testimonials on attitudes toward and intentions to use digi-MHSs for mental health promotion, favoring students' over employees' testimonials (IG1 versus IG2). In addition, there was a full mediation effect of similarity on intentions (students' versus expert testimonials). Thus, the acceptance-facilitating role of similarity seems to be a promising future focus when designing information aiming at promoting the adoption of digi-MHSs.

Furthermore, we found a full mediation effect of source credibility on attitudes, with student testimonials being assessed as more credible than those by experts (IG2 versus IG3). In contrast, there were no mediation effects of source credibility on intentions. Interestingly, there were no differences between the IGs in source credibility, while the aCG assessed the information significantly as more credible than participants receiving expert testimonials. Potentially, the expert testimonials were not optimally designed, could have been presented by recognized experts and additionally integrated critical statements. Increasing credibility can be a starting point, which may be promoted by certification and quality seals. Since fall 2020, the Digital Healthcare Act allows for the prescription of certified health apps in Germany (Gerke et al., 2020). Yet, many concerns persist among health professionals, especially regarding data security (Heidel and Hagist, 2020). Future studies on acceptance-facilitating interventions could therefore focus on balancing information on the benefits (safety, effectiveness) with contraindications of quality-approved mental health apps.

Limitations

Limitations of this study include multiple testing (i.e., risk of false positive findings, "p-hacking"), fictional, positively framed testimonials and unequal group sizes for testing the effects of testimonials in RQ1.

Out of $n = 368$ data sets, $n = 184$ (37%) were removed mostly due to withdrawal of consent, dropping out prior to randomization or unrealistic participation time, as shown in Figure S1 (**Supplementary Material 2**). Nonetheless, this rate corresponds to other online studies using the *virtual lab* (Apolinário-Hagen et al., 2021).

Due to the integration in a Master thesis project, the recruitment period was limited and scheduled in the early winter semester 2020/21. Furthermore, we did neither measure the semester nor mental health status, except for stress, to reduce the amount of identifiable or sensitive data.

In addition, it may also have been useful to repeat health messages to achieve more robust persuasive effects (Suka et al., 2020). Furthermore, we did not include information on the costs of eMHSs to reduce the amount of attributes and given the universally free access to healthcare in Germany.

Finally, it should be considered that about two-third of the sample were distance-learning students who differ from traditional students in demographic background and study conditions (Harrer et al., 2021), whereas the Covid-19 pandemic contributed to at least comparable distance study conditions in fall 2020. Moreover, online education and the unavailability of face-to-face support may have had an impact on the acceptance of digi-MHSs.

CONCLUSION

Taken together, this experiment identified positive influences of first-person testimonials on the acceptance of digi-MHS among university students, indicating that even such simple narrative interventions may be an option for information campaigns. Specifically, program information supplemented with students' testimonials could be useful in increasing behavioral intentions. In a next step, the most relevant domains for fostering perceived similarity and credibility could be explored in more detail. Further insights into these mediating effects on acceptance may help develop tailored information on digi-MHSs.

DATA AVAILABILITY STATEMENT

The datasets presented in this study can be found in online repositories. The names of the repository/repositories and accession number(s) can be found at: https://doi.org/10.7802/2287.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Ethics committee of the University of Hagen, Germany (EA_278_2020). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

JA-H conceived the study idea and study design, initiated the study, wrote the first draft of the manuscript, and coordinated and finalized the article. LF and JW sought ethical approval. CS, JW, LF, MH, FW, DE, and DL made relevant contributions to the study design and interpretation of data. JW programmed the online questionnaire, recruited participants, and collected and analyzed data under supervision of LF and CS within JW's master thesis project. FW and JA-H cross-checked the data underlying the manuscript and prepared the data set for sharing for non-commercial purposes. All authors read the manuscript, provided feedback, and approved the final version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyg.2021.738950/full#supplementary-material

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Remote vs. In-person Delivery of LearningRx One-on-One Cognitive Training During the COVID-19 Pandemic: A Non-inferiority Study

Amy Lawson Moore[1], Terissa Michele Miller[1] and Christina Ledbetter[1,2]*

[1] Department of Psychology, Gibson Institute of Cognitive Research, Colorado Springs, CO, United States, [2] Department of Neurosurgery, Louisiana State University Health Sciences Center, Shreveport, LA, United States

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Ioana Roxana Podina,
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University of Bucharest, Romania

***Correspondence:**
Amy Lawson Moore
amoore@gibsonresearch.org

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The COVID-19 pandemic challenged in-person delivery of cognitive training. Some clinics pivoted to remote delivery for those impacted by lockdowns, illness, or fear of exposure to the virus. However, it was unknown if remote delivery using teleconferencing technology was as effective as in-person delivery. The current study compared the outcomes of remote delivery to in-person delivery of ThinkRx cognitive training during 2020. The sample included 381 child and adult clients from 18 cognitive training centers. One group ($n = 178$, mean age = 12.3) received traditional in-person delivery of cognitive training. The second group ($n = 203$, mean age = 11.7) received remote delivery of one-on-one cognitive training *via* Zoom teleconferencing. Each client was assessed before and after the intervention using the Woodcock Johnson IV Tests of Cognitive Abilities. Clients completed an average of 112 h of cognitive training delivered by a clinician in 90-min sessions 3 or 4 days per week. Paired samples *t*-tests revealed significant differences from pretest to post-test across all constructs for both groups. After Bonferroni correction, MANOVA revealed no significant difference in changes scores between the two intervention groups on any of the subtests. With very small effect sizes, linear regression analyses indicated that age was a significant predictor of change in working memory and processing speed for the in-person group, and a significant predictor of change in overall IQ score for the teletherapy group. Non-inferiority analyses indicated remote delivery is not inferior to in-person delivery on the primary outcome measure of overall IQ score along with processing speed, fluid reasoning, long-term memory, and visual processing. Although in-person training results were slightly higher than remote training results, the current study reveals remote delivery of cognitive training during COVID-19 was a viable alternative to in-person delivery of cognitive training with little practical differences based on the age of client.

Keywords: cognitive training, teletherapy, virtual therapy, brain training, LearningRx

INTRODUCTION

When the COVID-19 outbreak caused much of the United States to lockdown, many providers of in-person cognitive training were challenged to continue delivering the intervention through teleconferencing technology (Owens et al., 2020; Lee et al., 2021). Educators and clinicians scrambled as well to adopt remote delivery options, and evidence-based research began to trickle in on the non-inferiority of these interventions (Doraiswamy et al., 2020; Koonin et al., 2020; Monaghesh and Hajizadeh, 2020; Wosik et al., 2020).

There is over a decade of research substantiating the effectiveness of remote delivery of mental health interventions (Andersson and Cuijpers, 2009; Andersson et al., 2011; Herbert et al., 2016). Remote delivery is needed now more than ever for offering more timely diagnoses and interventions (Smith et al., 2017; Lee et al., 2021), increasing the reach of treatment options for patients in underserved settings (Nelson and Patton, 2016) or with distance, health and/or time constraints (Acierno et al., 2017; Ratzliff and Sunderji, 2018; Owens et al., 2020). Research confirms comparable outcomes for remote and in-person delivery of a wide variety of psychological and cognitive treatments (Backhaus et al., 2012; Bashshur et al., 2016), reveals corresponding user satisfaction for both methods (Cox et al., 2017; Müller et al., 2017), and affirms greater cost-effectiveness in most cases (Hubley et al., 2016).

Additionally, the literature on cognitive training is rife with research on independent-user, digital-based cognitive training apps, games, and devices (Bonnechère et al., 2020; Irazoki et al., 2020; Owens et al., 2020). Yet there are very few published articles regarding remote-delivery of cognitive training interventions as telehealth, described by Gately et al. (2019) as a "live, synchronous encounter that employs a videoconferencing software." Thus the current study attempts to address this gap regarding the potential non-inferiority of remote delivery of one-on-one cognitive training vs. in-person one-on-one cognitive training using the LearningRx methodology.

The efficacy and effectiveness of the LearningRx cognitive training methodology has been previously demonstrated in multiple studies on various populations including children with learning struggles (Carpenter et al., 2016; Gibson et al., 2015; Jedlicka, 2017; Moore et al., 2019a), children with ADHD (Moore et al., 2018), adolescents and adults with brain injury (Ledbetter et al., 2017; Moore et al., 2020) and adults with age-related cognitive decline (James et al., 2019; Moore et al., 2019b). Results have included statistically and clinically significant changes in working memory, long-term memory, processing speed, fluid reasoning, visual processing, auditory processing, and Word Attack skills as well as reported improvements in self-esteem, self-discipline, cooperative behaviors, mood, perseverance, activities of daily living, and reduced oppositional behaviors and academic struggles. Changes in brain network connectivity, changes in the Default Mode Network (DMN), and correlations between changes in IQ score and white matter integrity have also been documented following LearningRx cognitive training (James et al., 2019; Moore et al., 2020). Because cognition is complex, cognitive training should match that complexity by targeting the multiple cognitive skills used for thinking and learning. Brain training applications and programs that only target one or two skills such as working memory or attention, fail to address the variety of constructs required for complex thought. The LearningRx methodology is designed to target multiple overlapping cognitive constructs aligned with the Cattel-Horn-Carrol theory of cognition, the most widely recognized intelligence theory and the one in which most intelligence tests are based. This comprehensive nature coupled with human delivery of the LearningRx methodology yields an advantage over digital game applications.

Although the research results on LearningRx have been robust, it was unknown if remote delivery of the intervention was as effective as the traditional in-person delivery model. Therefore, the current study compared the outcomes of clients who received remote training of LearningRx cognitive training during the COVID-19 pandemic with clients who continued to receive in-person training during the same time period. This is an important question to answer given the inherent benefits of the LearningRx methods and the transfer effects beyond the trained tasks that have been widely documented thus far. These transfer effects situate the one-on-one delivery of cognitive training at an advantage over digital applications and continue to be the holy grail of cognitive training research. If these benefits can extend to the remote environment, the program could be made available to people who are experience barriers to access including a global pandemic, severe weather, illness or injury, or geographical distance between potential clients and a cognitive training center.

MATERIALS AND METHODS

Sample

The sample was comprised of $n = 381$ clients from 18 cognitive training clinics, including 353 children and 28 adults. Inclusion criteria included clients at least 4 years of age, completion of a cognitive training program in 2020, and completion of both pre and post intervention assessments with the Woodcock Johnson IV Tests of Cognitive Abilities. Records of children under 4 years of age were excluded. Group 1 ($n = 178$) received traditional in-person delivery of cognitive training and will be referred to henceforth as the "In-Person" group. Group composition was 39% female ($n = 69$) and 61% male ($n = 109$) with a mean age of 12.3 (SD = 8.6). Diagnoses included ADHD ($n = 45$), autism spectrum disorder ($n = 11$), dyslexia/reading disability ($n = 38$), speech and language disorder ($n = 15$), and traumatic brain injury ($n = 1$). There were 165 children (mean age = 10.5) and 13 adults (mean age = 35.1). Group 2 ($n = 203$) received remote delivery of cognitive training *via* teleconferencing and will be referred to henceforth as the "Remote" group. Group composition was 42% female ($n = 86$) and 58% male ($n = 117$) with a mean age of 11.7 (SD = 6.5). There were 188 children (mean age = 10.4) and 15 adults (mean age = 28.1). Diagnoses included ADHD ($n = 59$), autism spectrum disorder ($n = 10$), dyslexia/reading disability ($n = 47$), speech and language disorder ($n = 18$), and traumatic brain injury ($n = 7$). **Table 1** shows the distribution of age and sex by group. All records were included in the analysis after determining a missing data

TABLE 1 | Distribution of age and sex by group.

	In-person group	Remote group
Children		
Age 4–7	30	35
Age 8–12	87	98
Age 13–17	48	56
Male	103	109
Female	62	79
Total children	165	188
Adults		
Age 18–29	7	11
Age 30–49	3	2
Age 50–69	2	2
Age 70+	1	0
Male	6	8
Female	7	7
Total adults	13	15
Total	178	203

percentage of only 1.3%. Little and Rubin (2002) indicate that data loss <5% will result in the same conclusion as if the dataset were complete.

Procedures

De-identified digital records were collected from 18 cognitive training clinics that provided the LearningRx cognitive training program during the COVID-19 pandemic. Individual records included quantitative test results from an assessment performed before and after the intervention using the Woodcock Johnson IV Tests of Cognitive Abilities, and qualitative results from an exit survey administered by each training center at the conclusion of the intervention. Ethics approval for the acquisition and analysis of the records was granted by the Institutional Review Board (IRB) at Gibson Institute of Cognitive Research in accordance with exempt research Category 4 of 45 CFR 46.101(b)(4). Permission to use the records for research was granted in writing by clients age 18 and over or by parents of clients under the age of 18 in accordance with the Declaration of Helsinki.

Intervention

In-Person Cognitive Training

The core LearningRx program, called ThinkRx, is a 230-page curriculum with more than 1,000 variations of 23 basic training tasks sequenced by difficulty and complexity and paced by a metronome beat or stopwatch. Based on the Cattell-Horn-Carrol (CHC) theory of a multiple construct view of cognition, the training procedures target multiple cognitive skills including various aspects of working memory, long-term memory, processing speed, visual and auditory processing, fluid reasoning, and attention (Schneider and McGrew, 2018). No task is trained in isolation, however. Instead, training tasks target overlapping cognitive skills. For example, the memory training task illustrated in **Figure 1** targets visual working memory, processing speed, sustained attention, visual processing, and rapid task switching. The trainer creates a pattern of five cards with similarly-sized shapes on one side of the workboard, allows the client to study the pattern for 3 sec, then covers the pattern and asks the client to reproduce it on their side of the workboard. Paced by a metronome, the client is also asked to count by three's on every other beat while completing the task. This is a description of just one variation of this training task. It can be delivered in 34 different ways. For example, a more difficult variation utilizes 8 cards with shapes of different sizes.

The trainer utilizes hands-on materials including work boards, shape and number cards, blocks, Tangrams, and speeded activity worksheets to deliver the program. Hands-on tasks may be loaded by the trainer with additional verbal tasks to train rapid task switching ability. In the traditional delivery method, clients attend their training sessions sitting one-on-one across a table from their cognitive trainer (see **Figure 2**). The trainer paces the session, manages frustration levels, provides dynamic feedback and motivating verbal persuasion, adds deliberate distractions to mimic real world learning and working environments, and helps the client apply what's learned in training to tasks outside of the training environment. This human-delivery format is a departure from the ubiquitous digital "brain training" methods described in much of the field's literature. In addition, this model of interaction is illustrative of Bandura (1994) self-efficacy theory by providing all four sources of self-efficacy for learning including modeling, mastery experiences, verbal persuasion, and guided management of the physiological response to stress. In the current study, the in-person training group received the intervention in the traditional one-on-on setting.

Clients completed an average of 112 h of cognitive training delivered by a cognitive trainer in 90-min sessions 3 or 4 days per week. A complete description of the training tasks, the number of variations per task, and the cognitive constructs targeted by each task was previously published in Carpenter et al. (2016). In brief, **Table 2** illustrates the constructs targeted by the program, the number of training tasks that target each construct, and the number of variations for each training task.

Remote Training

To approximate the in-person training experience, clients in the remote training group were sent an identical set of hands-on materials, metronome, and an external webcam on a tripod that projected their workspace for the trainer during each videoconferencing session. The trainer used both tangible materials visible on the webcam as well as pdf versions of the workboards for the client to see projected on their monitor. The interactions and time in training were identical between the groups. A video that illustrates two training procedures delivered through both methods is available at https://youtu.be/Xb65X2HVf_E. **Figure 2** illustrates the difference between in-person and remote delivery of an example training task.

For both training delivery methods, the curriculum is adaptable for different ages and skills levels. Although the training tasks are the same for everyone, older clients may master the early, easier variations within the first couple of training sessions. Their sessions would then focus on the more challenging variations of the tasks. For all ages, more time is

FIGURE 1 | Example of a training task.

focused on the tasks in which the struggle is greatest with very little time spent on tasks that are easy for each individual. Therefore, it's plausible that some clients spend more time on working memory tasks, for example, if that's a construct in which they are most deficient. Other clients may have stronger working memory and thus their training session may be more focused on building competency in other skills. The great number of task variations enables the trainer to individualize the protocols to match the client's needs and skills.

Outcome Measures

Woodcock Johnson IV Tests of Cognitive Abilities (WJ IV)

Each participant was administered the Woodcock Johnson IV Tests of Cognitive Abilities (Schrank et al., 2014) immediately before and after the intervention. The WJ IV measures individual cognitive constructs as well as a composite IQ score, in comparison to an age-based normative group. For the current study, we selected the overall IQ score as well as subtests used by LearningRx centers to report pretest to post-test change The subtests were chosen based on their ability to measure key constructs in the Cattel-Horn-Carroll (CHC) theory of cognition (Schneider and McGrew, 2018) which is the theory in which most major IQ test are based. The LearningRx program is also based on CHC theory which recognizes the complex overlap of multiple broad and narrow cognitive skills. A description of each measure is below.

Overall IQ Score

IQ score was measured using the General Intellectual Ability composite which represents a measure of overall intelligence and cognitive performance. It is a weighted composite of Tests 1–7 in the core WJIV battery. This composite score has a median reliability of 0.97.

In-Person Delivery of a Visual Processing Task

Remote Delivery of a Visual Processing Task

FIGURE 2 | In-person vs. remote delivery of an example training task.

Working Memory

Working memory was measured by the Numbers Reversed test, a classic task where the examinee is asked to hold an increasingly complex set of numbers in awareness and then orally reverse the sequence. This test has a median reliability of 0.88.

Long-term Memory

Long-term memory was assessed using the Visual-Auditory Learning subtest where the examinee memorizes a set of symbols and their corresponding words before being asked to “read” sentences of symbols based on remembering the associated words. This test has a median reliability of 0.97.

Processing Speed

Processing speed was measured by the Letter-Pattern Matching subtest which requires the examinee to make visual symbol discriminations among a series of increasingly more complex letter patterns in a 3-min time limit. This test has a reliability of 0.91 for ages 7–11 and ages 26–79 and a reliability of 0.88 for ages 14–17.

Visual Processing

Visual processing was measured by the 2-part Visualization subtest which captures performance in visual feature detection and the mental rotation of objects. The first part asks the examinee to identify two or three individual pieces that combine to form a completed shape. The second part asks the examinee to identify rotated block configurations that match the target configuration. This test has a median reliability of 0.85.

Auditory Processing

Auditory processing was measured by the 3-part Phonological Processing subtest. The first part asks the examinee to listen to a sound and then produce a word that contains that sound either at the beginning, in the middle, or at the end as prompted by the examiner. The second part assesses word recall ability, and the third part requires the examinee to substitute a sound in a word to produce a new word. This test has a median reliability of 0.84.

Sustained Attention

Sustained attention was measured using the Pair Cancellation subtest which asks the examinee to find and mark repeating and increasingly more complex patterns of shapes within a 3-min time frame. This test has a reliability of 0.89 for ages 7–11 and ages 14–17 and a reliability of 0.95 for ages 26–79.

Fluid Reasoning

Fluid Reasoning was measured by the Concept Formation subtest which targets inductive logic by requiring the examinee to derive a rule from each stimulus set of shapes with various characteristics. This test has a median reliability of 0.93.

Qualitative Exit Surveys

When clients at LearningRx centers finish a cognitive training program, they are asked to complete an exit survey about their experience. The open-ended question on the survey asks them to “Please share with us the changes you have seen as a result of the LearningRx training.”

Data Analyses

Quantitative Data Analyses

Within Group Change

De-identified data were transferred from EXCEL to SPSS Version 27 for analyses. To evaluate the significance of pretest to post-test change within each intervention group, we conducted paired samples *t*-tests on the pre and post WJIV standard scores. To control for multiple comparisons, we applied a Bonferroni correction to the significance threshold making the adjusted

TABLE 2 | Cognitive constructs targeted by the LearningRx training program.

Construct trained	# of Tasks	# of Variations
Auditory analysis	5	53
Auditory blending	1	11
Auditory discrimination	5	57
Auditory processing	4	48
Auditory segmenting	1	12
Comprehension	5	155
Divided attention	11	314
Executive processing	4	154
Fluid reasoning	5	159
Long-term memory	4	147
Computation	6	197
Processing speed	12	380
Saccadic fixation	2	88
Selective attention	5	189
Sensory motor integration	7	156
Sequential processing	1	17
Short-term memory	5	134
Simultaneous processing	10	317
Sustained attention	11	359
Visual processing	9	273
Visual discrimination	3	118
Visual manipulation	5	176
Visualization	10	271
Visual span	4	147
Working memory	12	431

alpha $p < 0.006$. To determine the magnitude of significance, we calculated effect sizes using Cohen's d defined with Cohen (1988) general guidance of small (0.2), medium (0.5), or large (0.8) effects.

Between Group Differences

To evaluate any baseline differences between the two intervention groups, we conducted a multivariate analysis of variance (MANOVA) on all pretest scores. Then, to evaluate differences in change scores between the two intervention groups, we conducted a multivariate analysis of variance (MANOVA) with the dependent variables being the difference between pretest and post-test standard scores for each construct, or change scores. To control for multiple comparisons, we applied a Bonferroni correction to the significance threshold making the adjusted alpha $p < 0.006$. To determine the magnitude of significance, we annotated effect sizes using multivariate eta square defined as small (0.01), medium (0.06), and large (0.14 or higher).

Non-inferiority

To determine if the remote training method of delivery was not inferior to the in-person method of delivery, we used the non-inferiority margin as described by Walker (2019). First, we determined what percentage of the traditional gains were necessary to preserve in the new delivery method. Although a preserved fraction of 50% is common in non-inferiority trials (Althunian et al., 2017), we opted for a more rigorous threshold by choosing a more conservative and clinically relevant 75% preserved fraction of the effect based on the results from prior controlled studies on the in-person delivery method along with the clinical judgement of 6 cognitive training experts we polled. We used two previous controlled trials of LearningRx (Gibson et al., 2015; Carpenter et al., 2016) plus the current study to determine the pooled mean change across constructs weighted by sample size for traditional in-person delivery ($M = 12.5$ standard points) and then applied the 75% threshold to determine the delta for the current trial ($\Delta = -3.75$). To meet the 75% preserved fraction of the effect seen in the in-person group and to conclude non-inferiority of the remote training method, the lower end of the 95% confidence interval (CI) around the mean difference in each score change could not be lower than the non-inferiority margin of -3.75. We calculated the 95% CI for each outcome variable using the following formula:

$$(\mu_{\text{new}} - \mu_{\text{control}}) \pm 1.96\sqrt{\frac{\sigma^2 new}{\mathbf{n\ new}} + \frac{\sigma^2 control}{\mathbf{n\ control}}}$$

Where "new" represents remote and "control" represents in-person, and 1.96 is the z value required for a one-tailed alpha of 0.025.

Differences by Age

To determine if age was a significant predictor of change on any of the constructs measured, we conducted hierarchical linear regression analyses using age in months as the predictor variable and change in standard score on each measure as the outcome variable. We included the pretest score in each model as a covariate predictor block. To control for multiple comparisons, we applied a Bonferroni correction to the significance threshold making the adjusted alpha $p < 0.006$. To determine the magnitude of significance of the overall model, we annotated effect sizes using R square. To determine how much of the variance in each dependent variable is explained by age after controlling for pretest scores, we squared the Beta coefficient and converted to a percentage.

Qualitative Data Analyses

We used a standard grounded theory 3-step process of coding, analysis, and development of themes (Kiger and Varpio, 2020) to evaluate the written statements made by the 304 of the 381 participants who completed the exit survey at the end of the intervention. This inductive analysis ensures that themes emerge from the data instead of creating pre-determined themes of expected adherence (Charmaz and Thornberg, 2020). During the thematic analysis, the qualitative researcher was blind to group identification. The analysis began with line-by-line reading of comments without coding or categorization, followed by a second review while note taking to ascertain the wide variety of responses. Then, data were coded at the phrase level and then themes were evaluated and clarified by the research team. Finally, the responses were unblinded to group identification for comparison of themes between the two groups.

TABLE 3 | Paired sample *t*-tests of pretest to post-test change by group.

	In-Person				Remote			
WJ4	**Pre (SD)**	**Post (SD)**	***p***	***d***	**Pre (SD)**	**Post (SD)**	***p***	***d***
IQ	92.9 (16.2)	104.7 (16.8)	0.000	1.19	90.9 (16.6)	100.9 (16.1)	0.000	1.07
WM	94.6 (15.8)	104.6 (15.4)	0.000	0.69	92.8 (16.8)	100.9 (16.3)	0.000	0.51
LTM	99.4 (12.7)	108.2 (13.5)	0.000	0.78	98.9 (12.9)	107.1 (14.4)	0.000	0.77
PS	93.2 (14.0)	100.8 (12.5)	0.000	0.74	91.9 (15.2)	98.4 (15.2)	0.000	0.54
VP	100.9 (13.8)	108.4 (13.7)	0.000	0.63	99.2 (14.3)	105.9 (14.1)	0.000	0.60
AP	89.2 (15.8)	104.1 (15.2)	0.000	1.23	88.1 (16.3)	100.3 (15.6)	0.000	1.07
Attn	92.1 (13.5)	103.6 (14.3)	0.000	0.95	92.1 (14.3)	101.2 (13.7)	0.000	0.79
FR	100.6 (16.2)	110.6 (16.6)	0.000	0.93	98.1 (17.2)	107.9 (17.4)	0.000	0.84

Significance level set at Bonferroni-corrected alpha p < 0.006. d, Cohen's d effect size; WM, working memory; LTM, long-term memory; PS, processing speed; VP, visual processing; AP, auditory processing; Attn, sustained attention; FR, fluid reasoning; IQ, IQ score composite.

TABLE 4 | MANOVA of standard score change by group.

Woodcock Johnson IV Measure	In-Person Group Mean Change Score (SD)	Remote Group Mean Change Score (SD)	*F*	*p*	η^2
IQ Score	11.7 (9.8)	10.0 (9.3)	1.8	0.178	0.005
Working Memory (WM)	10.0 (14.4)	8.1 (15.9)	1.2	0.273	0.004
Long-term Memory (LTM)	8.8 (11.2)	8.2 (10.6)	0.64	0.426	0.002
Processing Speed (PS)	7.6 (10.3)	6.5 (12.1)	0.98	0.323	0.003
Visual Processing (VP)	7.6 (11.9)	6.7 (11.1)	0.57	0.449	0.002
Auditory Processing (AP)	14.8 (12.0)	12.3 (11.5)	5.58	0.019	0.016
Attention (Attn)	11.4 (12.0)	9.1 (11.5)	6.18	0.013	0.018
Fluid Reasoning (FR)	10.0 (10.7)	9.7 (11.5)	0.001	0.971	0.000

Significance level set at Bonferroni-corrected alpha p < 0.006.

RESULTS

Quantitative Results

Within Group Change

After Bonferroni correction for multiple comparisons to an alpha of $p < 0.006$, paired samples t-tests revealed significant differences from pretest to post-test across constructs for both groups with medium to large effect sizes represented by Cohen's d as shown in **Table 3**. For the In-Person Group, the largest change was seen in auditory processing followed by overall IQ score, sustained attention, and fluid reasoning. For the Remote Group, the largest change was also seen in auditory processing along with overall IQ score, followed by fluid reasoning and sustained attention.

Between Group Differences

A MANOVA on pretest measures indicated there were no statistically significant differences between the groups at baseline on any of the pretest scores: IQ score ($p = 0.190$), processing speed ($p = 0.299$), auditory processing ($p = 0.391$), visual processing ($p = 0.211$), fluid reasoning ($p = 0.164$), working memory ($p = 0.291$), long-term memory ($p = 0.669$), or attention ($p = 0.948$). As shown in **Table 4**, the MANOVA on change scores revealed no significant difference in changes scores between the two intervention groups on any of the subtests after Bonferroni correction for multiple comparisons to an alpha of $p < 0.006$ (Wilk's Lambda = 0.97, $F = 1.32$, $p = 0.23$, $\eta^2 = 0.031$). The In-Person group saw slightly larger change scores than the Remote Group on all constructs measured, differing the most in auditory processing with a 2.5 point difference in standard score change.

Non-inferiority

To meet the 75% preserved fraction of the effect seen in the in-person group and to conclude non-inferiority of the remote training method, the lower end of the 95% confidence interval

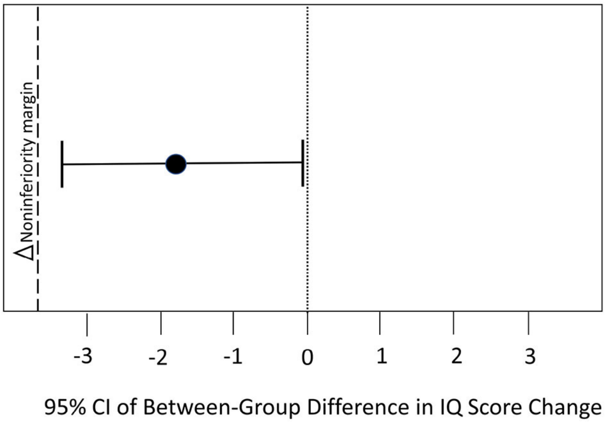

FIGURE 3 | Results of non-inferiority testing on overall IQ score.

around the mean difference in each score change could not be lower than the non-inferiority margin. IQ score is a composite index representing performance on seven cognitive constructs and serves as a indicator of overall cognitive function. We chose to use the change in overall IQ score as the primary outcome by which to report the non-inferiority analysis. The non-inferiority margin is −3.75 points. Therefore, to meet the 75% preserved fraction of the effect seen in the in-person group, the lower end of the 95% confidence interval around the mean difference in IQ score change could not be lower than −3.75. Results show the 95% CI of the mean between-group difference in IQ score change was −0.226 to −3.40, falling above the non-inferiority margin. Therefore, the remote delivery method is not inferior to the in-person delivery method in changing overall IQ score. **Figure 3** illustrates this analysis.

Using the same threshold, we evaluated non-inferiority for each of the remaining outcome variables. To meet the 75% preserved fraction of the effect seen in the in-person group and to conclude non-inferiority of the remote training method on each construct, the lower end of the 95% confidence interval around the mean difference in each score change could not be lower than the non-inferiority margin of −3.75. Non-inferiority was demonstrated for fluid reasoning (95% CI = −0.60, 1.91), processing speed (95% CI = −2.20, 1.16), visual processing (95% CI = −1.80, 1.43), and long-term memory (95% CI = −1.50, −3.39), but was inconclusive for the outcomes of auditory processing (95% CI = −6.80, −1.92), working memory (95% CI = −4.40, 0.58), and attention (95% CI = −4.60, 0.02). That is, part of the confidence interval fell below the non-inferiority margin for those latter constructs.

Differences by Age

As shown in **Table 5**, linear regression analyses indicated that after controlling for pretest scores, age was not a significant predictor of change in any of the cognitive test scores from pretest to post-test for the remote training group. For the In-Person Group, age was a significant predictor after controlling for pretest scores in working memory ($\beta = 0.190$, $p = 0.004$, $R^2 = 0.273$) indicating that for every year in age, the change in test score increased by 0.19 points from pretest to post-test. However, only 3.6% of the variance in scores can be explained by age. Age was also a significant predictor of change in sustained attention for the in-person group ($\beta = 0.270$, $p = 0.000$, $R^2 = 0.213$) indicating that for every year in age, the change in score increased by 0.27 points from pretest to post-test. However, only 7.2% of the variance in sustained attention scores can be explained by age.

Qualitative Results

The analysis of qualitative responses to the exit interview uncovered three predominant themes (cognitive changes, academic changes, behavioral changes) with 12 subthemes. *Cognitive changes* included the subthemes of cognitive test scores, memory, logic and reasoning, processing, and attention. *Academic changes* had subthemes of math skills, reading/writing, and grades/school performance. *Behavioral changes* included subthemes of confidence, personal responsibility, social skills, and mood/outlook.

Results indicate very little difference between the two groups in regard to the three primary themes. In the In-Person Training Group, 27.3% of the total comments were *cognitive changes*, 29.9% were *academic changes*, and 42.8% were *behavioral changes*. Similarly, in the Remote Training Group, 26.0% of their responses were *cognitive changes*, 31.1% were *academic changes*, and 42.9% were *behavioral changes*. These comparisons are illustrated in **Figure 4**.

Participants who commented about *cognitive changes* wrote things like, "He has gotten stronger with puzzles, logic, and his memory is better," "…better focus to complete homework," "…results of the tests showed that she significantly improved," and "…improved attention to detail." Most of the remarks about *academic changes* referenced reading and writing, which included statements such as, "…increased reading skills, increased reading fluency," "…a renewed enjoyment of reading," "Math skills and reading comprehension have grown," and "Her ability to read has and will open up so many doors for her." The largest percentage of responses were about *behavioral changes*, with a majority of remarks about confidence such as, "Her self-esteem has soared," "[He] has become much more confident in himself and his abilities," "She is happier," "Our son has become more independent in completing his homework," and "My daughter has shown tremendous growth in her courage to try new things." Most respondents were parents/guardians of cognitive training clients, although 7 were adult (over age 21) clients themselves. The responses from these adult participants did not differ from other remarks except for one which specified impact within the workplace: "…improved long and short term memory and visual processing when at work."

There was a total of 304 research participants who responded to the exit survey, with 79 who gave a general comment with no uniquely identifiable theme. These responses included statements like, "trainers were great," "we believe in the program," and "they helped our son." Thus, the thematic analysis outcome was evaluated based on 225 respondents who offered specific remarks, with a total of 271 unique comments from those who trained in-person, and 273 unique comments from those who trained

TABLE 5 | Regression analysis of age as a predictor of outcomes by group.

	In person group				Remote group			
	B	***t***	***p***	***R^2***	***B***	***t***	***p***	***R^2***
IQ score	0.186	2.4	0.016	0.091	0.169	2.4	0.018	0.128
WM	0.190	2.9	0.004*	0.273	−0.072	1.2	0.239	0.261
LTM	0.114	1.6	0.107	0.149	0.010	0.142	0.888	0.073
PS	0.059	0.89	0.372	0.263	−0.036	0.55	0.583	0.159
VP	0.054	0.78	0.434	0.198	−0.044	0.64	0.525	0.167
AP	0.087	1.2	0.214	0.190	0.065	0.99	0.319	0.176
Attn	0.270	3.9	0.000*	0.213	0.043	0.67	0.504	0.208
FR	−0.033	0.45	0.654	0.089	−0.104	1.5	0.124	0.114

**Significant at Bonferroni-corrected alpha $p < 0.006$. B, Beta coefficient of slope; R^2, effect size; WM, working memory; LTM, long-term memory; PS, processing speed; VP, visual processing; AP, auditory processing; Attn, sustained attention; FR, fluid reasoning; IQ, General Intellectual Ability composite.*

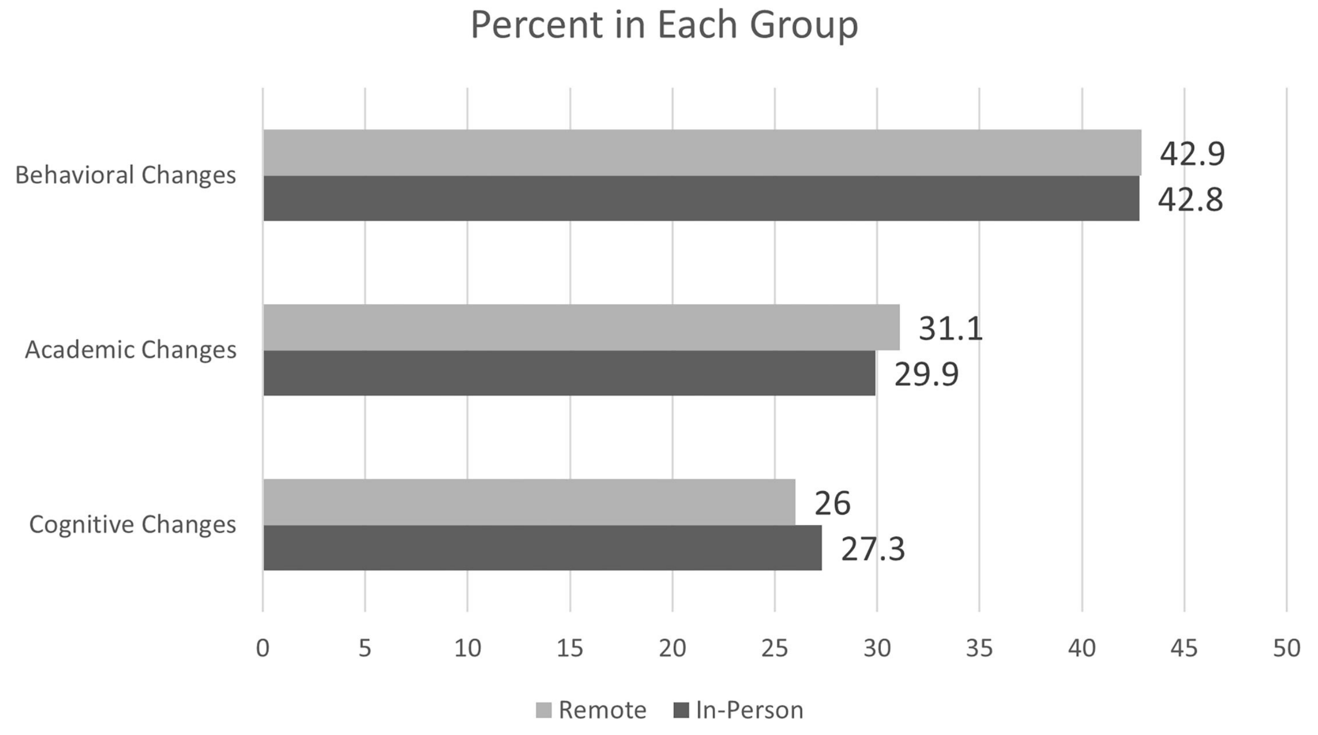

FIGURE 4 | Percent of each group reporting change in each theme.

remotely. Finally, about 6% of the overall responses in each group were negative, including dissatisfaction with cost, time commitment, results, or the process such as, “I was hoping to see more improvements in school and grades,” “It could have been better adjusted for age,” and “It was not a bad experience, but I think the program is overpriced and requires a huge time commitment.”

DISCUSSION

The aim of the current study was to address a gap in the literature regarding the potential non-inferiority of remote delivery of one-on-one cognitive training vs. in-person one-on-one cognitive training. The efficacy of the LearningRx in-person cognitive training methodology had been previously demonstrated in multiple studies (Carpenter et al., 2016; Moore et al., 2019a,b, 2018), but it was unknown prior to this study if remote delivery of the intervention was as effective as the traditional in-person delivery model. We found statistically significant changes across all constructs measured (working memory, long-term memory, processing speed, visual and auditory processing, attention, reasoning, and overall IQ score) for both intervention groups with robust effect sizes. We also found no statistically significant differences between the two delivery methods on any of the measures. Inferiority analyses demonstrated that remote delivery is not inferior to in-person delivery for the primary outcome measure of overall IQ score and for the individual constructs of processing speed, fluid reasoning, long-term memory, and visual processing. Inferiority analyses was inconclusive for auditory processing, working memory, and attention since part of the 95% confidence interval fell below the margin. Finally, we evaluated the qualitative outcomes and found three themes consistent in both groups: changes in cognition, changes in academic skills, and changes in behavior and psychosocial functioning.

Because the results were so similar between the two methods of delivering this intervention, the current study suggests that remote delivery is a feasible alternative to in-person delivery of the same intervention which enables more widespread access to this cognitive training program. The implication of this benefit should not be understated given the potential barriers to in-person access including another global pandemic, severe weather, illness or injury, and geographical distance between potential clients and a cognitive training center. These barriers are significant given that the LearningRx program is only available in-person in 70 locations, most in highly populated areas. Rural areas of the country lack access to a training center within driving distance. In addition, our post-COVID society is cautious about face-to-face contact and a virtual alternative to this intervention may help to allay anxiety about potential exposure to illnesses. Further, remote access enables continuity of care more easily should a client be traveling or experiencing a mild illness or injury. Although additional research is necessary to evaluate equivalence of the two methods given the results of the inferiority analyses, the finding of statistically significant pretest to post-test changes on all constructs in both delivery methods lends additional evidence to the existing body of research on the effectiveness of the LearningRx training program. Future research should evaluate motivation as it is historically a key contributor to performance. Adding quantitative psychosocial outcome measures would also strengthen future research and continue building the case for transfer effects beyond the trained tasks and cognitive measures.

Although there were no statistically significant differences in changes on cognitive test scores between the two groups, it is worth noting that the In-Person Training group did achieve slightly higher change scores than the Remote Training group on all of the constructs measured and non-inferiority could not be confirmed for three of the individual constructs. There are several possible reasons for this trend including Zoom fatigue for the Remote Training participants who were already spending their day learning and working virtually during the pandemic. Another possibility is the strength of engagement may have been less in a virtual environment vs. an in-person environment. Finally, the degree of external stimuli is greater in the traditional, in-person method of delivering this intervention in a busy open-concept training room at LearningRx centers. Having up to 15 training stations in the same room forces participants to focus on only the relevant stimuli and tasks while tuning out the noise and motions surrounding them. This increased intensity may give the In-Person Training group the slight edge over the Remote Training group participants who wore headphones and trained in quieter surroundings.

The strengths of the current study include a robust sample size with diverse ages, giving us a solid understanding of the feasibility of adapting the in-person delivery method across age groups. Another strength of the study is the ecological validity of evaluating real-world outcomes. The data were extracted from actual cognitive training clients who were living through a global pandemic—a quintessential scenario in which pivoting to remote interventions is necessary. A final strength of the study is the inclusion of qualitative data to evaluate transfer effects of both delivery methods. Indeed, the themes uncovered through the qualitative analysis were consistent with themes uncovered in prior research on the LearningRx cognitive training methods (Ledbetter et al., 2017; Moore et al., 2018, 2019a,b, 2020).

There are a few limitations worth noting, however. First, the groups were pre-existing and not randomly assigned. Although the groups were similar in demographics and the ecological validity of the findings is supported by the evaluation of pre-existing groups, the lack of random assignment does make the study design less robust. Next, the small number of adult participants reduces the ability to completely generalize the results to an adult population without further study. However, the regression analysis did not suggest that the results differ with much practical significance by age. The final limitation is that we did not quantify changes in constructs beyond cognition such as motivation, depression and mood, or self-efficacy. However, the addition of the qualitative data did allow us to identify trends in transfer effects and increase the value of the study to the field.

CONCLUSIONS

The current study analyzed real-world data from an adaptation of a well-established in-person cognitive training method to a teletherapy delivery method during the COVID-19 pandemic in 2020. Results indicated that remote delivery was not only feasible but showed similar results as in-person training with little practical differences based on the age of client. These findings support the use of remote delivery of the LearningRx one-on-on cognitive training intervention and suggest the barriers to access of the traditional in-person delivery can be reduced through remote availability.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Gibson Institute of Cognitive Research IRB. Written informed consent to participate in this study was provided by the participants' legal guardian/next of kin.

AUTHOR CONTRIBUTIONS

AM acted in the capacity of primary investigator, conducted the quantitative data analysis, and drafted the manuscript. CL acted as co-PI, created the study design, oversaw data acquisition and storage, and edited the manuscript. TM drafted the literature review, conducted the qualitative data analysis, and edited the manuscript. All authors contributed to the article and approved the submitted version.

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The Session Wants and Need Outcome Measure: The Development of a Brief Outcome Measure for Single-Sessions of Web-Based Support

Santiago de Ossorno Garcia[1]*, Louisa Salhi[1,2], Aaron Sefi[1,3] and Terry Hanley[4]

[1]Kooth plc, London, United Kingdom, [2]School of Psychology, University of Kent, Canterbury, United Kingdom, [3]Department of Psychology, University of Exeter, Devon, United Kingdom, [4]School of Environment, Education and Development, The University of Manchester, Manchester, United Kingdom

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***Correspondence:**
Santiago de Ossorno Garcia
sossorno@kooth.com

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Single-session, brief interventions in therapy for young people make up a large proportion of service provision, including in digital mental health settings. Current nomothetic mental health measures are not specifically designed to capture the benefit or 'change' directly related to these brief interventions. As a consequence, we set out to design an outcome measure to concretely demonstrate the value of single-session interventions. The Session Wants and Needs Outcome Measure (SWAN-OM) aims to capture in-session goals and focuses on being user-centric, elements critical to the success of single-session and brief interventions which typically are asset-based and solution-focused. We describe the 4-stage process that was followed to develop this measure: (I) classical item generation and development, (II) content and (III) face validity pilot testing, and (IV) a user-experience approach with young people using framework analysis. This final stage was critical to ensure the integration of this outcome tool into a web-based digital therapy setting, a context which adds another layer of design complexity to item and measure development. This iterative methodology was used to overcome the challenges encountered and to place the needs of the young people and service practitioners at the centre of the design process, thus ensuring measure usability. To end, we highlight the main lessons learnt from engaging in this design process. Specifically, the needs of a measure for single-session interventions are considered, before outlining the learning associated with integrating the measure into a digital mental health platform. Both of these areas are emerging fields and, as such, this study contributes to our understanding of how an idiographic patient outcome theory driven measure can be created for use in a web-based digital mental health therapy service.

Keywords: single-session counselling, brief interventions, therapy outcome measure, iterative design, web-based therapy, digital mental health, patient-reported outcome, idiographic measurement

INTRODUCTION

For many who seek mental health support, one session with a therapist can prove sufficient (Hymmen et al., 2013), with 58.6% of individuals in one study reporting the single-session met their needs after a 12-month follow-up period (Hoyt et al., 1992). Therefore, as many service users will engage in potentially only one session, the impact of any therapeutic intervention cannot be measured or followed up on in the traditional way using pre-post measurement after a reasonable period since the intervention took place. Mental health services typically utilise a battery of nomothetic clinical measures to track patient needs, progress and intervention outcomes (Sales and Alves, 2016; Lloyd et al., 2019). These have been very useful in more traditional clinical settings which offer longer, structured interventions, such as those seen in the United Kingdom, in Child and Adolescent Mental Health Services (CAMHS) and within change programs, such as Improving Access to Psychological Therapies (CYP-IAPT) (Batty et al., 2013). However, even though the majority of sessions is part of structured interventions in CAMHS, a large proportion of the children and young people population still only use the service for one single-session (Edbrooke-Childs et al., 2021). Therefore, alongside more nomothetic measures, patient-centred outcomes are being increasingly used (Collins, 2019). These routinely collected Patient-Reported Outcome Measures (PROMs) have been seen to be useful in mental health settings and provide the patient with a more holistic progress measure that reduces treatment failur and enhances positive effects of the intervention (Brattland et al., 2018; Lambert and Harmon, 2018). PROMs are important as they align more with patient-perceived change and progress rather than measurement being centred around the clinician perceived symptomatic progress (Collins, 2019; Flannery and Jacob, 2020). Therefore, the use of nomothetic PROMs aims to give the patient a voice in their mental health journey, but they fail to capture individualised wants and needs in treatment and measure the person's experience of change, which may not be shown in clinical measure alone. Idiographic PROMs (I-PROMs) are aligned more closely to the patient-centred approach to therapy (Wheat et al., 2018) and show promise to be transferable to digital mental health services, as they can provide tailored cues for therapy to each user, they appear to enable the person to 'tell their story', and are proven to improve patient-clinician communication (Greenhalgh et al., 2018). Therefore, in this paper, we discuss the development of an I-PROM for single-session therapeutic interventions in a digital mental health service.

Digital Mental Health Access

Digital mental health settings are increasingly being accessed, partially due to the increased need and resourcing of mental health services (Mohr et al., 2013), but also perhaps more importantly due to the increased choice, offering and flexibility that digital mental health services present (Sweeney et al., 2019). Nomothetic PROMs are not always tested or designed with the digital mental health provision in mind, and they are often reported to be alienating by children and young people (Sharples et al., 2017). Furthermore, in an online therapeutic context, service users have been shown to score higher overall on nomothetic measures than the clinical population (Mindel et al., 2021).

Within web-based therapy services, similar to what is observed in CAMHS, a large proportion of the requests from service users is for single-session therapeutic support or drop-in therapeutic engagement with practitioners at the point of seeking support (Hanley et al., 2020). This type of therapeutic engagement requires an understanding of the wants and needs of the service user at that specific time, with a focus on collaborative problem solving (Schleider and Weisz, 2017; Fleming et al., 2018; Schleider et al., 2020a,b). Single-sessions and drop-in therapy sessions can be one-off or very intermittent and differ from a structured or ongoing therapeutic engagement that resembles traditional online web-based therapy or counselling programmes with regular sessions across time with a consistent practitioner (Chorpita, 2019).

Measuring Single-Session Outcomes

Currently, there are known helpful aspects of single-session or drop-in therapeutic interventions. For example, a review by Hymmen et al. (2013) identified some of these as having the opportunity to talk about a problem, receiving helpful advice, feeling supported, being referred to other resources and having direct access to the service. However, even though there are known service user wants and preferences, there is not a sufficient outcome measurement for this type of intervention which translates these patient wants into achievable outcomes. There are limitations in measuring the outcomes of single-sessions as they are often stand-alone therapy sessions with no follow-up engagement opportunities. Within these therapeutic interventions, patients often have a specific focus, a need or aim to achieve something or find solutions; therefore, practitioners provide support or information directly related to client needs, with the awareness that an individual may only need one session to attain what they need (Dryden, 2020; Kachor and Brothwell, 2020).

To our knowledge, there are currently no suitable or specifically design outcome measures to provide evidence that single-sessions are useful to the service user. Both in digital and in face-to-face settings, there is limited feedback on whether the service user's session was useful, sufficient or even if the user decided to withdraw from seeking therapy after their first session. Therefore, developing a measure for this specific type of intervention will be useful and applicable in a range of therapeutic services.

The use of nomothetic clinical measures is not a suitable or effective measure of progress in this scenario, whereas a more idiographic assessment that measures the individual service user wants and needs enables the outcome measure to be tailored to this type of single-session which differs across service users (Haynes et al., 2009). This is a problem for all single-session intervention but can be an even larger problem for digital mental health platforms where users can be anonymous and 'drop-in' to the service intermittently. Therefore, there is an overarching need for a suitable measure for single-session or drop-in therapeutic interventions that applies both to digital and face-to-face mental health services.

Hymmen et al. (2013) identified 18 studies looking at the effectiveness of single-session therapies, yet they only found six of the studies used standardised outcomes and from those six studies the standardised outcomes selected were diverse, reiterating the need for a specifically design outcome measure for single-session therapy.

Some single-sessions and brief interventions are targeted to specific problems and common mental health difficulties like anxiety, depression or addictions (Coverley et al., 1995; McCambridge and Strang, 2004; Weersing et al., 2017), making use of symptom-specific outcome measures like the Beck Depression Inventory (BDI–II; Beck et al., 1996), Pediatric Anxiety Rating Scale (Research Units on Pediatric Psychopharmacology Anxiety Study Group, 2002) or the Severity of Dependence Scale (Gossop et al., 1995). Others take a more general approach and select outcome measures that look at overall wellbeing measuring general health and functioning for children and young people (Perkins, 2006; Perkins and Scarlett, 2008). In either case, these measures lack the immediacy of change that is required for short-term interventions and may dilute its capabilities to demonstrate emotional changes and positive outcomes. To our knowledge, only one standardised instrument, the Counselling Progress and Depth Rating Instrument (Bagraith et al., 2010; Chardon et al., 2011), was designed to report counsellor integrity for the session and it was administered in online environments, but this was designed to analyse transcripts (Dowling and Rickwood, 2013), which makes it difficult to use as a routinely collected outcome measure. Many studies in single-session interventions rely on using individualised measures like clinical interviews and counsellor feedback to monitor treatment outcomes, for instance, the use of goals (Feldman and Dreher, 2012) and structured assessments (Denner and Reeves, 1997). In their review, Beidas and colleagues (2015) identified different instruments used for treatment monitoring and evaluation, such as the Brief Problem Checklist (Chorpita et al., 2010), Pediatric Symptom Checklist/ Youth Report (PSC & Y-PSC; Jellinek et al., 1988) or the Strength and Difficulties Questionnaire (Goodman, 2001). The Youth Counselling Impact Scale (YCIS; Riemer and Kearns, 2010) may be suitable for tracking outcomes and alliance for each session, but not extensively used in single-sessions, brief interventions or digital contexts. Such findings demonstrate the lack of consensus in outcome measure use for single-session interventions. Other studies have also used standardised questionnaires that focus on the experience of the service, such as the Client Satisfaction Questionnaire (Larsen et al., 1979), or general functioning and wellbeing scales, for example, the Outcome and Session Rating Scales (Duncan et al., 2003; Bringhurst et al., 2006), in an attempt to measure the effectiveness of single-sessions (Perkins and Scarlett, 2008; Kachor and Brothwell, 2020). Overall, the variety of methods that aim to capture meaningful change or outcomes from single-sessions demonstrates a lack of consistency in such measurement and highlights the need for a tailor-made outcome measure for this type of therapeutic intervention.

The Framework for Creating a Single-Session Measure

To make a single-session outcome measure scalable, the measure needs to be rooted in the theoretical rationale for why children and young people attend single-sessions and what outcomes are achievable in a single-session. Examining common needs among the population who access single-sessions will allow aggregation of needs being met as an outcome and their wants for these sessions. Yet we aim to retain the user-centred approach to allow tailored responses from the individual alongside the common needs. This is important as these sessions are very individualised to the wants and needs of each service user (Schleider et al., 2020b).

The measure development of the session wants and needs outcome measure (SWAN-OM) was developed in conjunction with a web-based therapy service (Kooth which is a web-based digital mental health platform for Children and Young People). In 2019, Kooth undertook a Theory of Change study to examine the key ingredients of web-based support. This method was chosen to evaluate the service to reflect the non-pathologised nature of the service, to examine the wants and needs of users rather than clinical diagnoses, the evaluation described a high-outcome level matrix representing the common wants and needs often seen in the service. In consultation with practitioners, academics and service users, the study identified input, process and outcomes for distinct different elements of the service and interventions, one of which was focussed around 'responsive support', the delivery of drop-in, often single-sessions of support through chat (Hanley et al., 2020).

The Theory of Change thus helped identify some key indicators of change and impact in single-sessions, that reflected the wants and needs of users through the analysis of transcribed sessions of single-session support and drop-in, developing a framework of outcomes that are commonly seen in the service for these types of brief intervention.

From examining Kooth's Theory of Change (Hanley et al., 2020; Hanley et al., 2021), it was apparent that an I-PROM measure will be a suitable measure option. This will provide an individualised tool that explores changes in 'in-session' goals around wants and needs. Overall this measurement tool aims to provide a marker for the service user about what they want to achieve from their session and encourages reflection after their session to determine if they achieved what they wanted, providing a solution-focused framework for the single-session. A relational, person-centred measure was needed that enabled reflection of session progress, in-session goals. The measure needed to be asset-based that related to the wants and needs of the service user rather than symptom focus. This measure, along with other potential tracking outcomes, aims to be a useful therapeutic tool, providing a which can be used as a cue for a therapist when is seen by the practitioners. The use of an I-PROM for single-sessions will also facilitate routinely data collection. So aggregated data from the measure across service users can be collected for monitoring data on the analysis of this I-PROM by aggregating the scores of the common goals that you can find in the instrument, while providing the option to develop individual goals (Jacob et al., 2021). I-PROMs have increased currency especially for person-centred support service provision within children and young people population, while other measures can be used, no idiographic measure exists or has been designed specifically for single-session work.

In developing the SWAN-OM measure, there were unique demands on this measurement tool which contributed to the outcome design and methodology given the digital setting. Some of these demands may seem unique to a web-based therapy service; however, increasingly outcome measurement tools used in face-to-face services also need to be user friendly on digital technology, providing acceptable and to use outcome tools on electronic devices. This poses an additional layer of complexity when designing a person-centred outcome measure to ensure it meets digital accessibility standards and can be used in therapeutic settings. Consequently, to overcome these challenges, a unique design process was undertaken. Due to the fast-paced nature of digital settings and the importance of user acceptability and engagement with this measure, an iterative, phased approach was favoured for the development of the instrument. This took an item generation approach based on a Theory of Change for web-based therapy service, then utilised content (Zamanzadeh et al., 2015) and face validity testing (Allen and Yen, 1979; Nevo, 1985; Anastasi and Urbina, 1997; Hardesty and Bearden, 2004), to finally conduct user-experience testing to design using framework analysis (Ritchie and Spencer, 1994; Ritchie and Lewis 2003), with the focus to integrate this outcome tool into the web-based therapy service. This type of methodology aims to accelerate the process from inception-to-design-to-realisation (Honary et al., 2018) and is useful when designing for digital settings where human-computer interactions are important to examine. The rationale behind this methodological choice is that there are three critical phases to the development process: create, trial and sustain. Within each of these, there are design and evaluation elements to iteratively improve the tool of measurement following best practices (Mohr et al., 2017; Boateng et al., 2018) and taking into consideration the applied context of a web-based service. For each of these phases, we involved different stakeholders to reflect and provide feedback on the design processes. This provided the views and perspective of service users and practitioners, both of whom have experience with single-session therapeutic interventions and would have valuable insight into the acceptability and effectiveness of the new SWAN-OM instrument. This design process aims to put emphasis on the user when designing mental health outcome measures (Honary et al., 2018) and their participation.

Therefore, in this paper, we showcase the design of a novel I-PROM, the SWAN-OM. There were specific considerations for application to web-based services by using a user-centred and participatory approach for its design. Single-session and drop-in interventions in mental health services are common among children and young people when accessing these services. There is a substantial gap in how to measure these types of interventions and not many instruments designed to overcome this gap. Digital web-based mental health service adoption is increasing across populations providing an accessible way for people to access emotional support and counselling online. The use of outcome measures is proven beneficial for counselling and therapeutic sessions in general, but none of those outcome measures has been designed for a digital context delivering single-session interventions. This manuscript describes the methodologies and iterative design that researchers conducted inside a digital web-based therapy service, linking user experience with classical questionnaire development theory to illustrate the creation of the SWAN-OM in four design phases. We discuss valuable lessons learnt from this novel design process and challenges that researchers may encounter when designing instruments for web-based therapy services and digital interventions more broadly.

METHODS AND FINDINGS

To design the SWAN-OM, a four-phase design process was conducted with different data collection methods pertinent to each phase: starting with (I) item creation using domains and construct definition to determine the items within the scale. Following the creation of the individual items and the item domains, these were then tested to examine (II) content validity. This involved experts to assess the ability of the items in measuring the properties of the measured constructs. From this stage (III), face validity was examined by consulting with both service users and practitioners through piloting the instrument within the service. Then finally, of high importance when developing a measure for a digital platform is (IV) user-experience testing. This was conducted through participatory workshops in conjunction with young people who represented digital mental health service users. At each phase of development, there are iterative changes and improvements to the measure as well as the enquiry to the different stakeholders that utilise the measure.

In each of the phases, the methods used are described sequentially in sections alongside the findings that supported the methodological design of each phase. This demonstrates the iterative decisions made during the measure development.

Phase I: Item Generation

Items were generated to represent the main wants and needs of young people from single-sessions or drop-in sessions. Initially, four domains of wants and needs were identified from Kooth's Theory of Change that represent the needs for mental health support in children and young people that access the web-based therapy service (Hanley et al., 2020; Hanley et al., 2021). Such domains were also previously explored investigating the goals collaboratively set by young people at the onset of their contact with the service (Hanley et al., 2017; Jacob et al., 2020). These domains allowed to set the parameters of the constructs that the measure will be seeking to capture concerning what children and young people seek in an online service, for example, whether individuals seek informational or emotional support and whether this support was directed to support interpersonal or intrapersonal change.

These four domains (see **Figure 1**) were used alongside a framework which was derived from qualitative thematic exploration of transcripts from children and young people. Importantly for the SWAN-OM development, there was a focus on only service users who engaged with Kooth in a single-session or a brief manner over a non-specific period of time without accepting or being offered structured sessions of support (see **Figure 2**). Both the domains and the framework enabled the initial item generation. The main aims of these items within this measure were to help the young person to articulate what they wanted or needed from the session and capture if their in-session goals were met after that session.

Participants

Two researchers (female and male) from the Kooth research team took part in this phase. The two researchers knew each other and had worked on similar research projects previously. Both researchers had previous knowledge of Kooth as a service and reviewed the literature and data available on Theory of Change developed for Kooth.

Design and Procedure

Firstly, the two researchers independently coded the themes from the tree (**Figure 2**) in each domain of the outcome matrix (**Figure 1**), the coding was shared in structured meetings to achieve coherence between items, themes and domains.

The researchers reached consensus using the nominal group technique (Van de Ven and Delbecq, 1972) to resolve any discrepancies from their independent findings, raising issues and discussing the discrepancies systematically to achieve a list of coded items with the respective theme and domain from the matrix (see **Supplementary Table S1**). A combination of deductive and inductive approaches was applied for each domain and theme to generate items that reflected the theme and domain of interest. Despite some instruments with similar statements being identified through the literature review and assessment process, most of the statements were generated in an inductive manner using the transcript data generated in the thematic tree within the framework.

Each item was composed of two paired statements, the first is presented before a therapeutic session asking about the in-session goals (the service user's want or need for that session). These correspond to the domain and theme and were prompted by the overarching question; 'Why have you come to chat today?'. The second is a follow-up statement presented after the therapeutic session that aims to capture if the in-session goals (want or needs for that session) were achieved. This is captured on a 10-point Likert scale.

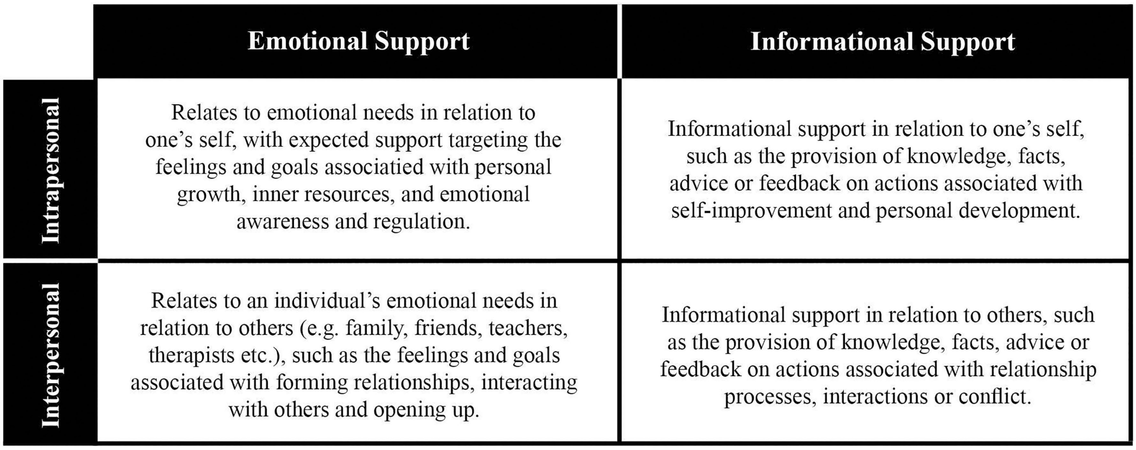
Results

A set of 46 item statements were generated for the domains and themes identified in both frameworks (See **Supplementary Table S1**). This set of statements was constructed into a pool of items used to be further validated in the next phase of development through content validity approaches and expert assessment.

Phase II: Content Validity

Validity is defined as the instrument's ability to measure the properties of the construct under study (DeVon et al., 2007). More specifically, content validity is the ability of the items to represent the domain intended to be measured (Zamanzadeh et al., 2015). Experts are often used to judge the content of the measure to determine the clarity or comprehensiveness of each item, as well as the relevance based on the domain and aim of the measure.

The aim of these workshops was to determine the extent to which the items were representative of the outcomes of single-sessions and brief interventions at Kooth defined by the four outcome domains representing the wants and needs



	Emotional Support	**Informational Support**
Intrapersonal	Relates to emotional needs in relation to one's self, with expected support targeting the feelings and goals associatied with personal growth, inner resources, and emotional awareness and regulation.	Informational support in relation to one's self, such as the provision of knowledge, facts, advice or feedback on actions associated with self-improvement and personal development.
Interpersonal	Relates to an individual's emotional needs in relation to others (e.g. family, friends, teachers, therapists etc.), such as the feelings and goals associated with forming relationships, interacting with others and opening up.	Informational support in relation to others, such as the provision of knowledge, facts, advice or feedback on actions associated with relationship processes, interactions or conflict.

FIGURE 1 | Kooth high-level outcome matrix – Domains for SWAN-OM.

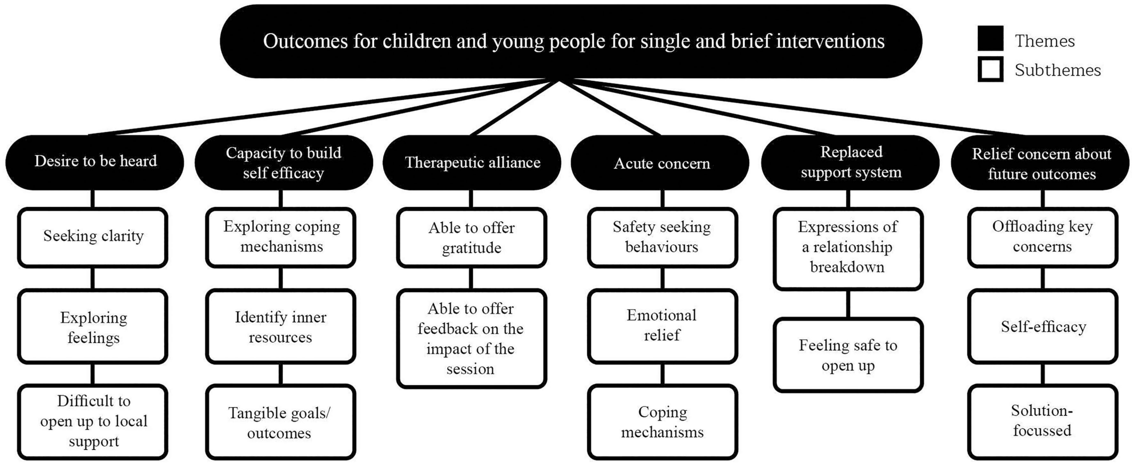


FIGURE 2 | Thematic tree for single and drop-in brief interventions in Kooth.

commonly found in users seeking online mental health support within the service.

Participants

To assess content validity, a group of eight experts from the research, clinical and product teams at Kooth was recruited. The experts formed an expert reference group (ERG). Experts were required to have previous knowledge of Kooth's Theory of Change (Hanley et al., 2020) and recognised experience within the service for at least 1 year; all experts were part of the same organisation with a previous working relationship.

Design and Procedure

Item Content Validity indexes (CVI) were assessed through an online questionnaire and a workshop with ERG members, the survey was administered in advance to the workshop to all experts who provided their CVI scores on the initial pool of items proposed and the CVI findings between experts were discussed in a remote workshop using Zoom[1] in order to make decision on exclusion, inclusion and modification of items after the ERG panel review.

Item Content Validity Questionnaire

The ERG completed an online questionnaire that asked them to rate each question on its relevance and clarity, the questionnaire contained the initial 46 items developed in phase 1 to be scored by the experts. Each question contained a 4-point Likert-scale response for both relevance and clarity (i.e. relevance responses on a scale from not relevant, somewhat relevant, quite relevant to highly relevant and clarity responses on a scale from not clear, somewhat clear, quite clear to highly clear). An open-ended text box was also provided for the experts to add comments or offer suggestions, or examples to rephrase an item.

Item Content Validity Index Calculations

The Item Content Validity Index (I-CVI) of each indicator for both relevance and clarity was calculated (calculated from the questionnaire responses). This involves calculating the sum of the experts scores for each item and dividing by the number of experts (Zamanzadeh et al., 2015). Items that scored equal to or over 0.75 on both relevance and clarity were automatically included for the next round. If both relevance or clarity received a score of lower than 0.5, the item was excluded, and if one or both items were between 0.5 and 0.75 the item was included in the list to review in the workshop.

The relevance scale-CVI/Ave (S-CVI/Ave), which is the average of the I-CVIs for all items on the scale, was also calculated for each high-level outcome matrix domain (**Table 1**). The average item quality is important to examine as we are interested in item quality, rather than the average performance given by the experts (Polit and Beck, 2006). The gold standard of acceptable CVI scores and the number of experts required to ascertain robust calculations has been hotly debated in the literature, with a recommended number of experts ranging between two and nine, and CVI between 0.78 and 1 for excellent content validity (Yusoff, 2019).

Expert Reference Group Workshops

An online workshop with the same expert panel (N = 8) was then conducted to evaluate the items which attained a low-mid I-CVI score for either relevance or clarity. An important aspect of this workshop was to also investigate the qualitative feedback that experts provided through free-text around accuracy, interpretability and appropriateness. Each item for review was re-assessed by researchers and further proposals were created for each item to present in the workshop to the ERG using the qualitative information suggested in the questionnaire. The workshop presented each item indicator once at a time for its assessment, alongside revised versions, the workshop used a polling system to ask experts whether they: wanted to keep

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[1] https://zoom.us/

TABLE 1 | I-CVI scores for each item selected from the expert workshops.

Item	Statement pre-chat	Statement post-chat	I-CVI Relevance	I-CVI Clarity
Emotional interpersonal domain				
Item 1	To feel safe to tell others in my life what is going on	I now feel safer to tell others what is going on	0.875	0.75
Item 2	To share my story with another person*	I felt comfortable sharing my story with another person*	0.625	0.75
Item 3	To feel comfortable opening up to people in my life	I feel more comfortable about the idea of opening up to people in my life	0.625	0.875
Item 4	To feel comfortable accessing support offline	I now feel more comfortable asking for support offline	1	1
Item 5	To work through some difficulties in my relationships*	I have started to work through some difficulties in my relationships*	0.75	0.375
Item 6	To be able to understand others	I was able to ask questions to help me to understand others	0.75	0.75
Item 7	To explore my problems with someone	I was able to tell someone about my problems	0.875	1
Emotional intrapersonal domain				
Item 8	A safe space to explore how I feel	I got a safe space to explore how I feel	1	0.875
Item 9	To feel better now	I feel better	0.875	0.75
Item 10	To discover how I can help myself to feel better	I can now help myself feel better	1	0.75
Item 11	To talk about something I have not told anyone before	I was able to talk about something I have not told anyone before	0.875	0.875
Item 12	To explore what is possible on Kooth	I understand what is possible on Kooth	0.875	0.875
Item 13	To be able to work out a situation I am in	I was able to work out the situation I was in	0.75	0.875
Item 14	To be ok with my feelings	I am ok with my feelings	0.75	0.75
Item 15	To feel listened to	I felt listened to	0.875	0.875
Item 16	To explore how I feel	I was able to open up about my feelings	0.875	1
Item 17	To feel in control of how I receive my support	I had a say in what we talked about	0.875	0.75
Item 18	To understand my feelings and behaviours*	I understand my feelings and behaviours better*	0.75	0.5
Informational interpersonal domain				
Item 20	Discover how to find the people who can help me	I can now identify people who might be able to help me	0.75	0.875
Item 21	To learn how to relate with others	I can identify new ways to relate to others	0.75	0.75
Item 22	To identify goals that will help me improve my relationships	I know the steps to take to improve my relationships	0.75	0.875
Item 23	To understand or improve my relationships with others	I have the tools to better understand my relationships with others	0.875	0.875
Item 24	To learn how to manage conflict with others	I now feel more confident managing conflict with others	1	1
Item 25	To identify solutions to manage my relationships*	I have identified possible solutions to manage my relationships*	0.875	0.625
Item 26	To find out how useful it is to talk to someone*	It was useful to talk to someone*	0.75	0.625
Informational intrapersonal domain				
Item 27	Some information about how to keep myself safe	I got some information about how to keep myself safe	0.875	0.875
Item 28	To find ways to help me worry less	I have found some ways to help me worry less	0.875	0.75
Item 29	To learn how to feel better	I have learned ways/skills to feel better	1	1
Item 30	Able to manage my situation better	I feel able to manage my situation better	1	0.75
Item 31	To identify ways I can help myself	I have identified ways to help myself	1	1
Item 32	To learn the steps to achieve something I want	I understand the steps to achieve my goal	0.875	0.875
Item 33	Information on how to feel more confident	I feel more confident in my abilities	0.75	0.75
Item 34	To identify a solution to a problem in my life*	I have found a possible solution to a problem in my life*	0.75	0.625

**Items reviewed from the expert workshop I-CVI reported before inclusion.*

the original version, accept revisions proposed by the researchers or remove the item entirely.

Results

I-CVI Results

The initial results from the questionnaire showed a healthy range of content validity for each item, alongside highlighting the indicators where further revision was required or excluded. Nine items were excluded as they did not meet the criteria scoring below 0.75 for clarity or relevance in the I-CVI. Ten items were identified for review with the expert panel as their I-CVI ranged between 0.5 and 0.85 in clarity and relevance to determine its change, inclusion or exclusion from the measure. From this, 26 items above 0.75 in the I-CVI for clarity and relevance were included in the measure. A further calculation of S-CVI for each domain was also conducted presenting acceptable levels of content validity for each scale (**Table 2**).

TABLE 2 | S-CVI/Ave scores for each quadrant.

	Emotional interpersonal	Emotional intrapersonal	Informational interpersonal	Informational intrapersonal
S-CVI	0.71	0.77	0.72	0.80

Expert Workshops Results

After the appropriate revisions based on the advice from the ERG workshop, the indicators were consolidated into a final list of 34 items to be included in the pilot study for the measure. I-CVI for each item relevance and clarity was calculated (**Table 1**). Twenty-seven items (79%) were marked as relevant and clear with I-CVI scores between 0.75 and 1 for both scales. Two items score below the threshold in relevance (I-CVI = 0.625) but scored highly on clarity. In addition, five items scored below for clarity (I-CVI = 0.5–0.625) but highly on relevance, these items were still included after the expert panel feedback. The majority of items scored in the instrument was considered clear and relevant; in addition to I-CVIs, Kappa scores were calculated for each item to control for agreement due to chance (See **Supplementary Table S2**). The results on the content validity indexes provided a good case to take the initial SWAN-OM to the next phase.

Phase III: Face Validity

Face validity relates to how much responders judge the items to be an appropriate measure on the constructs that the scale intended to measure (Allen and Yen, 1979; Nevo, 1985; Anastasi and Urbina, 1997; Hardesty and Bearden, 2004). Therefore, in this phase, we now move from creating the measure to piloting the measure by examining the face validity of the instrument in the context it is intended to be used in. Here, we aim to examine the appropriateness of the measure for single-session and brief interventions. The measure was trialled in Kooth (a web-based therapy service) to examine the perspective of both service users (children and young people) and practitioners.

Pilot With Practitioners

Participants

Practitioners at Kooth volunteered to participate in the pilot study (N = 7). The SWAN-OM was successfully administered to 89 distinct service users accessing Kooth service during six of piloting within the digital mental health service.

Design and Procedure

The selected 34-items developed in the content validity phase (phase 2) were trialled for 6 weeks on the Kooth platform with eligible service users (piloted on new drop-in users, with the presumption that they would only use Kooth for a single-session or a series of brief interventions).

Two initial training sessions were conducted to familiarise the practitioners with the workflow for administering the measure during therapy sessions. Practitioners administered the measure manually in the web-based therapeutic chat sessions and recorded the change score and any feedback. Following acquiring consent, the practitioners presented the text ‘Why did you come to chat today?’ and presented the four initial questions, relating to each domain: (1) I want to explore more about how I relate to other people (emotional-interpersonal), (2) I want to understand myself more (emotional-intrapersonal), (3) I want to learn some skills to try with other people (informational-interpersonal) and (4) I want information about something important to me (informational-intrapersonal). When a young person selected a response, the practitioners selected the item indicators relating to the selected domain into the chat text box. These items aim to inform the practitioner of the service users wants and needs of that specific session.

As the chat and intervention neared its end, the practitioners provided the follow-up items that matched the young person’s initial selected items. Young people then rated how much they thought the chat had achieved the item aims, on a scale of 1–10. The practitioners also note down their observations about the measure, as well as any record of any feedback ascertained directly from the young person.

Two workshops were conducted during the pilot phase: one midway through to present initial findings and gain feedback, and one at the end to present overall findings and collate any further feedback. The workshop allowed reflections by participants that were used in future phases of the measure design.

Results

Pilot Test Results Within Kooth

From the 89 distinct service users who received the measure, there were a total of 196 administrations of the measure. From this, there were 164 ‘change scores’ recorded. There were 32 instances of no score recorded (N = 15), in most cases because the user left the chat early or the connection dropped out before the follow-up was administered.

The pilot study revealed that service users were selecting indicators from the two intrapersonal domains over 91.8% of the time, with indicators in the interpersonal domains only selected a total of 16 times (**Table 3**). Over half of the participants involved in the pilot (55.6%) only selected one indicator ($n = 50$), and 33.3% of participants selected between 2 and 4 indicators (two indicators: $n = 11$; three indicators: $n = 10$; and four indicators: $n = 9$). Because there was no limit on the number of indicators a service user could select, there were several participants (N = 10) who chose over five, with 13 indicators being the maximum chosen.

The results of the follow-up ratings show early indications of young people finding the measure helpful in achieving their single-session wants and needs. **Figure 3** chart shows the frequency of response scores for those who completed the entire measure (N = 164) which indicated if their chat session achieved what they set out to achieve (initially measured in the pre-chat indicators). Only 9% of trialled participants said that their in-session wants and needs were not met (rating < 5), whereas 32% said they were somewhat met (rating between 5 and 7) and 59% responded that their session did help them achieve their session wants and needs (rating of 8–10).

Workshop Results: Practitioner and Young People Feedback

Overall the feedback was positive, with both practitioners and young people commenting that the SWAN-OM helped focus the chat and provided a framework for the conversation that

TABLE 3 | Frequency of indicators chosen within each domain.

Domain	Count of indicators selected	Frequency (%)
Emotional interpersonal	9	4.6%
Emotional intrapersonal	119	60.7%
Informational interpersonal	7	3.6%
Informational intrapersonal	61	31.1%
Total	196	100%

Total (N = 196) represents 89 distinct service users, choosing on average, 2.3 indicators each.

easily allows for exploration of a topic in session. Other positive feedback from young people was that the questions were informative and interesting, it helped them generalise their thoughts and feelings into achievable wants and goals, and could be used to quickly build trust with their practitioners.

One of the most interesting, and pressing, findings of the pilot was the disparity between domain selection, with less than 10% of service users selecting indicators in the interpersonal domains. Upon reflecting on these results with the practitioners in the workshops, it became evident that this might not be a true reflection of the needs for those seeking brief support in the service, for instance, many young people come to chat to discuss problems with their relationships despite choosing an intrapersonal domain indicator. One of the reasons why this might not be reflected in the results is because of the wording of the initial interpersonal questions: 'I want to learn some skills to try with other people' (informational-interpersonal) and 'I want to explore more about how I relate to other people' (emotional-interpersonal). Some of these initial findings were used to construct the activities for the usability testing phase with children and young people in phase 4.

Phase IV: Usability Testing

To sustain the digital use of the measure, it has to be suitable from a user-experience (UX) perspective but also be digitally feasible (i.e.: presentable on different digital screens). Workshops with young people (focus groups and surveys) were conducted to explore the usability of the measure and its design. Workshops and usability testing exercises were done iteratively with different groups of young people, refining the instrument and goals for each workshop. Formal and more informal systematic methods of data collection are used during this phase, serving different purposes and formative goals for the creation of SWAN-OM in a web-based environment.

Remote Workshops and Surveys With Young People

Participants

For the workshops, young people were recruited from external mental health advisory and patient representative groups who had experience using mental health services. All participants were presented with an information sheet and gave informed consent. Each group had between 2 and 8 participants ($n = 38$, female = 31; male = 7) ranging from 14 to 24 years old (representative of Kooth's service users). Sessions were virtual but not video recorded, but field notes were taken in all workshops for transcription. Workshops lasted on average 50 min and all participants received reasonable monetary reimbursement of £15 for their participation.

The acceptability survey was administered to children and young people recruited from Kooth (N = 8) of which 50% were female (N = 4), 25% were male (N = 2), 12.5% were agender (N = 1) or preferred not to say (N = 1) with an average age of 16 (Range = 14–17, SD = 0.99). Young people came from varied backgrounds with five from a white British background, two from a mixed background and one from an Indian background. Both ethnicity and gender were self-reported variables in the survey.

Design and Procedure

Nine workshops were conducted in total. These were all remotely done over Zoom (see footnote 1) using Miro, an interactive board software[2] to present and guide the activities with the participants. The main aims of the workshops were to address outstanding questions, such as: how to categorise the reactive measure statements (domains vs. themes – see open and close card sort activity below), how to reduce the number of statements, whether the wording was clear and understandable, and how to best display the flow of the measure on Kooth as a platform. Open Card Sorting Workshops. Three of the nine workshops focused on open-sort card activities with young people (N = 13). Card sorting is a user-centred design methodology that helps to discover how users find information in a system (Fincher and Tenenberg, 2005), open card sorting presents no constraints on the activity and allows participants to group the statements freely (Righi et al., 2013).

Participants were given a set of cards representing the initial piloted 34-item statements from the measure, participants were then asked to group and sort the cards in an appropriate way. The final groupings in each workshop were formed through consensus between participants, facilitators delivered instructions that summarised main findings from the workshop and enabled reflection on the points that summarised the workshop findings and a final round of instructions solved conflict to reach agreements between participants discrepancies. Each grouping from the workshop findings was then described by the participants to ascertain meaning that was noted in the boards of each workshop, voting was not needed as participants tended to converge into agreements within workshops. We used the workshop field notes and observational findings to reduce the number of statements and change the wording of those that were highlighted as problematic or difficult to understand during the activities.

Workshops were also used to explore the appropriateness of the four higher-order domains (1. Emotional; 2. Informational; 3. Interpersonal; and 4. Intrapersonal). After these workshops with young people and the earlier workshops with experts, six themes were formed in which the statements were categorised as: (1) 'To understand the help I can get'; (2) 'To share my

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[2] https://miro.com/

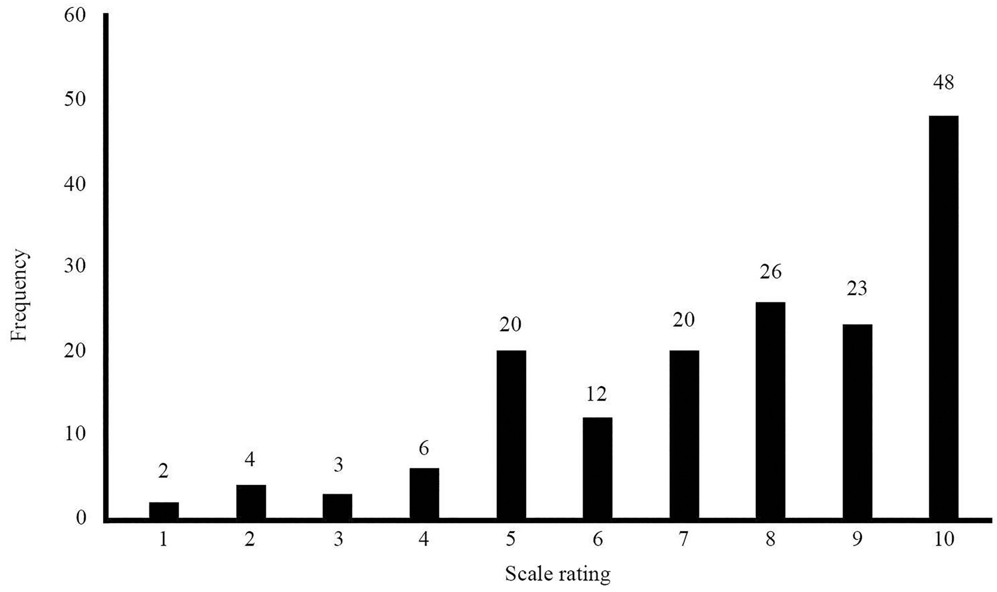

FIGURE 3 | The distribution of response scores to the post-session SWAN-OM on the scale 1–10, where 1 = strongly disagree to 10 = strongly agree.

story with someone'; (3) 'To set and achieve goals'; (4) 'To explore my emotions'; (5) 'To improve my relationships'; and (6) 'To learn ways to cope'. These themes were later one used on closed card workshops to determine the items that best fitted the themes.

Closed Card Sorting Workshops. Two of the nine workshops ($n = 10$) used closed card sort activities. Closed card sorting activities constrain the users to enable constructs or categories to be tested (Righi et al., 2013). Therefore, in these workshops, six categorical themes which were predefined from the open card sorting and expert workshops were presented to participants: (1) 'To understand the help I can get'; (2) 'To share my story with someone'; (3) 'To set and achieve goals'; (4) 'To explore my emotions'; (5) 'To improve my relationships'; and (6) 'To learn ways to cope'. Participants were given a set of cards representing the initial piloted 34-item statements from the measure and asked to group them into the six categorical themes. Similarly, to in the open card sorting workshops, for the closed card sorting, the item allocation to themes in each workshop was formed through agreements between participants, item allocations were summarised at the session and facilitators enabled reflection on the main findings and solved conflict to reach consensus facilitators used robin rounds to all participants to encourage participation on the main points summarised from the workshops and note each participant opinion.

From the closed card sorting workshops, we found that participants were able to differentiate between intrapersonal and interpersonal wants and needs from the domains of the instrument. Participants addressed the themes as more accessible and understandable than the domains. The themes were perceived as appropriate by participants, one participant quote from one of the closed card workshops reflected this: 'I quite like them [themes], I think it cover most of the options, and the write up option, makes me feel that Kooth is trying to get the best of the young people', participants discussed the appropriateness of the themes for covering universal needs and wants from people accessing mental health services for the first time, it also provided with further evidence on the importance of individual personalisation of outcomes for single-sessions.

Acceptability Survey. The aim of the survey was to complement the evidence and iterative changes to SWAN-OM from the open and closed card sorting activities. The survey was used to provide clarity around the acceptability of the statement wording and receive qualitative feedback about each of the final statements. A Likert scale 0–10 (0: Bad wording; 5: Nor bad nor good; and 10: Good wording) presenting each of the reduced statements (20 remaining items) was used to explore any problems with the final wording of statements. The survey also asked young people to explain their understanding of their statement in an open-ended question ('Tell us your opinion about the statement') and a multiple-choice question presenting the 'themes' to select under what category they think the statement fitted best.

Qualitative Analysis of the Workshops

Each workshop's field notes were transcribed and analysed using a deductive framework analysis approach (Ritchie and Spencer, 1994; Ritchie and Lewis 2003); qualitative exploration of each collected field notes (N = 25) was used, this qualitative method allowed enough flexibility to analyse this type of data. A matrix was developed establishing deductive 'themes' that were of interest for the study: (a) Domains as an intuitive way to understand support for young people and Establishing new themes (or ways) to group statements; (b) Suggestions for new statements; Reduction of statements; and Comments about wording.

The content of the field notes was coded and analysed by two Kooth researchers with no previous relationships with participants. Researchers familiarised themselves with raw data and provided the framework of exploration for the *a priori* defined questions of interest about the measure (Srivastava and Thomson, 2009). Extracts from the field notes were identified, coded and indexed within the framework, data from each workshop were charted to present the information in the matrix and summaries of all workshops were created for each theme. The findings were presented to the workshop facilitators to ensure the interpretations were grounded in the experiences of participants.

Results

Quadrant and Theme Exploration. Participants unanimously agreed that categorising the statements by 'themes' was perceived as less difficult than categorising by the domains. For example, comments from participants like 'they are all [statements] about accepting your emotions, exploring feelings and being ok' provided information to create a 'theme' named 'Exploring my emotions', while other comments, such as: 'these statements are about finding out how to get support on Kooth and staying in control' exemplify how the theme 'To understand what help I can get' was created, other themes like 'To learn new ways to cope' arose from the work with young people in the workshops 'They're all [grouped statements] about identifying a problem and managing it: how to fix things and get what you want. [Participant E] suggested the term "coping with your problems"', coping seemed to resonate with participants in different workshops and be part of the lexicon of young people when looking at statements from the measure one participant said, 'Maybe you can group something together about coping mechanisms or self-care'.

This provided enough evidence to discard the quadrants as a way to display and organise the statements and favour the use of 'themes' in the measure as an intuitive way to display and group the statements. These themes were taken into the closed card sorting exercises to be tested.

TABLE 4 | Average score for each item's survey acceptability.

Statement	Average	SD
To feel safe in my relationships	7.25	1.11
To be able to open up to people in my life	8.50	0.95
To be comfortable asking for help outside Kooth	7.88	1.77
To explore difficulties in my relationships	7.38	1.40
To talk about something personal to me	7.00	2.14
To feel better	7.75	2.21
To explore how I feel	7.38	1.62
To feel listened to	7.63	1.99
To be more comfortable with my feelings	7.00	1.41
To learn how to relate to other people	6.88	1.63
To learn how to manage conflict with others	7.75	1.57
To identify solutions to improve my relationships"	6.75	2.82
To find out how helpful it is to talk to someone	6.50	2.41
To learn how to feel better	7.88	1.35
To identify a solution to a problem in my life	7.75	1.90
To learn the steps to achieve something I want	7.13	1.83
To identify ways to help me worry less	7.88	1.35
To find ways I can help myself	7.25	1.38
To find information about how to keep myself safe	8.38	1.50

The average represents the mean score on a scale of 1 to 10, with SD representing the Standard Deviation.

Reduction of Items and Changes to Item Wording. The original 34-items produced for the measure were identified by product developers and designers as too overwhelming and lengthy for a digital environment. Observations in the open and closed card sorting workshops were captured surrounding relevance, confusion, ambiguous meaning or similarities between items perceived by participants. Some items were identified as being too similar to each other, making the case to reduce the total number of statements by combining some. This was reflected in comments, such as 'To identify solutions to manage my relationships' and 'To identify goals that will help me improve my relationships', which are very similar. This led to the development of a new item 'To identify solutions to improve my relationships'. When tested, some items were misread or confused, these items were therefore clarified. Some items were about ambiguous concepts, for instance, 'safe space' was perceived as very subjective by young people: 'safe space is a bit vague, it has many possibilities'. Therefore, the original statement 'A safe space to explore how I feel' was revised into 'to explore how I feel'.

As a result of the card sorting workshops, a final number of 20-items were kept or amended out of the original 34-items.

Acceptability Survey Results. Overall young people understood each of the statements (**Table 4**), with the average level of understanding of all statements being ranked at 7.54 (SD = 0.53). These results help to provide further evidence on the changes that the measure experience after the iterative changes of usability testing.

The open-ended question responses were assessed for each statement to determine whether the overall opinion for each statement was positive, negative or neutral. A Fleiss kappa was computed to assess the agreement between three raters in the perception of the statements. Fleiss' Kappa showed that there was a fair agreement between the three randomly selected unique rater's scores, K = 0.23, $p < 0.001$. Thus, we can conclude that the young people had moderate positive opinions on the item statements.

Participants generally agreed that the measure would be acceptable and useful to young people. For example, one participant said 'I like that it's down to the point though and tells you in simple terms what practitioners want'; another commented that it 'definitely was not overwhelming'; and another said they thought it was 'really good because it might help to organise your feelings'. Some of this feedback collected in the survey open-ended questions synthesise the goals and aims for the SWAN-OM as an I-PROM measure of single-session that is adequate for young people accessing a web-based mental health service.

DISCUSSION

In this paper, we discuss a novel method to design an outcome measure within a digital therapeutic setting for single-session therapeutic support. With this research, we aim to highlight the strengths of designing outcome measures with a digital context in mind and the value of engaging in iterative design from item generation and reduction to usability testing and participant engagement. Here, we discuss the key elements of the design process as well as our lessons learnt and limitations and strengths of this design.

Single-sessions and brief interventions are being increasingly used to provide therapeutic support and have been seen to be an effective method of therapeutic support (Schleider and Weisz, 2017). However, there are limited ways to measure the impact or benefit of these interventions, especially at scale. Importantly, a fully nomothetic or clinical symptomatic-based outcome measure is not suitable for this type of therapeutic intervention, as discussed in the introduction to this paper, we would not expect a change in symptomatology directly after one therapy session. I-PROMs, however, are useful as they align more with patient-perceived progress rather than measurement being centred around the clinician perceived symptomatic progress (Collins, 2019; Flannery and Jacob, 2020) but still allow for aggregation of scores. Therefore, we identified that this style of measures is particularly appropriate for measuring outcomes from single-session or drop-ins as they are commonly informative, asset-based and solution-focussed (Dryden, 2020; Kachor and Brothwell, 2020). It is therefore critical to align a novel outcome measure being designed to the type of intervention to appropriately assess and measure outcomes. Consequently, in this paper, we described the method of designing a new, digitally enabled I-PROM for single-session therapeutic interventions that directly measures service user wants and needs as they enter their therapeutic chat session.

Developing an instrument with pre-session item selection and post-session measurement of wants and needs for single-session, provided the most suitable method of capturing outcomes from the intervention. The novel combination providing common wants and needs alongside a free-text option enables the alignment with the expected outcomes from this type of person-centred therapeutic intervention. The instrument provides the flexibility for both users who come with individualised specific needs, as well as those who need guidance to structure their needs and wants for a single-session. Specific considerations were taken around the wider implications of designing an effective instrument for young people in the age of digital technology and the move to web-based therapeutic chat sessions, such as the sessions delivered at Kooth. The key stages of developing this digital person-centred measure were item creation, content, face validity and usability testing. We took an iterative design process to enable small but substantial changes to the measure to be made to ensure usability, clarity and accessibility of the measure (Mohr et al., 2017) for young people in a digital web-based therapy service. The ongoing aim is that the SWAN-OM can be used not only in the tested service, but also in wider web-based and face-to-face services that utilise computer-based outcome measures but that are importantly aligned with person-centred therapeutic support and offer single-sessions.

As the SWAN-OM has been designed in the long term for a range of services, it was important in the design process that experts, practitioners and service users were involved in the development of the measure, both in relation to the items and measurable constructs, but also the experience of using the measure and its therapeutic application; hence, we put users and main stakeholders at the centre of the design process (Honary et al., 2018). This led to an agile way to design particularly suited to the development of measures for a digital or technology-assisted therapeutic service, combining classical methods of survey development and novel methods of participatory research to achieve an optimal user experience.

Overall the current feedback from both practitioners and young people throughout the design process provided positive comments about the SWAN-OM, saying that it helped focus the chat and provided a framework for the conversation that easily allows for exploration of a topic in a single or drop-in session. Other positive feedback from children and young people was that the questions were informative and interesting, it helped them generalise their thoughts and feelings into achievable goals and could be used to quickly build trust with their practitioners.

From the current pilot and usability testing, we obtained positive feedback and rich qualitative evidence for the feasibility and accessibility of the measure. However, when using the SWAN-OM there could be an effect of social desirability on SWAN-OM outcomes. As young people provide agreement ratings of how much they achieved what they wanted from their session with a practitioner, there may be a social pressure to positively rate their outcomes. In the digital therapeutic space, this may be less challenging to overcome than in a face-to-face therapeutic environment where the young person is identifiable and in a room with a practitioner. There is, however, some evidence to suggest that on wellbeing scales, social desirability bias only has a modest effect (Caputo, 2017). Yet it is still a consideration to take forward into future validation studies and iterations of the SWAN-OM design.

We have established some lessons learnt that illustrate the benefits and challenges of designing a novel outcome measure in a digital environment. In the item, generation phase where we developed a set of statements that are responded to before the chat which represents the wants and the needs for young people an understanding of the therapeutic outcomes of single-sessions was crucial. Previous work conducted with Kooth on their Theory of Change (Hanley et al., 2021) was instrumental in determining expected wants, need and outcomes of single-sessions (Hanley et al., 2021). This then enabled an initial item generation which mapped into Kooth's Theory of Change quadrants as main domains or constructs of the measure. Starting from a wider set of items enabled a systematic reduction of item statements through using content validity indexes and engaging with experts. This allowed us to evaluate the quality and relevance of items at an early stage. We found that researchers and designers may find it difficult to otherwise engage with the reduction of the item statements. Use systematic methods for reduction by using content validity indexes, and early engagement with an ERG may help to reduce bias and accelerate the design and development process of the instrument.

It is important to test the reduced number of items for face validity with a pilot within the web-based therapy service Kooth. From doing this, we were able to evaluate within the design process the acceptability of the SWAN-OM to service users and practitioners. Piloting the instrument in the relevant context is of key importance to get initial findings on the instrument scores and scales, as well as to examine outliers in answering the measure. In a digital context, software engineering and product developer's perspective need to be considered, how the measure will look from a UX perspective and the technical requirements that the instrument will need to be successfully implemented in the service. For the SWAN-OM, regular workshops while piloting involving the software engineering teams and developers enabled us to capture their views and technical preferences while inform them of the practitioners' feedback and research findings that contribute to the next phase of measure development.

The usability phase requires direct engagement with the population of interest, remote workshops can be a useful tool to overcome some barriers of access to the population that may be difficult to reach due to locations or time constraints. We recommend engaging experts by experience, as they can provide further insights into the frustrations and difficulties that service users face in their usual care. Different data collection tools can be used within the workshops and they may serve to gain insights on the design and wording of the tool and its statements, it is important to design workshops that are engaging for participants, and be open to change activities and purpose as research questions on testing may change as findings develop from each workshop iteratively. This type of engagement, though highly beneficial to agile outcome measure development, does lead to constraints in measure evaluation and this is something that needs weighing up throughout the process. As this measure development was conducted in an applied setting the iterative analysis of qualitative findings may influence some bias in the findings, but we hope this paper has demonstrated the benefit of this phased approach to develop an instrument and how to overcome some of the challenges that the researcher will find in similar contexts when developing an outcome measure aiming to demonstrate validity.

An important link to the type of therapeutic sessions the SWAN-OM provides measurement for is that they are single-sessions or drop-in session in which is assumed the service user may not come back for follow-up. Therefore, as the SWAN-OM is intended to act as an I-PROM, the instrument provides a mechanism for the service users to focus and reflect on what they would like to achieve in that session without having to respond to all items, in addition, to provide choice by selecting a 'want' or 'need' of their own if required. This makes the measure quick to complete and very tailorable to individual needs but may compromise the structural validity of the instrument. Articulating wants and needs relating to mental health and emotions is difficult especially for children and young people who may not have the mental health literacy or experience using emotionally descriptive language (Burns and Rapee, 2006) to self-direct these important conversations in chat. Consequently, design decisions with the SWAN-OM development resulted in providing six initial themes that allowed the service user to narrow down what they want to focus the chat on and then select up to three specific items within the selected themes, those items are representative of common wants and needs often seen in the service population. This decision to have a two-phased pre-session measurement, by providing initial themes and sub-theme items allowed a more natural display of the statements in a digital environment. This is intended to reduce the cognitive load on the service user (Sweller, 2011) and importantly avoid potential distress when presenting all statements at once. This design decision also allowed the measure to meet digital platform accessibility standards (WCAG 2.1, 2018).

There are drawbacks to the SWAN-OM being a two-phased, logic-dependent measure as not all items will be presented to all service users. Items are presented based on the themes chosen by the service users. There is no limit on the number of themes they can select but there is a limit on the number of item statements service users can select. This structural design makes it difficult to test psychometric properties of the SWAN-OM in a traditional way, such as factorial analysis, but concurrent and structural validity will still be examined in future studies relating to the ongoing development of the SWAN-OM and its novel structure as an I-PROM. The structural design of outcome measures needs to be considered especially in digital environments with flexibility around how the measure is presented. We recommend thinking about the knock-on effects of these decisions should be considered in advance, especially when designing later validation studies to determine what psychometric properties should be prioritised during the design and development process of the instrument, like the structure or dimensions of the instrument can be compromised.

Directly related to the design decisions and critical to the development of the SWAN-OM was the participatory approach. Involving children and young people in the conceptual and physical design and involving experts and practitioners from inception. This participatory approach ensured that the measure was usable, desirable and feasible to be implemented in a digital web-based therapy service. For example, by working with the practitioners from Kooth, we narrowed down the numbers of items service users can select to three items. This number was chosen to ensure that the young people's expectations of the session were managed and that their wants and needs were attainable as service users may have wanted no limitation in the selection of statements as their chat expectations to differ from practitioners and their capacity to meet those wants and needs. Young people also suggested adding a free-text option where children and young people can write their own bespoke 'want' or 'need' which their practitioner will get to see before the session. This importantly provides a space for service users to write bespoke session wants or needs that may not fit into the themes or statement options that SWAN-OM provides, even though these are relatively broad by design this ensures a person-centred approach to measure and maintains the idiographic nature of the instrument. An interesting and vital study will be needed to explore the wants and needs of the service users free-text responses. It will be useful to explore whether free-text responses align with any of the items commonly presented in the instrument and if there are underlying repeating themes there that might suggest other items needing to be added to the SWAN-OM or further domains are yet to be discovered representing the wants or needs of users accessing a web-based therapy service in a single-session fashion. Additional analysis and exploration into the use of the measure may inform and modify the SWAN-OM further and this demonstrates the value of reflection and iterative design in developing outcome measures.

In the development of outcome measures, in particular digital measures where the service users and practitioners are not in the same physical space, there is increased importance on using participatory involvement in the design to test the appropriateness of items and increase engagement with the measure before this is used more widely in therapeutic sessions. On the whole, the young people in the participatory workshops felt that the items were broad enough but still dealt with common issues facing young people; for example, we received comments from the workshops that the statement 'To learn how to feel better' was said to be 'A broad statement that directs the person towards coping techniques and advice' and in response to the statement 'To feel listened to' a young person commented that 'this is an excellent statement and very clearly outlines a problem that many young people face today where they aren't listened to and can easily let people give specific advice to the young person'. The young people who provided feedback in the workshops around the pre-session theme selection stipulated that this made the process less overwhelming for the children and young people to use and determine what they wanted or needed from a therapeutic chat session. Young people provided valuable feedback on the item statements as well; for example, 'To explore how I feel' rendered positive comments from participants, such as: 'This is a useful topic, and the statement is direct, while still covering many topics'. Additionally, young people stated that when service users select a statement, such as this 'they want to learn more about how they feel' is a useful item as 'sometimes it's hard for yourself to know that', and this statement allows them to therefore express this to the practitioner. This feedback is encouraging and combined with the pilot trial data from the face validity phase suggest the SWAN-OM measure is usable and acceptable for single-session therapeutic interventions from the viewpoint of the young people, who represent the age group of the service users who would use this instrument. Despite some participants of the workshop were neurodivergent, further research specifically targeting neurodivergent groups, such as dyslexia, autism spectrum and other conditions, may bring further insights on the interpretation of wants and needs displayed in the instrument, individual differences within these populations may influence the variability of scores and influence understanding and interpretation of the statement reducing effeteness. Working with neurodivergent populations may address other accessibility issues, some of them were raised in the workshops by participants, such as not having time pressure to complete the instrument, having the option to skip and to personalise the statements to tailor the session to the individual.

Using an iterative design process was beneficial to the development of the digital measure. However, it is difficult to work across practitioners, young people and software engineers who are building the measure. There can be some competing needs from these stakeholder groups, the software engineers and product managers may have specific needs for the measure to be accessible on a range of digital devices, whereas practitioners want something that aligns with their practice and service users are seeking a measure that helps them and can feel identified with while being easy and quick to use. This led to changes in the SWAN-OM, for example, there was a change from a 10-point scale to a 5-point scale to increase the compatibility on digital devices. Interestingly, some changes like this converged with feedback from the young people, here, they reported that the 10-point scale was too overwhelming and a 5-point scale was more intuitive. This is in line with prior literature, particularly into how younger children engage with Likert scales (Chambers and Johnston, 2002). Primarily children have been seen to engage in Likert scales with 3 and 5 points very similarly (Chambers and Johnston, 2002). Other research also shows similar responses across different scale lengths (Taherdoost, 2019). It is worth noting that using scales with 7–10 point ranges produces more reliable responses and more information from the respondents (Taherdoost, 2019). Nevertheless, it is important to balance scale reliability and response criterion validity with scale accessibility with the children and young adult audience in mind. This is particularly relevant as the younger service users engaging with the measure will be only 11 years old. It was, therefore, important to listen to the young people's feedback which is consistent with this, and given the information on the lack of change in responses due to scale length, we decided this was a valid change to make to the measure.

There was also converging feedback from service users and product developers for the change from quadrants to six themes. This highlights the need to be responsive in outcome measure design as even if the theoretical structure maps nicely to quadrants, if this is not intuitive or understood by the service users and only two quadrants are being selected from a product and measurement perspective this is not an effective tool. Ergo, even though there are varying needs from these participatory groups, the outcomes from the steering and feedback provide a more accessible and user-centred measure that aligns as an I-PROM. The iterative design process used allowed for changes like this to the instrument, without SWAN-OM being re-designed or halted in progress, the use of systematic methods for questionnaire development from psychometric literature (e.g. I-CVI) was also helpful to continue validating the changes made since foundation (Rattray and Jones, 2007).

Yet as discussed there are several limitations to be considered and this paper importantly represents the early development of a measure for the specific context of Kooth, which is the digital platform in which the measure was designed with the service in mind. This limits the generalisation of our findings beyond the relevance of this context and potentially the measure. Despite digital mental health services growing, transferring this tool and findings to other digital services or face-to-face services presents challenges that are beyond the scope of this paper. Of importance to note here, the nature of the constructs and domains and the purpose of the tool are yet to be examined in more detail and investigate the relevance of SWAN-OM measurement to person-centred outcomes and preventative interventions, and if those are aligned with the solution-focused approaches for single-session and drop-in interventions that take place at Kooth. Goals and idiographic measures can also be difficult to interpret and aggregate as a proxy of mental health improvement or goal achievement, as well as determine the thresholds for meaningful change statistically.

The next steps are to validate the SWAN-OM by comparing them to other measures, such as the Positive and Negative Affect Scale (Watson et al., 1988) to explore the immediate short-term emotional changes as a result of the intervention, the Experience of Service Questionnaire (Brown et al., 2014) to explore the experience and satisfaction with care and the YCIS (Riemer and Kearns, 2010) to evaluate the quality of the processes and intervention. These instruments will aim to test the concurrent validity of the SWAN-OM following the Donabedian framework (Donabedian, 1988) for quality of care. For this, the SWAN-OM will be implemented at Kooth Children and Young people's service as a routinely collected outcome measure for drop-in and single-sessions within the service. This will allow us to understand if the SWAN-OM outcome scores align with changes in emotional states before and after a chat session alongside with young people's perception of session satisfaction and positive impact. This future research will also provide further evidence about the instrument validity and may spur reduction of some statements that are not frequently selected within the service, transforming the measure. Moreover, future research should be exploring the transaction from a digital context to a physical context to find out the usability of the SWAN-OM across mental health services as a valid outcome measure for single and drop-in sessions for young people beyond the web-based therapy service Kooth.

In conclusion, the SWAN-OM development and design process demonstrate the complexities of designing an idiographic outcome measure for (1) digital settings and (2) for single therapeutic or drop-in sessions. In this research, we demonstrate a route to measure creation that is both integrated into a digital platform but also aims to apply to other digitally enabled settings, such as face-to-face therapeutic services, that offer single-session or drop-in services. The phased approach demonstrates the value of using theory and research literature to drive item generation and content validity of an outcome measure but also highlights the importance of the participatory research that involves stakeholders, such as experts, practitioners and more importantly young people, in shaping the design of the instrument and improve its face validity and usability as a patient-reported outcome that is user-centred and person-centre. This development process that is iterative and responsive to feedback and needs of the stakeholders from whom the measure is used causes limitations for a systematic design process and research methodologies and may add complexities for further validation stages to demonstrate good psychometric properties. Nevertheless, this phased approach enabled a more usable and appropriate outcome measurement for the targeted intervention, where none of the previously used instruments in the literature aligned with. We hope SWAN-OM will pave the way for accelerated digital outcome measure creation, filling the gap to measure single-session and drop-in interventions in children and young people. But also to motivate fellow researchers to embark on participatory approaches to the design, validate and identify appropriate outcomes measures that demonstrate the value and therapeutic potential of single-session and drop-in therapeutic contacts in the children and young people population.

DATA AVAILABILITY STATEMENT

The raw datasets presented in this article are not readily available because they contain information that can compromise the privacy of the research participants. Requests to access the datasets that support the findings of this study should be directed to research@kooth.com, upon reasonable request.

ETHICS STATEMENT

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964 and its later amendments. Ethical review and approval were not required for the study on human participants in accordance with the local legislation and institutional requirements for service quality improvement. Written informed consent to participate in this study was provided by the participants' legal guardian/next of kin.

AUTHOR CONTRIBUTIONS

SG and AS contributed to the conception and design of the study. LS and SG co-first authors organised the database, performed the analysis, wrote the first draft, and contributed equally to the manuscript. TH and AS wrote sections of the manuscript. All authors contributed to manuscript revision, read, and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyg.2021.748145/full#supplementary-material

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Keeping Connected With School: Implementing Telepresence Robots to Improve the Wellbeing of Adolescent Cancer Patients

Thomasin Powell[1], Jennifer Cohen[1,2] and Pandora Patterson[1,3]*

[1] Canteen Australia, Sydney, NSW, Australia, [2] School of Women's and Children's Health, University of New South Wales, Sydney, NSW, Australia, [3] Faculty of Medicine and Health, The University of Sydney, Sydney, NSW, Australia

Background: Adolescent cancer patients experience considerable absence from their education, contributing to poorer academic attainment and isolation from peers, and impacting wellbeing. Telepresence robots have been used to support the educational and social needs of young people with chronic illness. This article presents the results of the development and pilot-testing of a telepresence robot service in schools for adolescent cancer patients – the TRECA (Telepresence Robots to Engage CAncer patients in education) service.

Methods: Phase I used semi-structured interviews ($n = 25$) to assess the views of patients, parents, schools and clinicians on the benefits, acceptability, barriers, and enablers of utilizing robots in schools for adolescent cancer patients. Results from Phase I informed the development of the TRECA service. Phase II used semi-structured interviews ($n = 22$) to assess the implementation experiences of adolescent cancer patients, and their families, schools, and keyworkers who pilot-tested the TRECA service.

Results: Phase I demonstrated the need for telepresence technology in connecting adolescent cancer patients to school. Given the variable support during treatment, a telepresence robot service was considered an acceptable method of facilitating a school-patient connection. The recommendations provided in Phase I, such as the need for provision of ongoing education, training, and support to the patient and school, informed the development of the TRECA service. In Phase II, the themes of *The necessity of stakeholder buy-in*, *A facilitator of meaningful connection*, and *One size does not fit all* were generated. The TRECA service's flexibility in meeting the needs of its users helped facilitate meaningful connections. Participants reported that these connections provided patients an enhanced sense of agency and wellbeing. The importance of stakeholder buy-in and taking an individualized approach to service delivery were also highlighted. Stakeholder miscommunication and lack of knowledge were key aspects of implementation needing improvement as the service is rolled out on a larger scale.

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Cristina Costescu,
Babeş-Bolyai University, Romania

Reviewed by:
Csilla Horvath,
Radboud University Nijmegen, Netherlands
Angela Page,
The University of Newcastle, Australia

***Correspondence:**
Pandora Patterson
researchteam@canteen.org.au

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Conclusion: Using telepresence robots to connect adolescents to school during cancer treatment was regarded as highly acceptable, facilitating peer and academic connection. By making stakeholder-recommended improvements to the TRECA service's existing processes, the service will continue to grow in effectiveness and capacity.

Keywords: telepresence, robots, adolescent, cancer, education

INTRODUCTION

The Impacts of Illness and Cancer on Adolescents' Education

Illness can have a significant impact during adolescence as the young person and their family face the acute and long-term stressors of diagnosis, treatment, and condition management (Compas et al., 2012). In adolescents facing illness, an area that can be markedly affected is the ability to attend and engage with school. Compared to healthy peers or population norms, chronically ill students experience higher rates of absenteeism (Lum et al., 2017, 2019). They are also almost four times as likely to have academic challenges than healthy peers (Lum et al., 2019). Furthermore, greater illness and treatment side-effect severity have been associated with poorer academic performance, grade repetition and reduced educational attainment (Lum et al., 2017). Beyond academic outcomes, illness can also significantly impact students' psychosocial wellbeing. For instance, chronically ill students are more than twice as likely to be experiencing moderate to high levels of emotional distress, and almost five times more likely to have low social confidence than their peers (Lum et al., 2019).

Young people with cancer experience even more absences from school than those with any other chronic condition (Vance and Eiser, 2002). A diagnosis of cancer during adolescence can significantly interfere with an adolescent's quality of life in all spheres, including physical health, social support, wellbeing and self-perception, and the family environment (Kim et al., 2016; Penn et al., 2016). Although cancer experiences can vary widely, young people often experience long and difficult treatment periods with side effects such as reduced physical energy, changes in physical appearance, and pain and discomfort (Kim et al., 2016; Penn et al., 2016). This can result in long periods of recovery spent in hospital or at home (Penn et al., 2016). Consequently, many young people have prolonged or frequent periods of absence from school (Tsimicalis et al., 2018), which can lead to poorer academic attainment (Bonneau et al., 2011) and impact friendships (Barrera et al., 2005; Winterling et al., 2015). Survivors of childhood cancer are also more likely to need to repeat a school year compared to siblings (Bonneau et al., 2011) and matched population controls (Barrera et al., 2005), with diagnosis occurring during secondary school being a risk factor (Barrera et al., 2005; Bonneau et al., 2011). Feelings of loneliness and isolation from their school community and peers are also common for young cancer patients (Searle et al., 2003; Boles et al., 2017), along with experiencing anxiety about reintegrating with their peer network at the end of their treatment (Pinquart, 2017; Collins et al., 2019). Bullying is additionally a risk factor when they do return to school (Choquette et al., 2016).

Educational Support for Adolescents With Cancer

Given the social isolation experienced by chronically ill students, it has been suggested that schools complement academic support with additional practices focused on supporting patients' general engagement with school and promoting a sense of belonging (Leigh et al., 2016; Lum et al., 2017). Indeed, research suggests that maintaining regular contact with peers during periods of absenteeism may facilitate a smoother transition back into the classroom and schoolyard (Choquette et al., 2016). This regular contact enables young people to feel more positive about being in school and reduces apprehension about their return (Wilkie, 2012; Zhu and Van Winkel, 2014). As such, programs and services that connect young patients to the school environment whilst they are unable to attend in-person may improve wellbeing whilst they are away and protect against some of the negative outcomes of absenteeism. Given the physical, social, psychological, and academic impacts, it has been suggested that an integrated and multidisciplinary approach involving teachers, healthcare professionals, psychologists, and the family should be taken when schools support a student with a chronic illness such as cancer (Shaw et al., 2010). Furthermore, research has highlighted the value of individualized education plans and school re-entry programs that tailor school support to the specific needs of the patient and extend beyond educational outcomes by also supporting patients' psychosocial and physical needs (Leigh et al., 2016; Lum et al., 2017).

Information and Communication Technologies

Information and communication technology (ICT) is increasingly used to support young people to attend their classrooms and supplement the exchange of work between the school and patient (Hopkins et al., 2014). A diverse range of ICT methods have been trialed to support children and adolescents who experience long term absence from school due to chronic illness. These ICT methods have included BlackBerry devices (Fels et al., 2003), a telepresence app (Hopkins et al., 2014), videoconferencing facilities (Ellis et al., 2013), and ambient

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Abbreviations: ICT, information and communication technology; TRECA, telepresence robots to engage cancer patients in education; PD, participatory design.

technologies (Wadley et al., 2014). The few case studies which have been conducted suggest that ICT can assist children and adolescents with chronic conditions to keep in touch with friends at school and support wellbeing (Nisselle et al., 2012; Ellis et al., 2013; Wadley et al., 2014). Although these preliminary findings appear promising, some classroom teachers found the technology caused distraction in the classroom (Ellis et al., 2013).

Telepresence robots have been more recently used to support the education of children with chronic conditions (Page et al., 2020). Telepresence robots are remote-controlled devices with wireless connectivity allowing both video and audio connection, and can be mobile or stationary (Page et al., 2020). There have been very few studies assessing the acceptability of telepresence robots in schools for adolescent cancer patients. Looking at their effects on chronically ill students generally, a recent scoping review and thematic analysis examined the potential utility of telepresence robots for Australian schools, suggesting that telepresence robots can facilitate positive educational experiences and social development, reducing isolation (Page et al., 2020). This review also highlighted the issues of connectivity difficulties and privacy potentially reducing robot acceptability, and reported instances of lack of acceptance of the technology by school peers, leading to bullying (Page et al., 2020). A recent trial of telepresence robot technology with chronically ill students found that participants reported perceived increased connectedness and improved mood following the use of a telepresence robot (Chubb et al., 2021). Finally, a recent study by Weibel et al. (2020) specifically examined the impact of desktop telepresence robots with a one-way camera and two-way audio communication capabilities on children and adolescents with cancer. The authors found that the robot facilitated social and academic connection, allowing patients to feel included in their learning community, and reducing loneliness and patients' perception of being academically behind (Weibel et al., 2020).

The Current Study

In 2017, Canteen[1] began exploring the development of a telepresence robot service. This paper presents the results of a two-phase study on the development and pilot-testing of telepresence robots in schools for adolescent cancer patients. To maximize the chances of successfully developing and implementing a telepresence robot service, a participatory design (PD) approach was chosen (Clemensen et al., 2007) with users involved in each phase of the development of the service (**Figure 1**). PD allows users to be involved in the design and testing of a technical healthcare solution (Clemensen et al., 2017). This study represents the first three stages of the PD approach (Clemensen et al., 2017) outlined in "Phase I" and "Phase II" of **Figure 1** below, with stage four (outlined in "Phase III" of **Figure 1**) currently underway.

Phase I focused on *needs assessment* and *ideas generation* and aimed to assess the views of patients, parents, schools and healthcare professionals of the benefits, acceptability, barriers, and enablers of utilizing robots in schools for adolescent cancer patients. Results from the Phase I study were used to inform the design and implementation of the TRECA (Telepresence Robots to Engage CAncer patients in education) service. Phase II focused on the *pilot-testing* stage of PD and aimed to assess the implementation experiences of young cancer patients, and their families, schools, and keyworkers. Similar methodologies have been successfully utilized by other research groups to design and implement ambient technologies for chronically ill children (Wadley et al., 2014).

PHASE I: NEEDS, ACCEPTABILITY, BARRIERS AND ENABLERS FOR A TELEPRESENCE ROBOT SERVICE

Method

Design

Phase I was a qualitative study using semi-structured interviews to assess the views of patients, parents, schools and clinicians. It comprised the first two stages of PD: (1) needs and acceptability of telepresence robots (needs assessment), and; (2) barriers, and enablers (ideas generation) of utilizing telepresence robots in schools for adolescent cancer patients. The study protocol for Phase I was approved by The University of Sydney Ethics Committee [2017/770]. Telepresence robots were not utilized in Phase I.

Participants

To optimize the success of our future robot service, we conducted stakeholder interviews with the following key groups who were deemed essential for the implementation of a robot service: (1) Young people who were either currently receiving or had completed active treatment for cancer whilst they were in secondary school; (2) Parents/guardians of individuals who were receiving or had completed active treatment for cancer whilst they were in secondary school; (3) Individuals working in a teaching profession; and (4) Healthcare professionals working with adolescents with cancer. In total, 25 participants were recruited to Phase I: healthcare professionals (n = 8), schoolteachers (n = 8), adolescent cancer patients (n = 7), and parents of adolescent cancer patients (n = 2). None of the respondents were linked except for one patient/parent dyad. Most participants were female (n = 20), and participants were from several states across Australia including New South Wales (n = 8), Victoria (n = 10), South Australia (n = 4), Queensland (n = 2) and Tasmania (n = 1).

Procedure

Adolescent patients and parents of adolescent patients were recruited *via* invitations sent by Canteen psychosocial clinicians and through social media advertising. Teaching staff from a diverse range of school settings (e.g., public, private, and Catholic) and with a range of experiences in various locations of Australia were recruited through social media advertising. Healthcare professionals were purposively sampled from AYA cancer services and pediatric hospitals for their experience in working with adolescent cancer patients.

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[1] Canteen is the national Australian organization supporting young people (12–25 years) impacted by their own or a family member's cancer diagnosis.

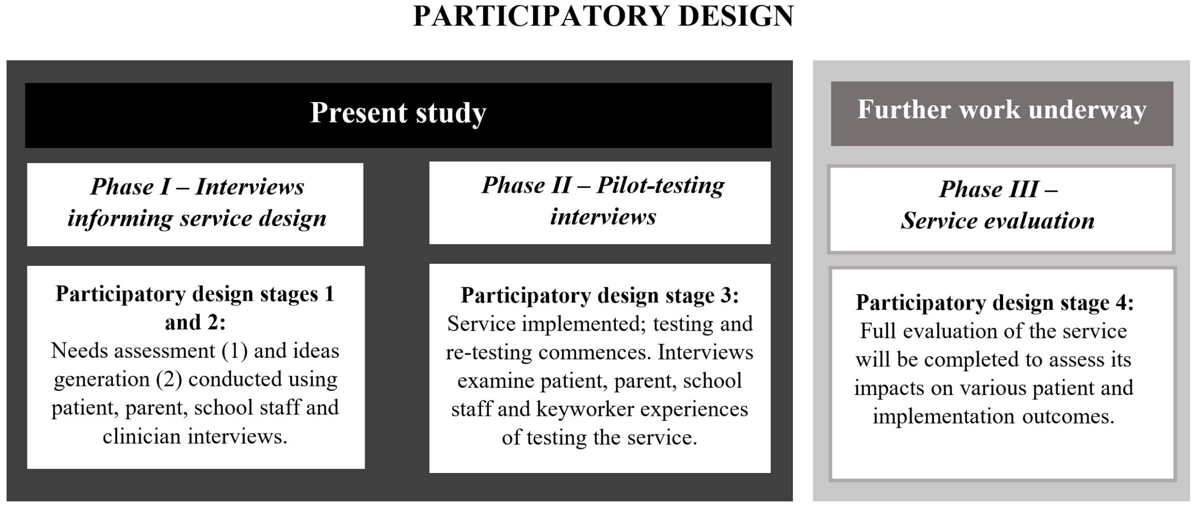

FIGURE 1 | Participatory design (PD) elements encompassed by each study phase.

Interviews

The semi-structed interview guide was developed by a multi-disciplinary group of researchers and clinicians (**Supplementary Appendix 1**). The semi-structured interview focused on the needs assessment and ideas generation stages of PD. The needs assessment questions focused on experience of schooling during treatment, schooling and academic support during cancer treatment, peer support, use of technology for schooling during treatment and experience of returning to school. In addition, the parents and healthcare workers were asked their views on the perceived impact of being hospitalized on an adolescent's wellbeing. In the ideas generation phase of the interviews, participants were asked about their views on the idea of a robot program for adolescents going through cancer treatment and perceived barriers and enablers to using a telepresence robot during treatment. The semi-structured interviews were flexible in nature and built upon the ideas, experiences, and needs brought up by the participants. Interviews were completed over the telephone by an experienced researcher. Interviews were audio-recorded to allow accurate verbatim transcription of the interview.

Analysis

Data were analyzed using content analysis as guided by Miles and Huberman (1994). Content analysis methodology involved the development of a coding scheme which was then applied to topics of interest within the transcripts. The interviews were analyzed inductively line-by-line and the codes were placed into emerging topics. The coding framework was informed by the data set and refined by the researchers to further data analysis. The data was coded by two researchers experienced in qualitative research.

Results

Stage 1: Needs Assessment

In the needs assessment phase of the interviews, two themes emerged: inconsistency of educational support during and after cancer treatment, and the impact of cancer on patient isolation and wellbeing (**Table 1**).

TABLE 1 | Needs assessment and ideas generation themes.

Identified theme	Description
Inconsistency of educational support during and after cancer treatment	Cancer treatment impacted school attendance, with supports provided variable. The impacts on education continued once treatment had completed with many adolescent patients finding it difficult to reintegrate back into the school environment.
Impact of cancer on isolation and wellbeing	Missing impacted social connections, isolating patients from their peers for an extended period.
Telepresence robots can support adolescents' education and isolation during cancer treatment	A telepresence robot was seen as a novel way to engage adolescents with their education and their peers during cancer treatment, facilitating reengagement back with school at the completion of treatment.
Assessing suitability of the robot for a young person	It is important to screen a young person prior to implementation of a robot to ensure they are suitable for the service.
Need for the school to be engaged in the process	It was important that education on the telepresence robot program is provided to the school and the young person's peers prior to, and during implementation of a robot.
Ensuring good user experience with the appropriate technology	The school must have the technical capacity to host a robot and ongoing IT support is required throughout the program.

Inconsistency of Educational Support During and After Cancer Treatment

Throughout the interviews, participants explained the impacts that cancer treatment had on the education of young patients and how well the education system could manage this. Participants often reported young people missing out on their education due to complex treatment regimes, treatment side effects and neutropenia. For many young people, attending school during treatment was a priority for them at the beginning of treatment. Despite the willingness of young people to attend school they could not always attend due to treatment side effects.

> *"In the beginning I was very persistent that I wanted to go to school… but with the treatment came tiredness and energy loss. In the middle [of treatment] I was reluctant to go [to school]… because I didn't have enough energy to get out of bed"* Patient

Throughout the cancer journey, there were often occasions when parents or teachers believed that the young person was well enough to attend school but did not encourage them to attend, as staying rested and focusing on their health was seen to be a bigger priority. It was common for students to fall behind at school considerably during the treatment period, but there also appeared to be a longer-term impact of treatment on their ability to stay in school. For young people who were able to attend school during treatment, families acknowledged that their attendance was more about peer connection than learning.

> *"If we were lucky we could get him to school once a month maybe. It was basically more for social [reasons] than really doing any work. Just to keep him engaged"* Parent

For patients who spent a lot of time in hospital, some hospital services had specialized positions whose role it was to facilitate the connection between the school and the patient. For some young people, there were supports in the form of tutoring, available through non-government organizations or hospital school programs. In noting the tutoring based supports available to young cancer patients, one healthcare worker stated "*…But one concern that comes up for a lot of families is that disconnect from school…I think connection is so important…*"

The way in which patients engaged with the education system during their treatment was variable. Some schools put systems in place to support students to continue with their education during treatment by speaking on the phone with the young person or sending work home. Some schools also facilitated ongoing peer connection with the students from the school and some participants suggested that facilitating peer connection during treatment improved the likelihood that a young person would attend school during treatment.

> *"…make sure [the patient] is engaged [with the school], making sure they stay in contact with their friends, making sure they understand what's happening day to day at the school. It's that everyday information that if you're not there for 2 weeks and you walk back in, that's an awful feeling"* Healthcare Professional

However, the education system was often reported to be inconsistent in the support provided to young people being treated for cancer. In some instances, young people relied on their friends providing the work and assignments from school.

> *"I always asked my friends, if the teachers give us anything just send it to me so I can try and at least do it"* Patient

Although a few students returned to school in a full-time capacity following treatment, most had a slow reintegration process, receiving modified work or alternate work assignments. For patients who missed quite a bit of school due to treatment, there was concern around going back to school and reintegrating with the school community.

> *"I sort of actually dreaded going back to school. In Year 9, [be]cause I sort of thought, it was virtually the first day of school all over again"* Patient

Another identified gap in the system was when treatment was completed and where educational supports from the hospital often stopped.

> *".If you asked families and young people where the gaps probably are, it's possibly down the track when they're off treatment and, you know, not at the hospital anymore. I imagine that's probably where there are still gaps"* Healthcare worker

If patients had some connection with their school during treatment, they often found it easier to reintegrate back to school once treatment is completed.

> "*There [are] definitely young people who are really motivated to stay connected and [for] some other young people their motivation to connect with school is not the same. So then the re-entry… can be really hard for them*" Teacher

Impact of Cancer on Isolation and Wellbeing

Adolescence was considered a challenging time to have a cancer diagnosis as peer development was key during this time. Participants acknowledged that being diagnosed with cancer as an adolescent was particularly isolating as it removed young people from their usual friendship groups. Young people noticed this more when they returned to school.

> *"I felt like everyone had made their friendship groups and connections. In some ways it's like a new student coming in.'* Patient

For many young people, the biggest impact from missing school during treatment was missing out on all the experiences they would normally have with their peers.

> *"I missed out on [camp] because I was sick. The stories and stuff that happened on the program, people got a lot closer… I had to sit out of it, which sucked a fair bit"* Patient

Participants highlighted the considerable impact which missing school could have on a young person's wellbeing. Increased anxiety was frequently mentioned, and some participants spoke of bullying and depression.

> *"One of the big things in youth cancer is that they become isolated from their friends and their peers and it can lead to depression"* Healthcare Worker

> *"I used to feel down that I wasn't able to go to school. I guess it did upset me"* Patient

Participants suggested that maintaining social connections during cancer treatment may help improve the wellbeing of young patients.

> *"One day [the young person] was laying down trying to sleep because that is all he wanted to do while he was [in hospital]. Then his friends rang him and in about 20 min he was sitting up in his hospital bed with a smile, chatting and laughing. That made a really big impact"* Healthcare Worker

Stage 2: Ideas Generation

During the interviews, participants were given an opportunity to discuss their views and ideas on the telepresence robot service and the barriers and enablers that would need to be addressed to ensure a successful service implementation. Participants considered telepresence robot technology to be appropriate for supporting an adolescent with their education and feelings of isolation during their cancer treatment. To facilitate a successful telepresence robot service, participants suggested: the need to assess whether the young person is suitable for the service, the need for the school to be engaged with the service throughout the implementation process, and the use of appropriate technology that ensures a good user experience.

Telepresence Robots can Support Adolescents' Education and Isolation During Cancer Treatment

There was overwhelming support for the use of telepresence technology as a novel and fun way to concurrently engage adolescents in their education and with their peers. The robot was considered a more acceptable form of technology than the use of a tablet alone because the robot could move about and be controlled by the young person from hospital or home.

> *"I think [the robots] are a really good idea as kids don't feel alone, that they have to go through [treatment] alone. They have friends, they can connect with their school, keep in touch with their friends, get to know what's going on at school'* Patient

Some patients reflected on the robot and how it may have facilitated an improvement in wellbeing if they had access to a robot during their treatment. The robot service was also seen as a way of providing patients' friends with an understanding of the patient's cancer experience, allowing their peers to develop social understanding, compassion, and empathy. The robot was also thought to facilitate reengagement with the school and peers when cancer treatment was completed.

> *"...[the robot] gives their classmates an opportunity to have more of an understanding of what they are going through as well. So [the patient] is not having to come back to school after a few months off and be bombarded with questions and people not knowing how to speak to them as well."* Healthcare worker

Assessing Suitability of the Robot for a Young Person

Participants suggested that some young people may not want to use the robot because they do not want to draw attention to themselves. This was emphasized by a statement from one of the patient participants:

> *"I didn't want the whole of my [school] cohort knowing that I was sick. I didn't really want people to see me as sick."* Patient

There were comments that not all patients would like the visibility of the robot, and the ability to have a choice of robot style or use of an avatar in place of the video stream would likely increase acceptance.

> *"...maybe the first thing a [patient] could do is create an avatar... and that would allow them...to turn off the camera on their side, they would be able to show the avatar"* Patient

Participants suggested that screening of the young person occurs, prior to implementation of a robot, to ensure they are suitable for the service.

Need for the School to be Engaged in the Process

Participants suggested there would likely be some resistance and concern from teachers regarding the privacy associated with having this technology in the classroom for fear of being videotaped. This same concern about privacy was highlighted as a potential issue with parents as well.

> *"a lot of teachers are really paranoid about being videoed.... some [teachers] are just concerned that that information might be videoed and then put on YouTube.... and make them look negative"* Teacher

Educators were concerned that having a robot in the classroom would be a distraction for other students, especially when the robot is first implemented. There was also concern about the nature of the physical school environment (i.e., stairs), making it difficult to maneuver a robot around the school to each classroom.

> *"...the number of schools that I have worked across, I'd say 80% had stairs. Depending on what of these areas were connecting would kind of dictate the viability of the robot"* Teacher

Participants highlighted the importance of providing adequate education to the teachers and support to the school prior to implementation of a telepresence robot. Education on the robot service and information about cancer could be extended to include students in the patient's year group and their parents.

> *"It would be a matter of just talking to the school and...getting on board with [the school] to work out how it would work and how you are going to implement it and talking to the kids on how does it all work"* Parent

To support the young person to successfully use the robot within the school environment it was suggested there be a main contact person within the school community to be a point of contact and to take responsibility for the robot. This could be done in combination with a student, using a buddy system, as a way of teaching responsibility.

> *"If there was a buddy system and the other student was to take on a role where they were responsible for [the robot] I think that's a really good thing"* Teacher

Ensuring Good User Experience With the Appropriate Technology

The importance of having technology with good user-experience was emphasized consistently throughout the interviews, especially when using it in a busy classroom where teachers would have limited time to manage any technological issues which occurred. Many of the participants mentioned the lack of Wi-Fi available on school property and within the hospital.

> *"...Because of our remoteness, the internet is a real issue for us...so that would be probably a very strong barrier"* Teacher

Schools would require screening at the start of the implementation robots to ensure adequate infrastructure is available within the school to support the telepresence robot service. The schools would also require ongoing support with technological issues to facilitate a successful implementation of the telepresence robots.

> *"It will come down to how easy [the robot] is to set up and to start because sometimes technology can get a little bit too complicated and when that happens it will get pushed to the side."* Parent

PHASE II: PILOT-TESTING OF THE TELEPRESENCE ROBOT SERVICE

Service Features

The TRECA service (see **Figure 2**) was developed based on the findings from the needs assessment and ideas generation stages of the PD process. As part of the service, patients and schools are provided with both the robot itself and ongoing multi-domain support. To facilitate the assessment of the young person's suitability for the robot's service, upon referral to the service, patients are assigned a psychosocial support worker (keyworker) who can check in with them regularly and provide support as needed. Prior to implementation of the robot, the keyworker also works with the patient, their family, and the school to develop an implementation plan, defining when and how their robot will be used (e.g., which classes they wish to connect to, whether it is used at recess and lunch time). Upon a patient's referral to the service, the patient's school (usually the school principal, vice principal, or head of student wellbeing) is contacted by the TRECA service coordinator, who provides them with an overview of how the service runs. If the school indicates their potential interest in supporting their student to access the TRECA service, the school is then provided with a written information pack outlining the service and technology. To maintain ongoing engagement with the school, the school is provided with staff training on how to use and store the robot and continual IT support throughout the period in which they are hosting a robot. Additionally, upon the robot's implementation in a school and with the consent of the patient, an information session (called When Cancer Comes Along; Wright et al., 2021) on the robot, cancer and its impacts, and where to get support, is offered to students in the same cohort as the patient. It is recommended to the school that the patient be assigned one or more "robot buddies" – close friends of the young person who can assist with the logistics of the robot each day (e.g., transport to and from class). The service coordinator oversees all components of the TRECA service to ensure communication is maintained between all parties involved, and that both the adolescent and school have a good user experience.

The Telepresence Robots

The TRECA service offers two types of robot to patients – the Double$^{\text{TM}}$, and the Kubi$^{\text{TM}}$, both of which enable patients to videoconference into their classroom/school. The Kubi$^{\text{TM}}$ comprises an iPad held in a base that sits on a desk in the classroom. The base enables the user to swivel the iPad so that they can look around the room. The Double$^{\text{TM}}$ robot comprises an iPad that is attached to a Segway base, enabling the user to remotely drive the robot around the school or classroom. Patients use a laptop or tablet (either their own, or one provided to them if needed) to connect to and control their robot from home or hospital. The robot connects either to a school's Wi-Fi network, or a cellular network, depending on which is most practicable. Prior to robot implementation, the robots' software's recording/photo taking function is disabled for privacy reasons. The TRECA service is provided free of charge.

Method

Design

In Phase II, a pilot-testing evaluation was conducted using semi-structured interviews to explore key stakeholders' implementation experiences of using telepresence robots to enable adolescent cancer patients to attend school remotely during their cancer treatment. The pilot-testing comprised the third stage of PD: testing and retesting (Clemensen et al., 2017). The study was approved by the University of Sydney Ethics Committee [2018/160] and the University of New South Wales Ethics Committee [HC200043].

Participants

A total of 22 participants took part in Phase II of the study, including patients ($n = 6$), parents of patients ($n = 6$), school staff members ($n = 5$), and Canteen keyworkers ($n = 5$). Participants fell into one of four groups: (1) Adolescents with a diagnosis of cancer or a hematological condition, who were receiving cancer treatment or had completed treatment but were unable to continue with their education full-time either due to their diagnosis or the side-effects of treatment; (2) Parents/guardians whose child was part of the TRECA service; (3) School staff who worked closely with a young person and their family on the TRECA service; and (4) Psychosocial keyworkers who provided support to the young person and family as part of the TRECA service. All participants were linked to at least one other participant except for one keyworker.

Procedure

When a young person had used the TRECA service for a minimum of 3 months, they and their parent/caregiver were contacted *via* email or text message to invite them to participate in the study. Participants were followed-up by phone, email, or text message no more than two times. Participants were informed that consent was voluntary and that they could withdraw from the study at any time without penalty. Additionally, a parent or guardian was asked to provide consent through the return of a signed consent form for young people aged 12–17 years. If the young person agreed to participate, their parent/caregiver, keyworker, and school representative that were involved with the implementation of the robot were contacted. All participants received an information sheet and consent form (including participants aged 12–17, who signed to indicate assent).

Interviews

The semi-structured interviews were designed by a multi-disciplinary group of researchers and clinicians (**Supplementary Appendix 2**). The semi-structured interview explored themes

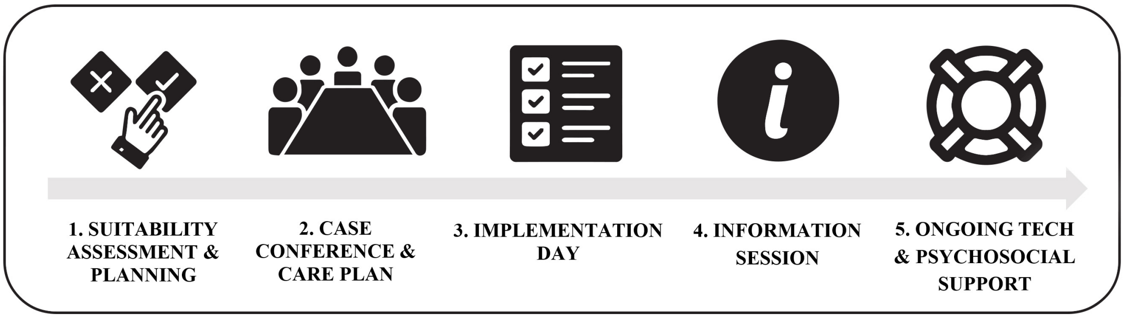

FIGURE 2 | Components of and progression through the telepresence robot service.

such as connection to school, impact of cancer on school experience, maintenance of relationships, and continued education, and perceptions of the robot itself and TRECA service. The semi-structured interviews were flexible in nature and built upon the ideas, themes and experiences brought up by the participants. Interviews were completed over the telephone by an experienced researcher and lasted between 19.15 and 47.63 min (M = 30.71). Interviews were audio-recorded to allow accurate verbatim transcription of the interview.

Analysis

The data was analyzed using a reflexive approach to thematic analysis, as described by Braun and Clarke (2006); Braun et al. (2018). For Phase II, the six steps to thematic analysis outlined by Braun and Clarke (2006) were followed to guide analysis: (1) Familiarization with the data took place by reading transcripts multiple times and noting down initial ideas regarding emerging patterns; (2) Initial codes were generated for interesting or significant data points by systematically examining each transcript; (3) Codes were collated into meaningful themes; (4) Themes were reviewed for clarity and coherency at both a code and broader data set level; (5) Themes were named and further refined in accordance to the overall picture of the analysis; and (6) Themes were reported in the context of the research questions and evidence base, and unpacked using extracts as examples. Data were analyzed using NVivo; a qualitative tool which supports comprehensive coding.

Results

Regarding participants' experiences of using a robot to enable patients to attend school remotely, a total of three themes were generated from the qualitative data (**Table 2**).

Theme 1: The Necessity of Stakeholder Buy-in

Ambivalence Versus Enthusiasm

The TRECA service is a complex service to implement due to the large number of stakeholders involved (i.e., school principal, teaching staff, school IT team, keyworker, service coordinator, Canteen IT team, patient, and family). It was clear that successful implementation of a robot required buy-in, commitment, and enthusiasm on the part of all stakeholders. This was particularly important when it came to the patient's school. Patients' experiences of utilizing their robot tended to be less positive in schools that were unable to dedicate sufficient time to the management of the service (e.g., not having a dedicated teacher to oversee the robot), or with staff that were skeptical or ambivalent about the service and resistant to making accommodations for it in the classroom.

> "*if [the school is] not supportive and if they're not on board, then it's not going to be effective. That young person's not going to feel comfortable using it.*" Keyworker

> "*We had one teacher tell him to log out and log back in again [at a later point], which I was particularly unhappy about. Because he's quite happy to sit there and read or do something else until she's ready for him.*" Parent

This was in stark contrast to schools with staff who were supportive, dedicated resourcing to the robot and were passionate about keeping the patient engaged. These factors resulted in a much more successful and positive experience for the patient.

> "*He's had no issues whatsoever.... Because school did so much work prior to [patient] starting to use the robot, I think that had a big impact on it.... They've just gone, really, above and beyond. He wanted to go to band practice while he wasn't there physically; they made sure they sent a drum home so that he could still play through the robot. Whatever they can do to make him feel included, they've done. I think that's just really taken any worry off for [patient] and everyone.*" Keyworker

The Impact of Poor Communication

School staff and keyworkers were often unclear of what their responsibilities were with regard to contributing to the service, impacting these stakeholders' abilities to buy into and fully engage with the service.

> "*I don't think anyone was actually really sure who was actually in charge of [the robot].*" Teacher

Lack of robot software/hardware, usage, or process knowledge also had a significant impact on buy-in, with teachers' concerns about privacy and unfamiliarity with how to use the robot resulting in resistance to utilizing it in their classroom.

TABLE 2 | Phase II themes and subthemes.

Theme	Subthemes	Description
Necessity of stakeholder buy-in	a. Ambivalence versus enthusiasm. b. The impact of poor communication.	Stakeholder buy-in and supportiveness improves patient experience, with communication issues around lack of knowledge and role unclarity impacting buy-in. Clear communication and training are needed to engage stakeholders.
A facilitator of meaningful connection	a. Many kinds of connection. b. Connectedness improves wellbeing. c. The ability to connect fosters a sense of agency.	Connection to different spheres (e.g., social vs. educational) held different meanings depending on patient needs. Connectedness facilitated by a robot appeared to reduce patient distress, improve mood, and foster a sense of agency.
One size does not fit all	a. Not always suitable. b. Catering to the unique needs of each patient.	Certain individual and environmental factors may make some patients less likely to benefit from a robot. Service individualization and flexibility is key in meeting individual needs.

> "*I think that one of the downfalls is that teachers don't necessarily or always know how to use it. Or how to not just use it as in how to make it work – but how to incorporate it in the classroom*" Parent

> "*the worry... was with privacy issues, the ability to maybe be recorded, or the lessons to be recorded and then who's going through [those recordings]?*" Teacher

Additionally, communication breakdowns regarding when the robot was going to be used, whose responsibility certain tasks were, and who needed to maintain various aspects of it also led to delays or missed opportunities for the patient to use their robot on a number of occasions.

> "*I think there was a problem with engagement, or communication, or maybe someone to be fully assigned to the task of making sure that the robot was in the class at the moment [patient] was going to connect. Because it happened several times, that he was going to connect but the robot wasn't there – it was not ready for the connection.*" Parent

Finally, a factor impacting buy-in on the part of the patient was the frustration and/or loss of confidence experienced as a result of having to contend with technical difficulties in some of the robots. Although it was acknowledged that technical issues are to be expected with any technology-based service, the impact of not always rectifying these issues in a timely manner on patients' engagement with the service was highlighted.

> "*it was dogged with technical issues and what happened was that, with that, I suppose [patient] lost confidence in using it... it was really adding to the stress of everything.*" Parent

As a result of these issues, it was clear that strong and timely communication between stakeholders, and thorough information provision and training of patients, keyworkers, and school staff prior to implementation was needed to fully engage stakeholders in the service.

> "*the more training and support that there is for [keyworkers] to just have a general understanding of what's going on and how to use [the robot], the more empowering that's going to be for the staff to confidently support the young person.*" Keyworker

Theme 2: A Facilitator of Meaningful Connection

Despite the complexity of the set-up and ongoing running of the service, participants consistently reported the value that the TRECA service had in facilitating meaningful connections for patients during a time of their lives where they otherwise feel extremely isolated and disconnected.

Many Kinds of Connection

Facilitation of connection to various spheres was reported by participants, with these connections holding different meanings for patients depending on what their values and goals were when entering the service. Participants described the benefit in patients flexibly being able to use their robot more for academic or socialization purposes, depending on individual needs. However, the importance of the social connection to the classroom environment was emphasized over and above that of the academic connection the robot provided.

> "*I really loved also just being in class and just listening, not necessarily doing the work, but still just involved and feeling like a part of the group, a part of the class... So just keeping me included in my friendship group, my class group, the conversation*" Patient

The breadth of social connection that the robot was able to provide also encompassed connections to the wider school community.

> *"It helped me to stay connected and stay close to especially my core group, but not just my core group, all my peers. So just even rolling down the hallway and seeing everyone and just, once again, being in that environment and in that sort of group in collection, it makes you feel like you're a part of something*" Patient

The robot also provided patients with a sense of connection to their friendship group. One way in which this was facilitated was through assignment of "robot buddies."

> *"[each morning] his friends will come and open the door for [the robot], make sure he can get [it] out [into the hallway], and he'll go to his lesson with his friends*" Keyworker

Although the facilitation of social connection was the key drawcard of the service for many participants, its ability to enable patients to keep up with their classwork, preventing them from falling behind their cohort, was also seen as a core benefit for many.

> "*when I did his initial assessment, the real only stress that was identified in that was around the lack of attendance to school and his drive to do his favorite subjects, so he could get into career path he wanted. So, I think that providing him with that opportunity to attend in an alternative way, was really beneficial for him*" Keyworker

Connectedness Improves Wellbeing

A strong link was made by participants between patients' sense of connection to their peers, school community, and schoolwork, and their wellbeing. The ability for a patient to use their robot appeared to reduce distress or anxiety and improve mood, either because it provided an avenue of social support, or because it prevented the young person from feeling as though they were falling behind on schoolwork.

> "*What I have found is that in term three [patient] was connecting and it was really great that he could do that in between treatments, and I think that kept him buoyant in terms of his emotional wellbeing*" Teacher

> "*I get really anxious if I'm falling behind. Just to be in the class, just to hear what's going on, even if I'm not doing work, just eased me a bit.*" Patient

The Ability to Connect Fosters a Sense of Agency

Connection to school additionally provided patients with a sense of agency during a time where they have little to no control over their cancer treatment and experience. Using a robot gave patients the choice to take part in the normal day-to-day activities of attending class or talking to their friends, but on their own terms.

> "*They're not in control of the cancer, they're not in control of the medication that they have to take, so anything that they feel like they can control in their environment is really important and it just gives them that sense of control as well. So they can tune in when they want*" Parent

> "*it's on my terms; it makes me feel like I'm accomplishing something – when I'm having a bad day and I can go into school.*" Patient

Theme 3: One Size Does Not Fit All

Not Always Suitable

The TRECA service was not suitable for all young patients who met the service's admission criteria, with certain individual and environmental factors playing a role in reducing potential benefits. For a few young people, concerns about stigmatization and peers' perceptions of them or the robot impacted significantly on their experience:

> "*It was kind of weird especially because I am older and everyone was kind of like, "what is that?," and then it just made me feel quite uncomfortable to use and I would have rather just been in school. It made me feel like I stood out more than I already did*" Patient

For some patients, rather than helping them to feel more connected, using a robot instead intensified their feelings of disconnection from their school, peers, and friends. Limitations of the robot meant that it was sometimes unable to facilitate as rich of a connection as would be achieved with the patient's physical presence in some situations. For instance, the robot's audio capabilities could make hearing what someone was saying difficult when others were talking, and limited mobility meant that full participation at recess or lunchtime was not always possible:

> "*I think this is probably one of the biggest issues [that] anyone in this situation at this age would probably say is, "The mates don't want to hang out in an area that's going to be quieter." Because they want to be kicking a ball or something like that... And I think he probably feels a little bit left out because of that.*" Teacher

Furthermore, participants reflected on the fact that for some patients, using a robot reminded them of what they were missing out on, and was thus an upsetting experience. As a result, it was suggested that more work could be done prior to implementation in preparing patients for the possibility that they may experience distress when using their robot.

> "*I [had been] with that class for about 6 years, and when I walked back in [on my robot] and I wasn't there in person with them and I couldn't do stuff with them, it really made me get emotional... I was just feeling sad, and I couldn't do anything. I couldn't be with my friends*" Patient

Another consideration raised regarding patient suitability for the service was that young people who are disinterested in school prior to their illness may not engage as well with the service in comparison to those who are highly connected to school.

> "*I'd say [patient engagement] really depends on the young person and what their attitudes are toward school and why they're using it. In my experience, most of the young people that have received a robot are pretty passionate about school and, before being diagnosed, were getting really good grades and had a real sense of belonging at their school... I can imagine it would be really different for a young person who doesn't like their school; doesn't engage well in class.*" Keyworker

A final point regarding suitability that interviewees expressed was that the intensity of treatment and subsequently how unwell the young person became was often a barrier to robot use. For some patients, this inability to use their robot due to illness became a source of distress. Participants spoke about the need to consider whether certain phases of an individual's cancer journey will be less conducive to robot use than others due to the impact on health.

> "*I just feel for me, personally, I was sick in that first couple of phases [to the point] where I couldn't do anything. I felt guilty for just letting it sit there when someone else could have been using it and using it to its actual potential.*" Patient

Catering to the Unique Needs of Each Patient

Patients utilizing the TRECA service often had changing needs and preferences, and frequently experienced a highly unpredictable cancer journey. As such, taking an individualized approach when implementing a robot was critical. Participants reported seeing various features of the Kubi^{TM} and Double^{TM}

robots as being appropriate for some patients, and not appropriate for others, highlighting the importance of providing patients with the ability to choose the type of robot that will best suit their needs.

The perceived utility of the Double^{TM} robot's key feature of being able to "drive" around the classroom or school appeared to depend on a number of factors, including the purpose of use, school layout (e.g., presence of stairs), personal preference, and the types of classes it was used for. Generally, participants emphasized the value of this feature for patients who tended to be younger and wanting to use their robot for social connection.

> "*I think it [the service] absolutely needs it [the robot] moving around because it makes you feel like you're actually there, rather than just Skyping in. You can walk around with your friends. It's just that extra level that just tops it off and makes it amazing. It wouldn't be the same without moving it, I feel like, and if you were going to work in a different area with [your friends] or sit around or stand up around recess, you get that face-to-face conversation.*" Patient

Others emphasized the benefits of the Kubi^{TM} over the Double^{TM} for patients who are older and only wanting to use a robot solely for academic reasons.

> "*I think I'd [prefer to] just have [a robot] that could go on the desk and it could still turn around, but not sort of move around the classroom... Once you sit at a desk, you stay there until the period is up, so there's not really a need, and a lot of people wouldn't have recess and lunch, I feel like - if they're older - with their friends. There is not that need to sort of move around.*" Patient

Allowing for further customization of the experience, both the Double^{TM} and Kubi^{TM} provided patients with the option to turn their camera off when connected to their robot. This option can be utilized if patients have concerns about showing their face to their peers and teacher when they are feeling unwell or self-conscious of their physical appearance. Indeed, participants described the value of this function in allowing patients to choose not to be seen, or to simply listen in class rather than join in on discussions and activities, when needed.

> *"most of the time I could see everything, but no one could see me because I didn't want them to, and I didn't talk, I just listened in... [being seen] was just uncomfortable. I didn't need it, as I said before, I didn't really need people looking."* Patient

The utility of having the patient trial the robot prior to full implementation, to further clarify their individual practical needs and preferences for using the robot in the classroom environment, was also reported.

> "*the trial was so important, I think, out of everything, and him being able to just go around the school and find out what works for him – if there's any barriers or anything that won't work, or we need to adapt or change – while no-one was in the school. That was really great. Even just in his classrooms. The teachers had laid out a spot on the carpet where [patient] could park the robot, and by doing that trial we realized that it was really too far away from the [white]board and we needed to adapt that.*" Keyworker

DISCUSSION

Given the significant school absences young cancer patients can experience (Tsimicalis et al., 2018), the present study investigated the development and pilot-testing of a telepresence robot service that enables patients to connect to school socially and academically. The Phase I needs assessment and ideas generation demonstrated the need for, and relevance of, telepresence technology in connecting young cancer patients to school and supporting their educational needs. Considering the variable support provided to patients undergoing treatment, a telepresence robot service was perceived as a novel and acceptable method of facilitating a school-patient connection, potentially reducing the impacts of the isolation felt during cancer treatment. The findings and recommendations provided in Phase I, such as the need for ongoing education, training and support to the patient and school, were utilized to inform the development of the TRECA service. Phase II examined the implementation experiences of young people using the TRECA service. Findings from Phase II showed the importance of stakeholder buy-in, the valuable connections that the robots facilitated, and the need for an individualized and adaptable service to meet the varying education and psychosocial needs of adolescents with cancer.

Results from Phase I highlighted the educational and wellbeing impacts that cancer has on adolescents. Participants reported the need for solutions to support patients' education during cancer treatment, as there was inconsistency in the support available to adolescents during their cancer experience. Participants also highlighted the isolation patients felt during their cancer treatment, as they were not able to connect with their peers in the school environment. Research has shown that prolonged absenteeism from school has impacts not only on cancer patients' academic attainment but also on their peer relationships (Winterling et al., 2015), leading to social isolation (Tsimicalis et al., 2018) and increased risk of bullying (Collins et al., 2019). A previous study assessing the use of telepresence robot technology with child and adolescent cancer patients found that the technology facilitated both social and educational connection (Weibel et al., 2020). In the present study, the use of telepresence robots was endorsed as an acceptable solution for adolescent cancer patients, with a robot's dual potential of facilitating education and ameliorating isolation within the school environment.

Recommendations from Phase I highlighted the importance of assessing whether a young person is suitable for the robot's service. For this reason, the TRECA service includes a referral to a psychosocial support worker (keyworker) who can work with the patient, their family, and the school to develop an implementation plan, defining when and how their robot will be used. The results from Phase I also showed the importance of the implementation of a telepresence robot into the school environment being complemented by ongoing education, training and support for the patient, their family, and the school to ensure the school stays engaged with the robot service. Indeed, previous research suggests that to achieve integration of the telepresence robots in the classroom, school staff training is required to ensure teachers are confident to use the technology (Weibel et al., 2020). General education with a patient's peers has also been suggested to be protective against bullying of cancer patients by reducing fear of social interaction and improving peer acceptance of the cancer diagnosis (Collins et al., 2019). In addition to education, training, and support, Phase I recommendations also highlighted the necessity of implementing ongoing IT support into a telepresence robot service to facilitate a good user experience with the technology. Research suggests that technology issues with telepresence robots can detract from the positive experience of the telepresence robot, limiting its effectiveness (Weibel et al., 2020). As a result of our findings, we created the TRECA service – an integrated telepresence robot service for adolescent cancer patients. To ensure this service was effective, education and training on the service and cancer was provided to the patient's teachers and peers, and ongoing IT support was implemented as an essential component.

Results from Phase II highlighted the importance of stakeholder buy-in for the success of a telepresence robot service, and how success can be impeded by insufficient communication. Participants reported a connection between positive patient experiences and school supportiveness, and that greater support and clarity was needed regarding the assignment of responsibility for the robot, how to use the robot, how the service runs, and privacy and technological issue management. The theme of the necessity of stakeholder buy-in further emphasized Phase I's finding that the implementation of a robot cannot be approached from a standpoint that views the robot itself as the key service component. Rather, the implementation of a telepresence robot should be viewed as a "wraparound" service with many interrelated parts, each of which have a critical role to play in the service's success. As such, adequately preparing and informing all stakeholders of their role and responsibilities ahead of the implementation day, appears to be key in potentially preventing patient and school staff stress, hesitancy, or disengagement.

These findings on the importance of stakeholder buy-in are supported by previous research by Page et al. (2020) that identified the essential need for planning to occur between stakeholders, and for support and training provision when implementing telepresence robots for chronically ill students. Furthermore, a review by Hinton and Kirk (2015) found that teachers have a lack knowledge of chronically ill students' healthcare needs, symptom and medication impacts, how they can adapt their teaching to accommodate student needs, and how long-term absence or a students' return to school should be managed. In addition, both qualitative and quantitative studies have found that teachers lack confidence in meeting the needs of students with illness and are concerned about risks and responsibilities associated with supporting these students (Wilkie, 2012; Hinton and Kirk, 2015). As such, patient and teacher experience may be enhanced by providing teachers with information about the purpose of the robot in the classroom, how they can effectively incorporate the robot into their teaching, and what their student's needs and preferences are. Guidelines and resources advising teachers on how the robot's hardware and software works, along with consistent provision of accessible and timely support, may also give patients and schools greater confidence in knowing how to manage the inevitable technical difficulties that arise in any technology-based service. Similarly to the present study, Page et al. (2020) also reported teachers' concerns about privacy impacted their willingness to use a robot. As such, ensuring adequate and accessible information is provided to schools about how the service mitigates common teacher concerns such as privacy and impact on workload may also improve school buy-in, and in turn, the patient's experience.

Another key finding from Phase II was the notion that the TRECA service was a facilitator of many kinds of meaningful connection, and that this connectedness underlay wellbeing and fostered a sense of agency for the young person. It was evident that some patients tended to choose to use their robot more for social connection purposes rather than academic reasons, and vice versa. The individualized nature of the TRECA service allowed facilitation of the kind/s of connection each individual patient valued based on their needs, preferences, and cancer experience. Indeed, given the TRECA service's core purpose is to improve patient wellbeing, this finding suggests that facilitating the kind of connection that is of most value to the individual patient, in the way that is most comfortable for them, is likely to result in the greatest benefit. Patient preference for a certain type of connection over another was also found by Weibel et al. (2020), who reported that incongruence between student needs and teachers' understandings of the purpose of the robot and how the patient wished to participate at school (preference for academic rather than social use) created a barrier. Phase II findings also showed that participants' preference for and use of various robot features (e.g., mobility, allowing face to be shown on-screen) differed from individual to individual based on their needs, further illustrating the importance of a flexible telepresence robot service. Interestingly, although previous research has suggested that mobile telepresence robots are likely more appropriate and better facilitate connectedness in a school context than stationary robots (Page et al., 2020), the present findings suggest that robots like the Kubi^{TM} (which is stationary but allows the user to swivel their viewpoint) may be a better fit for the needs of older students who are tending to use a robot more for academic reasons.

Results suggested that the social and academic connections facilitated by the robot appeared to improve patients' moods and/or reduce feelings of stress due to the way it enabled them to socialize or participate in schoolwork. These findings align with previous research. For instance, perceived social support has been negatively related to depression and anxiety in adolescents with leukemia (Çavuşoğlu and Sağlam, 2015), and school connectedness has been found to be predictive of future psychosocial adjustment in child and adolescent cancer survivors (Okado et al., 2018). The TRECA service also appeared to provide patients with a sense of agency and achievement during a time in their life that was otherwise void of choice. These results align with research demonstrating telepresence robots' positive impacts on the wellbeing and sense of autonomy of school students with a chronic illness (Page et al., 2020). Importantly, Belizzi et al. (2012) found many adolescent and young adult

TABLE 3 | Recommendations for implementing a telepresence robot service.

Domain	Recommendation
Initial information provision and training	– Chart outlining all stakeholder responsibilities and when/how they should be contacted. – Website housing all TRECA documents and resources. – Videos explaining the service in detail, demonstrating how to use and troubleshoot the robot. – Psychosocial support worker training and documentation on their role, how the service works, and the responsibilities of all stakeholders.
Specialized teacher training/information	– Video resources showing other teachers' experiences of the robot and tips for incorporating it into teaching method. – Patient preference survey given prior to implementation, indicating how patients would like to participate using their robot.
Technical information provision, training, and support	– Video resources showing other teachers' and schools' experiences with technical difficulties or privacy concerns that arose; video and written resources that can be referred to as needed showing how the robot works, and how to troubleshoot basic problems they may encounter. – Increasing staffing as the service grows to ensure response is as fast as possible. If a tech issue persists, consider replacing the patient's robot and troubleshooting the problem in-house so the service is impacted as little as possible.
Identification and management of potential barriers to suitability and success	– Formalizing the intake process to ensure key factors indicating suitability are assessed. – Providing psychoeducation to patients about potential for distress to be experienced, and putting in place a plan to manage concerns/potential for distress with keyworker as needed. – Providing psychoeducation to patients normalizing encountering of common barriers such as being too ill to use the robot sometimes. – Completing assessment of school and peer supportiveness with school prior to implementation; putting in place a plan to address non-supportiveness as needed. – Offering a pre-implementation trial to every patient.
Ongoing communication with the school	– Implementing a standardized system for communication between school and patient regarding attendance (e.g., app, online interactive timetable).

cancer patients report that "control over life" is a core aspect of life that is negatively impacted by cancer. Given loss of control has been linked to poor psychological and treatment adherence outcomes in child and adolescent cancer patients (Wicks and Mitchell, 2010), it has accordingly been advised that clinicians try to foster patients' sense of control in areas of their lives they are able to have control over (e.g., health promoting activities; Belizzi et al., 2012). As such, a telepresence robot service may be of great benefit in enabling patients to feel they have control and choice over their schooling and socialization.

Finally, the results from Phase II highlighted that a telepresence robot is not suitable for all adolescent patients being treated for cancer. Prior to a patient's acceptance into a telepresence robot service, it is recommended that the client's needs are adequately understood, and it is ensured their needs can be met by the service. For instance, is the kind of robot they prefer available? Are their expectations of the service realistic? Are they motivated to "attend school" and well enough to use a robot? Furthermore, providing psychoeducation on the benefits and potential negatives associated with using a robot (e.g., experiencing feelings of disconnectedness rather than connectedness) may enable protective factors to be put in place ahead of implementation. Service-users would also likely benefit from school and peer supportiveness being assessed prior to implementation. Where significant needs, barriers or concerns are identified through this screening process, psychosocial staff may be able to work with patients and schools to address these issues and ensure that schools are aware of patients' preferences. As evidenced in Phase II, a pre-implementation robot trial also provided valuable feedback on patient needs and preferences and identified practical barriers. A trial period may additionally assist with setting patient expectations and normalizing encountering of unavoidable hurdles such as the patient being too sick to use the robot some days or technological difficulties.

Recommendations for Implementing a Telepresence Robot Service

The pilot study allowed participants to provide insights into their experience of using a telepresence robot (**Table 3**). These valuable insights will be used to further refine and strengthen the TRECA service. The provision of ongoing information, training and support can facilitate stakeholder buy-in, ensuring sustained engagement with the service from patients, parents, and teachers. The identification and management of potential barriers to suitability and success with potential patients prior to the implementation of the robots' service is also recommended.

Strengths and Limitations

The strengths of the present study were its use of a PD process, which ensured that the telepresence robot service's planning, design, and implementation were guided by young cancer patients, parents, teachers, healthcare workers and psychosocial clinicians. In both phases of the study, participation from key stakeholders also ensured that a full picture of the impacts of and issues surrounding the service could be established. Limitations of this study included the potential that response bias may have occurred, where participants recruited to Phase I and II were those who tended to have a better experience with the service or more positive view of a robot service, and as such had a greater desire to take part in the study. Additionally, only young cancer patients and their parents, teachers, keyworkers and healthcare workers were included in Phase II's pilot testing, and as such, conclusions cannot be drawn about how a robot service may suit and benefit other populations (e.g., those with other illnesses or reasons for missing school).

Policy Implications and Future Directions

Using a PD framework (Clemensen et al., 2007), this two-phase study used interviews to assess stakeholders' views on using a telepresence robot service to connect cancer patients to school and understand stakeholder experiences of a subsequent pilot-test of this service. Phase I identified key stakeholder needs, potential service barriers and facilitators, and found high perceived acceptability. In Phase II, key themes were generated from interviews regarding the importance of stakeholder buy-in, facilitation of meaningful connection, and a telepresence robot service not being one-size-fits-all. The TRECA service's ability to be individualized and flexible in meeting patient needs enabled young cancer patients to connect academically and/or socially to their schools. Participants reported that engagement with the service appeared to enhance patients' sense of agency and wellbeing. The positive impact of a telepresence robot service has highlighted the need to consider how such a model may be embedded more broadly across the education system in Australia. In particular, we recommend that information about the service become commonplace amongst educators in Australia, with tools and information available to them to both offer this option as a point of referral for their students in the case of a cancer diagnosis; and, to decrease barriers of participation amongst the educators themselves. By applying stakeholders' recommendations from the present study to improve existing processes and procedures, the TRECA service can continue to grow in effectiveness and capacity.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are not publicly available as they contain potentially identifying and sensitive information. No ethical approval was obtained for the sharing of this dataset with researchers external to this project. Contact the corresponding author for further information.

ETHICS STATEMENT

The study was reviewed and approved by the University of Sydney and University of New South Wales Ethics Committees. Written informed consent to participate in this study was provided by the participant or a legal guardian/next of kin.

AUTHOR CONTRIBUTIONS

PP and JC contributed to the study design. TP collected the participant data. TP and JC analyzed the participant data. TP, JC, and PP prepared the manuscript. All authors read and approved the final manuscript.

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SUPPLEMENTARY MATERIAL

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Engagement in Digital Mental Health Interventions: Can Monetary Incentives Help?

Eliane M. Boucher, Haley E. Ward, Amelia C. Mounts and Acacia C. Parks*

Happify Health, New York, NY, United States

Digital mental health interventions (DMHI) are scalable and cost-effective strategies for increasing access to mental health care; however, dropout rates associated with digital interventions are high, particularly for open-access digital interventions. While some studies have focused on predictors of dropout from digital mental health programs, few studies have focused on engagement features that might improve engagement. In this perspective article, we discuss whether monetary incentives (MI) are one avenue to increasing user engagement in DMHI. We begin by reviewing the literature on the effects of MI for behavior change in health domains (e.g., dietary behaviors, substance use, and medication adherence). Then, drawing on a pilot study we conducted to test the effects of different levels of MI on usage and improvement in subjective well-being among users of a DMHI (Happify), we discuss the potential applications of MI for DMHI, the potential drawbacks of financial incentives in this context, and open questions for future research.

Keywords: monetary incentives, digital interventions, mobile apps, behavior change, user engagement

Edited by:
Ioana Roxana Podina,
University of Bucharest, Romania

Reviewed by:
Stefano Triberti,
University of Milan, Italy
Andreea Bica,
University of Bucharest, Romania

Correspondence:
Acacia C. Parks
acacia@happify.com

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INTRODUCTION

In 2021, 85% of U.S. adults reported having smartphones and 77% reported having broadband Internet (Perrin, 2021). Given increasing access to smartphones and the Internet, along with difficulties meeting the demand for health services (Thomas et al., 2009; Osborn et al., 2016), demand for digital behavioral interventions is growing. Recent research estimates more than 10,000 behavioral health applications are available for download (Carlo et al., 2019). The subset of these interventions that are evidence-based and science-tested is a cost-effective way of disseminating treatments to large populations while reducing structural and attitudinal barriers associated with in-person treatment (see Fairburn and Patel, 2018, for a discussion). For instance, people view the lower time commitments (e.g., traveling time and waiting in provider's office), increased flexibility (e.g., choosing the time of treatment and receiving treatment at home), and increased anonymity as perceived benefits of digital interventions (Gerhards et al., 2011; Ferwerda et al., 2013). People also seem willing to engage with health-related digital interventions; 50% of adults report using a fitness, medication-tracking, or other health-related application on their mobile phone (Mack, 2016). An even larger proportion (70%) reports being interested in using a smartphone application to monitor their mental health symptoms (Torous et al., 2014), particularly following the COVID-19 pandemic, when these tools were more accessible (Sorkin et al., 2021).

Internet-based interventions are also effective for addressing a variety of symptoms and conditions. Internet-based cognitive behavioral therapy (CBT) programs generally show moderate to large effects in terms of improving outcomes relative to control groups and may be as effective as face-to-face CBT (Cuijpers et al., 2008). Meta-analyses of digital interventions more broadly also find small to medium effects on outcomes including depression, anxiety, eating disorders (Sander et al., 2016), alcohol consumption (Kaner et al., 2017), and smoking cessation (Griffiths et al., 2018).

While the need for digital interventions is great, they have commonly struggled with low levels of engagement and high levels of dropout in clinical trials (Eysenbach, 2005) and in real-world roll-outs, especially when the cost to the user is minimal (Eysenbach, 2005; Cuijpers et al., 2008; Donkin et al., 2011). One review of user engagement for digital self-help interventions found that while downloads of such mobile applications are as high as 40,000 per month, only 7–42% of registrants engage in the moderate use of the application. Even fewer (0.5–28.6%) engage in sustained use or complete at least 6 weeks of the intervention (Fleming et al., 2018). Similarly, a review of real-world usage of mental health apps found that the median percentage of users who opened the app each day was 4%, and the median retention rate was 3.9% for 15 days and 3.3% for 30 days (Baumel et al., 2019). Consequently, while scalable and effective when used as recommended, low engagement prevents digital interventions from having their intended reach and impact.

Although some research has focused on the predictors of engagement at an individual level (Garnett et al., 2018), user-level variables, like personality and affect, may only account for a small portion of the variance in engagement (Sanatkar et al., 2021). Research on the impact of intervention features on engagement is largely in its infancy; however, what research exists suggests that programs involving more personalized advice and feedback (Strecher et al., 2008; Sharpe et al., 2017), a more individualized source (Strecher et al., 2008), email prompts (Alkhaldi et al., 2017), and text messages (Saslow et al., 2020) increase engagement. Research also suggests that support, from peers (Sharpe et al., 2017; Biagianti et al., 2018) or from therapists (Richards and Richardson, 2012; Mohr et al., 2013), increases engagement. Whereas monetary incentives (MI) are already used to promote user adherence to assessment schedules and data collection in research settings (Bentley and Thacker, 2004) and as a central intervention component in some key areas of behavior change, such as addiction (Petry, 2011), few studies have explored whether MI can increase engagement in digital interventions. Therefore, it is important to better understand what MI can (and cannot) do to improve engagement in digital mental health interventions (DMHI).

BEHAVIORAL ECONOMICS AND ENGAGEMENT IN BEHAVIORAL INTERVENTIONS

Although there is scant research on the use of MI in digital interventions, such incentives have been used as a public policy tool to influence health behaviors through legislation and subsidies for centuries (Vlaev et al., 2019). More recently, the use of MI to reward healthy behaviors has grown in popularity with healthcare systems, insurers, and research organizations. This method of increasing healthy behaviors and decreasing problematic ones involves providing people with rewards contingent on reaching a predetermined goal (e.g., negative carbon monoxide tests for smoking cessation, number of steps reached, etc.) (Giles et al., 2014). These interventions typically offer cash rewards or vouchers that can be redeemed for goods or services (Sigmon and Patrick, 2012). The value of rewards typically varies (e.g., one meta-analysis found that payments for MI studies ranged from $5.16 to $786; Giles et al., 2014). Instead of rewarding individuals with outside funding, some programs utilize loss incentive manipulation requiring individuals to deposit cash at the onset, which is then refunded once a therapeutic goal is reached (Sykes-Muskett et al., 2015).

Contingency management (CM) was originally designed to treat substance abuse. Some CM programs exist as a stand-alone intervention and directly incentivize negative drug tests (Barnett et al., 2011), whereas others reward patients for adhering to treatment (i.e., psychotherapy or medication) or a combination of adherence and negative tests (Rosen et al., 2007). Research supports that CM effectively reduces cigarette, opioid, alcohol, marijuana, and benzodiazepine use (Petry, 2011). According to one meta-analysis, CM is the treatment with the greatest effect for substance use disorders (Dutra et al., 2008), and often has off-target effects on related psychiatric symptomatology (e.g., depression and anxiety; Miguel et al., 2017). Beyond substance abuse, CM has also been effective in improving medication and treatment adherence (Haff et al., 2015), vaccinations (Mantzari et al., 2015), fruit and vegetable intake (Gardiner and Bryan, 2017), and exercise (Washington et al., 2014), contributing to improved mental and physical health among the general population and individuals with chronic conditions (Vlaev et al., 2019) including severe mental illness, diabetes, obesity, HIV, tuberculosis, osteoarthritis, and hypertension (Ellis et al., 2021).

MONETARY INCENTIVES IN DIGITAL INTERVENTIONS: SOME PRELIMINARY EVIDENCE

Despite evidence for the benefits of MI in face-to-face interventions, few digital interventions have incorporated these incentives; however, preliminary research suggests MI may be an effective engagement tool. In one study, participants downloaded a program called *Wellth*, which provides MI for engaging in specific health-related activities (e.g., medication adherence). Participants could earn up to $30 per month over 3 months. Of the 53 enrolled users, 54.72% completed the full 90-day program and 66% completed over 70% of the possible task check-ins *via* the app. Two-thirds of participants indicated MI increased their tendency to take their medication and adhere to their care plan (Granek et al., 2021). Similarly, in a naturalistic study of a 12-week digital fitness program, users who received MI for completing the program *via* their health plan were more than 12× more likely to complete the program than those who received no incentives (Wurst et al., 2020). However, to our knowledge, no randomized controlled trial on the effects of MI in digital interventions has been published.

Our research team conducted a pilot study on the impact of MI on engagement among Happify users that corroborates some of the observational evidence for MI. Happify is a self-guided DMHI accessible *via* smartphone or computer. It draws on various theoretical approaches to mental health including CBT (Beck, 1979), mindfulness-based stress reduction (Praissman, 2008), and positive psychology (Sin and Lyubomirsky, 2009), adapting evidence-based activities from these theoretical approaches into gamified versions. These gamified activities are organized into "tracks" that focus on a specific area of concern, like coping with negative thinking; users can also access activities outside tracks on demand. Happify use leads to significant improvement in mental health, including decreased symptoms of depression and anxiety, and increased resilience (Parks et al., 2018). Although engagement with the traditional, non-incentivized Happify program is better than comparable DMHI (Fleming et al., 2018), we were interested in whether MI could further improve engagement given that in some contexts, like clinical settings, higher levels of engagement may be required for clinically meaningful improvement.

In our study, new Happify users were randomly assigned to either a no incentives condition ($n = 41$), a sweepstakes condition where users were entered into prize drawings but received no MI ($n = 41$), or varying levels of MI ($n = 181$). Participants in MI conditions were rewarded for completing activities, progressing in tracks, and completing in-app assessments. Incentive conditions offered incrementally greater compensation for these tasks: base level (similar to what participants might earn in a research study; $n = 21$), 2× base level ($n = 30$), 4× base level ($n = 66$), 6× base level ($n = 25$), and 8× base level ($n = 39$). Aside from incentives, users had access to identical versions of the Happify commercial platform. We then tracked participants' usage of the program over time and tested the impact of MI on usage and changes in well-being between a user's first and last in-app assessment. Consequently, we focused on a subset of participants who completed at least two in-app assessments and thus were on the platform for 2 weeks or more.

Because the amount earned varied by user even within the same condition, we started by evaluating the relationship between MI and usage, treating the amount earned by each user as a continuous variable and time as a covariate (as this varied across users). Higher levels of compensation were associated with more usage, both in terms of active days on the platform, $\beta = 0.93$, $t(260) = 38.78$, $p < 0.001$, and activities completed, $\beta = 0.92$, $t(260) = 38.70$, $p < 0.001$. Higher levels of compensation earned also were associated with greater improvement in subjective well-being (based on our in-app assessment; see Parks et al., 2020, for a detailed description), $\beta = 0.30$, $t(261) = 5.16$, $p < 0.001$. Interestingly, the effect of MI on improvements in subjective well-being was mediated by the number of active days (Sobel = 2.22, SE = 0.08, $p = 0.027$), but not by the number of activities completed. This suggests that while MI increase both regularity and volume of usage, it is the increase in consistent usage that ultimately helps to improve outcomes associated with the intervention (in this case, well-being).

OPEN QUESTIONS AND CONSIDERATIONS

What Amount of Incentive Is Optimal for Behavioral Change?

Although there is promising preliminary evidence for the benefits of MI in digital interventions, the amount required to encourage engagement is unclear. Observational research of the Canadian health app *Carrot*, which rewards users for completing health-related quizzes and health risk assessments, found that a 10% decrease in points awarded for completing a quiz was associated with a 1% decrease in quiz responses (Brower et al., 2020), suggesting the mere presence of MI, rather than the amount of the incentive itself, may be important.

Our pilot study also sheds some light on this issue. Although earlier we treated the total amount earned as a continuous variable, we can also separate participants based on the amount of incentive offered. In our pilot, MI resulted in a higher percentage of active days (relative to total days since signup) on the platform, $F(6,256) = 11.45$, $p < 0.001$, and activities completed per week, $F(6,256) = 8.30$, $p < 0.001$. Users who received no incentives engaged with the program roughly as recommended (approximately two to three activities per week; see Carpenter et al., 2016), accessing the platform on 15.44% of the days since signing up for Happify (see **Figure 1**), and completing an average of 1.90 activities per week (see **Figure 2**). Users in the sweepstakes only condition accessed the platform slightly more, but averaged more than twice the number of activities per week. MI appeared successful in boosting usage beyond the recommended level; users who were offered MI accessed Happify at least twice as often and completed at least twice the recommended number of activities per week. However, differences between the different incentive levels were small, and while the relationship appears mostly linear, the difference between the two lowest incentive levels is negligible, whereas subsequent increases seem more impactful. The error bars in **Figures 1**, **2** also illustrate the large variability between users in whether MI increase usage; thus, while only differences between the 2× and 8× base level groups were significant, the variability coupled with our small sample may have undermined our ability to detect differences between groups. Nevertheless, these data suggest that paying more will not necessarily yield better outcomes and increasing MI may have diminishing returns.

Does Engagement and Behavior Change Revert When Incentives Are Removed?

How long MI should be offered and the impact of removing incentives on behavior also remain unclear. Some behavioral economists believe that increasing, rather than decreasing, incentives over time is most effective (Vlaev et al., 2019). This particular approach is common in programs for substance use; researchers argue that an escalating schedule of incentives should be offered until behavior change occurs, at which point incentives can be reduced without interfering with behavior (Stitzer and Petry, 2006). This monetary-based CM approach to substance use interventions has demonstrated

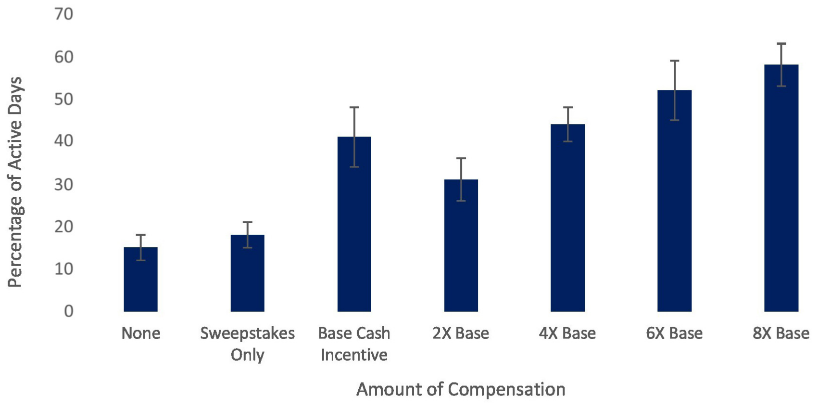

FIGURE 1 | Relationship between cash incentive level and percentage of active days on a digital mental health platform.

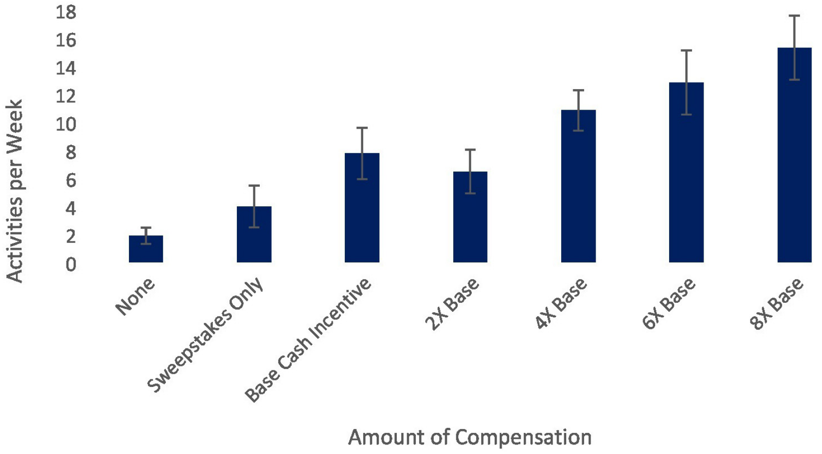

FIGURE 2 | Relationship between cash incentive level and activities completed per week on a digital mental health platform.

maintained gains even after treatment termination (Davis et al., 2016). But in other domains, gains appear to fade once incentives are removed (Paloyo et al., 2015). For example, research using activity trackers suggests incentives help increase physical activity initially, but these effects are not sustained when incentives are removed (Finkelstein et al., 2016; Agarwal et al., 2021).

One reason for the loss in improvement when incentives are removed is that MI might only target extrinsic motivation, and inhibit the development of intrinsic motivation. Indeed, a commonly reported concern with implementing MI widely is that it may hinder patients' development of intrinsic motivation to change health behaviors (e.g., Murayama et al., 2010). However, the effect of MI on intrinsic motivation remains unclear (Savioni et al., 2021), and evidence regarding the impact of financial incentives on intrinsic motivation is mixed (Petry et al., 2017). Relatedly, research on DMHI broadly, as well as specific research on the impact of MI (including our own pilot study) tend to operationally define engagement with usage metrics (e.g., active days and activities completed) and thus focus primarily on *technology engagement*. There is very little research that examines *patient engagement* in this context, or how MI impacts users' emotional and cognitive states regarding the intervention, the health behavior, or their underlying condition. This is an important distinction because usage metrics, or technology engagement, may be indicative of passive adherence that is ineffective at promoting health management and quality of life long-term (Graffigna et al., 2014; Barello and Graffigna, 2015), which may also explain why improvements in engagement or behavioral outcomes associated with MI are not always sustained once MI are removed.

Currently, there is no research exploring the effects of MI on motivation, how MI affects people beyond their observable behavior and symptom change, or on reducing or removing MI within digital interventions, and few studies of in-person interventions include follow-up periods beyond 6 months (Giles et al., 2014). Testing different MI models (CM vs. reduction over time vs. constant), the impact of extinction, the effects of MI on motivation to change, and moving beyond technological engagement are important avenues for future research. These research questions will help resolve the issue of whether or not MI can lead to real, lasting change.

Who Responds to Monetary Incentives and Who Does Not?

As discussed earlier, we noted a lot of variability in usage in our pilot study, even within conditions. The total amount earned also varied substantially within conditions (SDs ranging from $26.48 to $45.01), suggesting that even if people are offered larger incentives, they may not fully earn that incentive. This variability suggests some people may be more responsive to MI than others. For example, in substance use interventions, the impact of CM may depend on how responsive patients are to standard outpatient treatment (Forster et al., 2019). The benefits of MI may also depend on the behavior targeted by the intervention. Indeed, while CM appears effective for treating substance use, as noted earlier, the effects of MI on exercise may be temporary (Finkelstein et al., 2016; Hooker et al., 2018; Agarwal et al., 2021). Currently, MI research focuses on a single condition/behavior, so the extent to which effects vary depending on the condition or behavior of interest remains unclear. Research comparing MI effects across conditions will therefore be important to understand the contexts in which they are most effective.

Culture also plays a central role in how incentives are perceived; while they can be very effective if tailored to the target culture, a lack of cultural alignment can hinder success (Martin et al., 2017). For example, some research suggests smaller compensation amounts may be more effective for people from lower socioeconomic backgrounds (Vlaev et al., 2019). In addition, although motivation differs as a function of individualism and collectivism (Markus and Kitayama, 1991), research on the impact of MI in digital interventions, including our pilot study, included predominantly Western samples. Some research points to differences between Eastern and Western cultures in responses to MI on other behaviors, like purchasing intentions (Tercia and Teichert, 2016), emphasizing the importance of considering cultural differences. However, little research has focused on understanding whether individual or cultural differences influence the effectiveness of MI. To be scalable, it will be important to understand the factors that predict a patient's response to MI in digital interventions, including personality and cultural background.

CONCLUSION

Engagement is a crucial aspect of any DMHI (Eysenbach, 2005), making MI a hot topic in digital therapeutics. If we can determine how to optimize these incentives, there is great potential to increase uptake and retention metrics. Although the first digital therapeutic to receive FDA clearance, reSET, uses CM as part of its intervention (Maricich et al., 2021), there are still many questions we have yet to answer about the impact of MI in digital interventions. For example, do MI drive better clinical outcomes? Must participants always be rewarded to maintain usage? Is the cost/benefit ratio of the incentive and the relief of disease symptoms one that makes sense to payors? And in what cases are the effects driven by the incentives vs. true behavioral change that has taken place as a result of the incentives? Furthermore, there are ethical considerations and potential psychological implications of using money to incentivize participation (Ashcroft, 2011; Vlaev et al., 2019).

Our pilot data suggest MI have a clear impact on usage with our DMHI, but the impact is inconsistent. Therefore, the conclusion that "monetary incentives improve engagement" must be tempered by several caveats: (1) only on technological engagement or usage, (2) only if high usage levels are spread out over multiple sessions, (3) more money does not necessarily mean more benefit, (4) only if done in a way that leads to sustained change, and (5) there is large variability in how people respond to MI. Consequently, intervention developers must determine whether the additional cost of offering MI is worth the potential boost in engagement. For example, in the pilot we discussed here, participants in the highest incentive condition, who were offered 8× the amount as those at the lowest incentive level, were active an average of 12.50 more days and completed an average of 67.58 more activities. This increase may be worth the additional cost for some interventions, but not for others. Additional research adequately powered to explore the impact of incentive amount on both technological and patient engagement will be crucial to understanding how to optimally implement MI into digital interventions. It will take scientific input from every digital mental health manufacturer and science group using MI before we can fully understand the value, and potential pitfalls, of such incentives for improving digital product engagement. Nevertheless, we suggest that while a potentially useful tool, MI may not be a one-size-fits-all solution to the problem with engagement in digital interventions that one might have hoped for.

DATA AVAILABILITY STATEMENT

The data analyzed in this study are subject to the following licenses/restrictions: the data for the pilot study described in this article were collected as part of market research conducted by Happify Health using the commercial Happify platform. Due to user privacy concerns, individual data will not be shared and we present outcomes in aggregate form only. Interested readers may contact the corresponding author for additional information. Requests to access these datasets should be directed to EB, eliane@happify.com.

ETHICS STATEMENT

Ethical review and approval was not required for the study on human participants in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Data discussed in this manuscript were collected as part of market research and covered by our user agreement.

AUTHOR CONTRIBUTIONS

EB and AP conceptualized the idea for this manuscript. EB analyzed the pilot data. EB, HW, and AP wrote the manuscript. AM provided manuscript support. All authors contributed to the article and approved the submitted version.

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ORIGINAL RESEARCH
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Developing a Brief Tele-Psychotherapy Model for COVID-19 Patients and Their Family Members

Bruno Biagianti[1]*, Silvana Zito[2], Chiara Fornoni[2], Valeria Ginex[2], Marcella Bellani[3], Cinzia Bressi[1,2] and Paolo Brambilla[1,2]

[1] *Department of Pathophysiology and Transplantation, University of Milan, Milan, Italy,* [2] *Department of Neurosciences and Mental Health, Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, Milan, Italy,* [3] *Department of Neurosciences, Section of Psychiatry, Biomedicine and Movement Sciences, University of Verona, Verona, Italy*

Objective: The COVID-19 pandemic is negatively impacting the mental health of COVID-19 patients and family members. Given the restrictions limiting in person contact to reduce the spread of the virus, a digital approach is needed to tackle the psychological aftermath of the pandemic. We present the development of a brief remote psychotherapy program for COVID-19 patients and/or their relatives.

Methods: We first reviewed the literature on psychotherapeutic interventions for COVID-19 related symptoms. Based on this evidence, we leveraged ongoing clinical experiences with COVID-19 survivors and family members to design an intervention model that could be disseminated and integrated into the workflow of the mental health system.

Results: This 8-session model –inspired by constructivist and hermeneutic-phenomenological therapies– serves COVID-19 patients during hospitalization, remission and recovery. This model can also be delivered to people dealing with the COVID-19 hospitalization/discharge of a family member, or the loss of a family member due to COVID-19.

Conclusion: We described a remote psychotherapeutic approach to tackle the COVID-19 pandemic psychological aftermath. To date, the approach seems feasible and highly customizable to patients' needs. Studies are underway to test its preliminary efficacy. Once proven efficacious, this treatment model could provide a blueprint for future tele-psychology wide-scale interventions.

Keywords: COVID-19, tele-psychiatry, treatment development, digital mental health intervention, psychotherapy

Edited by:
Alexandra Voinescu,
University of Bath, United Kingdom

Reviewed by:
Yanxia Lu,
Shandong University, China
Hao Fong Sit,
The University of Hong Kong,
Hong Kong SAR, China

***Correspondence:**
Bruno Biagianti
bruno.biagianti@unimi.it

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INTRODUCTION

At the beginning of June 2021, the COVID-19 pandemic had affected 172,433,303 people worldwide, with 3,706,788 who died, and 155,086,546 who recovered. In Italy, out of a total of 60,379,981 inhabitants, 3,886,867 were infected and recovered from COVID-19[1]. On June 22nd, in the region of Lombardy, the total number of COVID-19 cases was 840,772, of which: 793,368

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[1] https://ourworldindata.org/coronavirus-data?country=~ITA

recovered, 33,757 died, while 13,647 were still positive cases[2]. These numbers not only describe the enormous impact of this phenomenon, but also shed light on its ongoing challenges.

Current predictive models show that during the (Dorman-Ilan et al., 2020) COVID-19 pandemic, the number of people with impaired mental health exceeded the number of people affected by the infection itself (Cannito et al., 2020; Delmastro and Zamariola, 2020; Fusar-Poli et al., 2020; Esposito et al., 2021). Those at greatest risk for mental distress are certainly COVID-19 patients and their family members (Landi et al., 2020; Tanoue et al., 2020). The psychological aftermath of this pandemic has been of unprecedented magnitude: COVID-19 survivors have risked their lives, have lost acquaintances or family members, and have spent long periods of isolation and social distancing, without being able to enjoy the physical presence of their significant others. Even during the recovery phase, the clinical management of COVID-19 sequelae and premorbid conditions has required the implementation of rehabilitation programs that have often neglected the psychological distress (Cereda et al., 2021; Negrini et al., 2021). Finally, despite the vaccination campaign, vulnerable individuals will likely have to live in conditions of partial or full restriction of their daily activities for a long time to come. On the other hand, family members and caregivers of COVID-19 survivors have experienced psychological distress during the hospitalization phase of their relatives, unable to offer personal assistance and receive adequate psychological support (Ying et al., 2020).

While many studies are available on the psychological impact the pandemic has had on the general population, few studies have considered survivors of COVID-19 (Cénat et al., 2021). The incidence and prevalence of psychological distress in COVID-19 patients varies by country and by study methodology (Cai et al., 2020), in a survey questionnaire study, report a psychological distress prevalence of 54.8% on a sample of 106 Chinese COVID-19 patients (mean age 45.7 ± 14) in early convalescence. Of these, 31, 22.2, and 38.1% met the criteria for excessive stress, anxiety, and depression, respectively. Authors highlight the difference with previous studies worldwide, where the incidence of mental disorders after major disasters ranged from 10 to 20%. Halpin et al. (2021) conducted a cross sectional study in the United Kingdom on 100 COVID-19 patients (68 ward, 32 Intensive Care Unit, mean age 64.5). PTSD symptoms were found in 23.5 ward patients and 46.9 ICU patients. Self-reported worsening of anxiety and depression was reported from 16.2 ward patients and 37.5 ICU. Finally, Imran et al. (2021) conducted a multicentric cross-sectional study in Dubai, with 103 and 85 COVID-19 patients evaluated at 4 and 8 weeks after discharge, respectively. They indicated a prevalence of anxiety symptoms (21.4 and 9.5%), depression (12.7 and 7.1%), and PTSD (8.7 and 4.7%). Unfortunately, no studies published to date indicate what is the prevalence and incidence of psychological stress in the relatives of COVID/19 survivors. In sum, the incidence and prevalence of psychological distress in COVID-19 survivors and their families have reached rates that go beyond the current possibilities of any mental health system to offer in-person services (Johnson et al., 2020) with the result that most users fail to receive the necessary support. For this reason, the public health systems of several countries have implemented *ad hoc* services for psychological support (Dong et al., 2020; Rosenberg et al., 2020). Since psychological suffering significantly reduces the quality of life (Corrigan and Buican, 1995; Choo et al., 2019) there exists an urgent need to intervene on the psychological suffering of COVID-19 survivors and their family members. Treatments that can be offered safely and on a large scale during the acute, weaning and recovery phases of the illness, without further burdening an already strained health system, are desperately needed (Fattori et al., 2021; Radfar et al., 2021).

Governments, policymakers, and stakeholders have called for action in this direction. Many countries have expanded their laws and regulations to allow for more widespread adoption of telemedicine systems by adding remote psychological therapies to their healthcare reimbursement lists. In Italy, on March 24th 2021 an open call for the adoption of telemedicine technologies and monitoring systems was jointly launched by the Ministry for Technological Innovation and Digitization, the Ministry of Health, the National Institute of Health and the World Health Organization[3].

The purpose of this article is to describe our attempt to respond to this call to action. We first reviewed the scientific literature on psychotherapeutic interventions that were designed to treat symptoms among COVID-19 patients, family-members, and caregivers. Based on this evidence, we leveraged the ongoing clinical experiences with COVID-19 survivors and family members to design a clinical intervention model that could be remotely administered and could easily integrate with the reimbursement system of the regional health service. The result of this process was the development of a brief remote psychotherapy program to be delivered via telemedicine.

STATE OF THE ART: EXPERIMENTAL TRIALS

The online search strategy was conducted through two of the major public scientific databases – PubMed and Scopus – and ended on May 30th, 2021. The following search terms were entered: ("COVID-19" OR "SARS-CoV-2" OR "coronavirus") AND ("psychotherapy" OR "online psychological treatment" OR "online therapy"). No date limit was set and only contributions written in English were included. Gray literature was not searched for. Both single-arm and randomized controlled trials, as well as qualitative studies, were considered for eligibility. Abstracts, reviews, meta-analyses, opinion papers, research protocols, qualitative studies, and papers without outcome data were excluded.

Seven studies met our criteria and presented findings from psychological interventions delivered to COVID-19 patients (see **Table 1**). Unfortunately, no studies are available on interventions for family members.

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[2] https://opendatadpc.maps.arcgis.com

[3] https://innovazione.gov.it/notizie/articoli/en/tele-medicine-and-monitoring-systems-a-call-for-technologies-to-contrast-the-spre/

TABLE 1 | Psychological interventions delivered to COVID-19 patients.

Article	Study design	Sample (*n*)	Age (mean ± SD)	Treatment period	Psychological intervention	Severity of the disease	Pre-post quantitative measurements	Main results
Dincer and Inangil, 2021	Randomized controlled trial	35 Experimental 37 Control	Experimental: 33.37 ± 9.58 Controls: 33.54 ± 9.83	Single session, 7 subgroups of 5 patient participants	EFT	Exposed to COVID-19	Subjective units of Distress Scale State-Trait Anxiety Inventory Tx-1, Burnout scale	The intervention group experienced significant reductions in stress, anxiety, and burnout compared to the control group.
Ferrario et al., 2021	Case-control study	181	75.27 ± 12.45	Not reported	CBT	Post-Acute	//	Of 86 patients in the COVID-19 ward, 75.59% underwent psychological CBT treatment, 11.6% were supported remotely, only 7% showed good adaptation. While for the general number of this sample (181), 35.91% required structured psychological treatment.
Ping et al., 2020	Qualitative study	25	//	1 month	UBPI	Exposed to COVID	//	Nurses who used UBPI techniques for 1 month provided positive qualitative results
Shaygan et al., 2021	Pilot cluster randomized parallel-controlled trial	Experimental: 26 Controls = 22	36.77 ± 11.81	2 weeks, 14 daily modules	CBT	Mild-to-Moderate COVID-19 = 19 Severe COVID-19 = 7	Connor-Davidson Resilience Scale Perceived Stress Scale	The results suggest that compared to controls, the intervention group had significantly greater improvements in resilience and perceived stress scores after 2 weeks.
Sotoudeh et al., 2020	Randomized clinical trial	30	Experimental: 41.92 ± 12.2 Control: 44.7 ± 14.2	Not reported	Not reported	Acute	Depression, Anxiety and Stress Scale 21 Symptom Checklist (SCL-25), WHO-QOL-BREF	Significant differences were found between the experimental and control groups in terms of quality of life, depression, anxiety, stress, and mental health.
Wahlund et al., 2021	Randomized controlled trial	Intervention (*n* = 335) Waiting list (*n* = 335)	45 (13)	3 weeks	CBT	Daily worry about COVID-19	Generalized Anxiety Disorder Assessment (GAD-7) Work and Social Adjustment Scale Insomnia Severity Index Montgomery–Åsberg Depression Rating Scale Self Assessment	Treatment yielded significant outcomes by reducing concern about COVID-19 for the intervention group compared to waiting list, likewise on all secondary measures: mood, daily functioning, insomnia and intolerance to uncertainty.
Wei et al., 2020	Prospective, randomized, controlled, 2-week study	Intervention group (*n* = 13) Control group (*n* = 13)	Intervention group: 40.8 ± 13.5 Control group: 48.5 ± 9.5	2 weeks	Self-help intervention (desensitization techniques)	Medium COVID-19 = 5 Severe COVID-19 = 7	Hamilton Depression Rating Scale Hamilton anxiety rating Scale	COVID-19 patients in the intervention group showed significantly reduced levels of depression and anxiety symptoms after 2 weeks, compared with those in the control group.

Abbreviations: CBT, Cognitive behavioral therapy; EFT, Emotional freedom techniques; SD, Standard deviation; and UBPI, Ultra brief psychological intervention.

Three studies investigated the effects of self-guided, online programs designed to offer remote psychological assistance to COVID-19 patients (Wei et al., 2020; Shaygan et al., 2021; Wahlund et al., 2021). Wahlund et al. delivered a brief digital self-guided psychological intervention based on CBT principles to COVID-19 patients. The 3-week intervention was delivered through an encrypted study website. Results from this study showed significant reductions in COVID-19-related worries in patients compared to healthy controls, as well as in secondary outcomes (Wahlund et al., 2021). Wei and colleagues structured their intervention on audio-recordings that covered four main aspects: breathing relaxation training, awareness (body scanning), "refuge" ability, and the butterfly hug method (Wei et al., 2020). COVID-19 patients and healthy controls could access this self-help intervention for up to 2 weeks. Significant reductions in depression and anxiety were found in patients compared to controls. Shaygan et al. (2021) designed a 2-week online intervention centered around psychoeducational cognitive–behavioral techniques, stress management techniques, mindfulness-based stress reduction, and positive psychotherapy. After 2 weeks, COVID-19 patients showed greater resilience and less perceived stress compared to healthy controls. Sotoudeh et al. (2020) implemented a brief crisis intervention package that was adapted from brief CBT protocols and scientific publications in the realm of emergency psychiatry. The package was delivered at the psychological center of a public hospital where COVID-19 patients were hospitalized. The authors found a statistically significant reduction in anxiety, depression and perceived stress, as well as an improvement in quality of life and overall mental health among COVID-19 patients compared to healthy controls.

Ping et al. (2020) studied the effects of an Ultra Brief Psychological Intervention (UBPI) model that was conceptualized in 2018 for the Malaysian context. The UBPI model includes intervention techniques borrowed from different psychotherapeutic approaches, is based on indications from the Psychological First Aid, and was adapted to the unique needs emerging from the COVID-19 emergency. Ping and colleagues remotely delivered USPI over video on medical and nursing staff and on the general population. Findings from the study showed efficacy and acceptability, despite raising some ethical questions about the risks associated with the confidentiality of information.

Dincer and Inangil (2021) selected a sample of non-clinical subjects and conducted a singlesession, online, group-based intervention centered on the principles of emotionally focused therapy, which is recognized as a treatment for physical stress and emotional distress. Findings showed a significant reduction in perceived stress, anxiety, and burnout among COVID-19 patients compared to controls.

Ferrario et al. (2021) implemented a psychological intervention based on principles of CBT in a large sample of patients with COVID-19, who were assisted by a trained psychologist either remotely or in-person – directly from the COVID-19 ward where they were hospitalized. Results were reported somewhat inconsistently: of the 86 patients in the COVID-19 ward, 75.59% underwent psychological CBT treatment, 11.6% were supported remotely, only 7% showed good adaptation. As for the whole sample, authors reported that around 36% required structured psychological treatment, without reporting efficacy data.

CONSTRUCTION OF AN INTERVENTION MODEL

Theoretical Framework

Our intervention model builds upon data currently existing in the literature, and harmonizes techniques and strategies deriving from several psychotherapeutic orientations (mainly of the third generation) into a brief psychotherapy program. The approaches that were integrated into the model are listed in **Table 2**. The combination of different approaches was necessary to overcome the limits imposed by the remote delivery (such as the reconfiguration of the setting) and the distance (ideal proxemic space). As a matter of fact, tele-therapy acutely limits the operationalization of therapeutic techniques based on in-person interaction, the sharing of the here and now, non-verbal and body language, with important implications on the development of transference and countertransference. Similarly, if on one hand tele-therapy allows patients and providers to bypass the risk (and/or fear) of exposure, on the other it makes it difficult to understand and deepen some inter-relational aspects. For example, our model does not consider the fluctuations of the relationship between the therapist and the patient along the way, such as the theme of building trust. Therefore, we considered it necessary to integrate various therapeutic techniques and strategies, in order to mitigate both the limitations presented by the screen and the difficulties in building a remote "connection."

Our model was developed along two main theoretical trajectories: constructivist therapy (Neimeyer and Mahoney, 1995; Neimeyer, 2001) and hermeneutic-phenomenological therapy (Chessick, 1993). Briefly, the constructivist model considers emotions in an evolutionary sense as an instrument of personal knowledge and growth. Constructive is also the connection between emotions and motivational systems (attachment system, fear of separation, and sadness-despair from loss). Given the short duration of the intervention, we considered it appropriate to exclude the constructivist part of attributing meaning to one's emotional reaction in relation to one's early life experiences. The hermeneutic-phenomenological approach assumes that, starting from the patient's narration, the main issues to be addressed emerge spontaneously, along with any discrepancies between the patient's lived experience and the factual nature of what they describe. According to this approach, the therapist highlights early on the patient's ways of suffering and coping, in hopes to identify together with the patient which ones are already familiar and which ones are novel. In the context of the patient's textual refiguration, by sharing clinical objectives the therapist makes room for interpretative cooperation: a commonality of intents that leads both, therapist and patient, to accept the fatigue of the clinical work (Ricœur, 1990). During all phases of the clinical work, suffering is contextualized both in the light of the recent traumatic experience (bereavement, hospitalization in intensive care, fear for one's life or that of a relative), and in the light of historical ways of suffering, so that the patient is able to recognize the meaning of the symptoms experienced.

This model is designed to be disseminated on a large scale: in line with the reimbursement system of the regional health service of Lombardy, 8 remote, 50-min, individual psychological sessions are offered weekly using secure video conferencing software. The severity of the clinical conditions of COVID-19 patients has largely influenced the sequencing of the intervention both for patients themselves and for their family members. We considered it appropriate to circumscribe the exploration of the different psychological targets within each session, given the unpredictable nature of the course of illness, and the possible onset of events that radically change the psychological state of patients and family

TABLE 2 | Psychotherapeutic approaches taken into consideration when designing our theoretical framework.

Theoretical approach	Definition	Strategies and techniques used to design our model	References
Cognitive behavioral therapy (CBT)	CBT focuses on the assessment of change in behaviors, emotions, and cognitions	ABC technique; Socratic Colloquium; Gradual exposures to feared situations; Relaxation techniques associated with the imagination.	Andersson and Carlbring, 2017
Dialectical behavior therapy (DBT)	DBT aims to manage emotions and behaviors through "a balance and synthesis of both acceptance and change." It uses the principles of (CBT) combined with awareness, acceptance, and dialectics.	Mindfulness, Tolerance to suffering, Regulation of emotions.	Eist, 2015; Huang et al., 2020
Compassion focused therapy (CFT)	CFT is an "integrated and multimodal approach that draws from evolutionary, social, developmental and Buddhist psychology, and neuroscience"	Evolutionary functional analysis of emotions: consult the safety/health function, tone of voice, look/smile Practice of perspective taking, recognition of challenges, letter of self-gratitude, compassionate images for oneself and others.	Gilbert, 2009
Acceptance and commitment therapy (ACT)	ACT aims to improve psychological flexibility, which refers to a person's ability to connect with the present moment more fully as a conscious human being and to engage in value-based action	increase psychological flexibility through six interrelated fundamental processes: acceptance, defusion, contact with the present moment, self as context, values and committed action	Fiorillo et al., 2017; Apolinário-Hagen et al., 2020
Schema therapy (ST)	ST is an integrative treatment approach that combines cognitive, behavioral, experiential, and psychoanalytic therapy techniques.	"Bridge" between coping modalities that reflect emotional regulation strategies (overcompensation, avoidance, or surrender), current problems and personal history	Zens, 2019
Online eye movement desensitization and reworking (EMDR)	EMDR is developed to reduce processing intrusive traumatic memories	Float back of stressful events linked to Covid-19, Desensitization, psychoeducation and stabilization. "Safe place," body scan and guided relaxation	Wilson et al., 2018; Tarquinio et al., 2020
Neuropsychological Cognitive Psychotherapy (PCN)	PCN integrates the most recent neuropsychological and biological knowledge are integrated with those deriving from the cognitive tradition, within a phenomenological- hermeneutic framework.	Imaginative Variation, Experience Refiguration, Experiential and Applied Learning	Liccione, 2013

members. What follows is a very schematic summary that refers to the "ideal" situation, where clinical conditions (of the patient, or of the relative of the patient) evolve linearly toward recovery.

Treatment Development

This model is designed to be applied to COVID-19 patients during hospitalization, after discharge, during the remission and recovery phases, as well as to COVID-19 survivors. Similarly, this model is intended to be delivered to people who are dealing with the hospitalization for/discharge after COVID-19 of a family member, or have lost a family member due to COVID-19. Based on our experience working with COVID-19 patients and family members, we have identified six clinical macro-areas that closely match those recently reported in the literature:

1) Traumatic and post-traumatic symptoms, mainly for those who have experienced hospitalization or are relatives of hospitalized patients (Cai et al., 2020; Kaseda and Levine, 2020). Emotional experiences that are often endorse include: worry and anxiety with catastrophic thoughts; moments of despondency and sadness (up to despair) with ideas of loss; anger, especially if the patient is young (anger from loss and anger from injustice); regret (for not having lived to the fullest the last time patient and family member saw each other); sense of guilt (for having transmitted the virus, for having contracted it in a less serious way). Guilt seems particularly relevant for family members, and often surfaces after moments of partial well-being during which they manage to distract themselves (as if to say it is not right to feel good while my family member is in the ICU);
2) For relatives of COVID-19 patients, suffering that originates from bereavement (Landa-Ramírez et al., 2020). Issues related to frozen grief: several patients also lost a parent to COVID-19, but when their significant other is hospitalized, it becomes more evident that they had frozen that grief, partially due to the absence of bereavement ceremonies;
3) Adaptation and functional reorientation due to somatic complications or sequelae (Ran et al., 2020). Many people affected by the COVID-19 experience directly or indirectly (as non-infected family members) report a subjective representation of reality characterized by recurrent, intrusive, and unwanted thoughts associated with the risk of/vulnerability to infection. Psychosomatic symptoms and self-perceived general health issues (gastrointestinal disturbances, fatigue, chest pains, palpitations, headaches, and difficulty falling asleep) are common and responsible for an increase in anxiety and an urge to use excessive and harmful protective measures even in safe places. Especially for COVID-19 survivors, the fear of the risk of returning to the experience of acute illness or contagion leads the subject to a constant body monitoring (control of blood pressure and saturation), to social and work avoidance, to the search for medical-clinical reassurance (emergency room visit, web searches) which reveal a strong desire to be assisted;

4) Identity reorientation following the traumatic experience (Halldorsdottir et al., 2021). In the younger age group, the theme of identity in development clearly emerges. A traumatic stress such as the COVID19 experience seems to undermine the construction and integration of aspects of the personality. Certainly, the short duration of intervention makes the psychological treatment of this macro-area and possible trajectories of identify development rather complicated;
5) Psychiatric symptoms triggered and/or exacerbated by the COVID-19 experience (Castellini et al., 2020; Belz et al., 2021). From a clinical point of view, the COVID-19 experience often exacerbates pre-existing symptoms. In other cases where subjects do not have a psychiatric history, pathological personological traits can emerge and require a range of flexible therapeutic strategies. In some cases, more serious symptoms such as depersonalization and derealization are the result of exacerbation of obsessive-compulsive personality traits that emerge because mechanisms of psychological resilience no longer are efficient.

Treatment Manualization

Eight remote, 50-min, individual psychological sessions are offered weekly using secure video conferencing software. Please see **Table 3** for a summary of the protocol.

Session 1

This session includes introductions, exploration of the patient's current experience space, and identification of the areas of suffering on the basis of the COVID-19 event. The narrative of the COVID-19 experience covers events of contagion, hospitalization, remission, recovery for both patients and family members. Information is collected regarding health conditions, clinical severity, length, and type of hospitalization, as well as particularly difficult moments. Space is dedicated to the float back of stressful events related to COVID-19 (situations, places, people, and images). The therapist is invested in forming the bases for therapeutic alliance, and the session usually ends with the validation of the suffering, an explicit offering of closeness and support on the part of the therapist, and an attempt to define shared goals for the therapeutic process.

Session 2

The information collected in the first session allows the therapist to create an initial diagnostic framework – both at a structural and functional level – and to identify unprocessed or unregulated emotions. In the context of the second interview, the therapist attempts to confirm the hypothesis developed during the first meeting and makes explicit their clinical goal. We believe this step is fundamental given the short duration of the intervention, so that patient and therapist can focus and work together more effectively. The shared goal is centered around learning to regulate disruptive emotions, in order to reach the level of resilience that is necessary to face the current adversities. Concomitantly, the therapist offers psychoeducation on the meaning of emotions, their manifestation in the body (heartbeat, breath, muscles, and bowels) and on the functioning of the worried mind (anxious and catastrophic thoughts).

Session 3

During session three, the therapist usually presents and practices techniques for emotion regulation, including: (i) bringing the mind back to the here and now versus the past and the future, and other mindfulness concepts; (ii) sensory motor techniques (e.g., tolerance window, grounding, posture modification, and breathing); (iii) stabilization techniques, for example "safe place"; (iv) body scanning and guided relaxation techniques; and (v) enhancement of resilience. In the event that patients have more resources or have demonstrated that they have self-monitoring skills and/or that they have successfully differentiated emotions at play, these emotion regulation techniques can be presented during session 2. Finally, with the aim of consolidating the sense of self-efficacy and self control that often derives from it, the therapist identifies and validates the intrapsychic and interpersonal resources associated with a greater degree of adaptation to the situation, including: a flexible personality; positive beliefs about self; identity roles and acceptance and commitment skills; work functioning; solid network of friends; family/loved ones.

Sessions 4–6

Based on the clinical material that has emerged in the first three sessions, the diagnostic framework and the identification of resources and vulnerabilities, the clinical macro-areas are addressed while respecting the patient's way of being as well as defense mechanisms.

Traumatic and Post Traumatic Symptoms

Certainly, the psychological picture is strictly dependent on the clinical conditions of the patient himself or of the family member:

- If the clinical conditions are serious, fluctuating, or worsening (active trauma), we believe it is appropriate to continue with validation, regulation techniques and resource consolidation as regulating emotions remains the most valuable tool in such circumstances. If new emotion regulation techniques are experienced and used successfully, they can become new valuable tools in the hands of the patient. It is useful to identify critical moments (e.g., the moment before going to bed and falling asleep; before and after the phone call from the hospital for family members), and at the same time imagine how to use emotional resources in such moments.
- If the clinical conditions are improving, there is more space to take distance from the emergency and observe it from afar (post-trauma). In general, we propose a work where used resources are recognized, and it becomes possible to face particularly challenging moments without reliving them (maintaining the "double focus"). By now, the exploration of sensations, emotions, movements, thoughts (such as hyperarousal, intrusiveness/surrendering, avoidance, hyper compensation) is usually more fluid, and allows the treatment and re-processing of the traumatic experience. The following techniques can be used: (i)

TABLE 3 | Goals, content, strategies, and techniques used in each session of the psychotherapeutic program.

Session number	Session goals	Session content	Strategies and techniques
1	Form the basis for therapeutic alliance validate the patient's suffering offer closeness and support	Introductions exploration of the patient's current experience space identification of the areas of suffering brief recapitulation of the patient's psychological functioning pre-COVID	Collection of information regarding health conditions, clinical severity, length, and type of hospitalization float back of stressful events related to COVID-19 (situations, places, people, images) identification of variables that regulate symptomatology and functional mechanisms that underlie the lack of wellbeing
2	Learn how to regulate disruptive emotions reach the level of resilience that is necessary to face the current adversities	Attempt to define shared goals for the therapeutic process create an initial diagnostic framework identify unprocessed or unregulated emotions	Psychoeducation on the meaning of emotions, their manifestation in the body (e.g., heartbeat, breath, muscles, bowels) and on the functioning of the worried mind (e.g., anxious and catastrophic thoughts)
3	Practice emotion regulation consolidate the sense of self-efficacy and self-control identify resources and vulnerabilities	Validate the intrapsychic and interpersonal resources associated with a greater degree of adaptation to the stressful situation, including: a flexible personality; positive beliefs about the self; identity roles and acceptance and commitment skills; work functioning; solid network of friends; family/loved ones	Bringing the mind back to the "*here and now*" versus the past and the future, and other mindfulness concepts sensory-motor techniques (e.g., tolerance window, grounding, posture modification, breathing) stabilization techniques, for example "safe place" body scanning and guided relaxation techniques enhancement of resilience
4–6	Address areas of clinical concern investigate defense mechanisms	*Traumatic and post-traumatic symptoms* validation, regulation techniques and resource consolidation exploration of sensations, emotions, movements, thoughts (such as hyperarousal, intrusiveness/surrendering, avoidance, hyper-compensation)	Imagery rescripting with a support figure that is able to mitigate the guilt/shame preponderance security, protection and care for one's own needs cognitive restructuring on "beliefs," cognitive biases, compassionate self-representation recognition of improvements that were made by the patients with their own resources.
		Grief navigate the phases of emotional processing: narration of the event; grounding, emotional regulation; modulation of motivational and affective systems; evolution of defense mechanisms from the most primitive (dissociation, denial) to the most advanced (depression)	Vocalization of suffering and emotional expressiveness awareness on defense mechanisms that tend to repress the memory processing of abandonment feelings and blaming tendencies representation remodeling with the respect to the relationship with the lost ones, with the goal of mitigating suffering
		Triggered or exacerbated psychiatric symptoms contextualizing the occurrence of known or new psychiatric symptoms assigning meaning to the worsening of such symptoms	Retracing the patient's history mentalization mood modulation and emotional self-regulation
7	Integrate the lived experience in the cohesive narrative of the self	Recognize patient's emotions/behaviors experienced during the acute phase as their own.	Validation of mental states and thought patterns experienced during the acute phase experience reformulation recognizing dualism whenever rethinking about the lived experiences – promoting dialectical thinking acceptance of new limitations and life adaptations
8	Discuss internal working models or relational patterns that have emerged during therapy closure	Summary of the therapeutic strategies that have been discussed during the sessions	Psychoeducation on relapse prevention description of risk mitigation strategies

Imagery rescripting with a support figure that is able to mitigate the guilt/shame preponderance; (ii) security, protection and care for one's own needs; (iii) cognitive restructuring on "beliefs," cognitive biases, compassionate self-representation; and (iv) recognition of improvements that were made by the patients with their own resources.

Grief

The experience of grief is treated incrementally, maintaining an attitude of empathic support and accompaniment during the various phases of emotional processing. These phases include: narration of the event; grounding, emotional regulation; modulation of motivational and affective systems; evolution of defense mechanisms from the most primitive (dissociation, denial) to the most advanced (depression). Given the brief duration of the interventions, realistic goals that can be set include the development of tolerance for suffering and the ability to attribute meaning to the event.

Psychiatric Symptoms Triggered and/or Exacerbated by the COVID-19 Pandemic

In our experience, the analysis of the emotions triggered by COVID-related events brings to the surface internal working models that have already emerged in the history of patients, such as the sense of guilt or the feeling of frustration for not being able to be useful. This analysis seems to facilitate the connection between the current lived experience and other difficult moments of life, thus allowing the experience to be "absorbed" and perceived as coherent to the self. Psychiatric patients who develop COVID-19 symptoms usually experience an exacerbation of pre-existing symptomatologic traits. We believe that retracing the patient's history, contextualizing the occurrence of known or new psychiatric symptoms, and ultimately assigning meaning to the worsening of such symptoms are useful management techniques that can help patients navigate the challenge and develop stronger skills.

Sessions 7–8

The last two sessions are dedicated to the process of integrating the lived experience in the cohesive narrative of the self. Unless there are specific open topics or needs, patients are encouraged to recognize the emotions/behaviors they had during the acute phase as their own. Sometimes this process already begins in previous sessions, and some patients recognize their own internal working models when narrating COVID-19 related moments that they have recently experienced. For example, when her spouse was discharged from the ICU and returned home, a patient said that she was surprised by how bothered she felt toward the newly-found and much-desired closeness with her husband. During the sessions, she developed the ability to recognize the feeling of seeing her personal space invaded as a coping mechanism that she had always put in place after long periods of distance from loved ones (after the holidays away from her daughter or after her husband's business trip).

The last session (Session 8) usually includes psychoeducation on relapse prevention and alert signs, especially around the symptoms of anxiety (panic attacks, somatization) and depression (rumination, mood). Along with risk mitigation strategies, patients are offered a summary of the therapeutic strategies that have been discussed during the sessions, and encouraged to reflect on the tools they can now use if and when symptoms arise in the coming future. Undeniably, relapse prevention and closure of the therapeutic process poses some critical challenges: in the face of a symptomatic improvement, a brief psychotherapy program can reveal internal working models or relational patterns worthy of further understanding and treatment, especially for those with dysfunctional personality traits and low emotional competency. However, we believe that the eschatological power of this brief therapeutic program centered on COVID-19 related experiences precisely lies in the possibility of generating in patients a desire for growth and awareness that goes beyond the adversities of the present moment.

FINAL CONSIDERATIONS

The opportunities presented by technology to disseminate new psychological models have revolutionized the field of mental health. Tele-psychiatry services make it possible to overcome the barriers posed by traditional mental health services during and after hospitalization of COVID-19 patients. Different lines of evidence indicate that different age groups, regardless of educational levels and psychopathological characteristics, have enough tech literacy to handle video calls and engage successfully with therapists. Using the support of technology to deliver psychotherapeutic services has been largely experimented in high-income countries during the COVID-19 pandemic. Despite obvious advantages in the continuity of treatments during restrictions, tele-psychiatry services face some limitations. As Liem et al. (2020) highlighted in a recent article, confidentiality, competency, compliance, consent and contingency should be addressed as ethical standards for tele-mental health. Once these aspects are addressed and the technological infrastructure is in place, the response to the COVID-19 emergency is likely to go beyond a temporary increase in the use of tele-psychiatry, and could represent the basis for a future standard of psychological assistance in the course of emergency situations that require restriction measures in domestic and social welfare contexts.

A plethora of services, interventions, tools has been redirected and used in response to COVID-19, most of which fell outside our database and literature search. Albeit narrow in scope, our endeavor was to exclusively find theory-driven models and protocols that were studied in a research environment. Namely, we were interested in developing, describing and illustrating here an intervention model that is based on the principles of psychotherapeutic practice, scientifically sound and easily scalable. We believe that non-specific psychological programs, tools, or interventions often do not meet the standards of psychotherapeutic practice, thus limiting the depth and breadth of the clinical work that the psychopathology of COVID-19 patients often requires.

Because the proposed intervention results from the integration of components from a variety of therapeutic approaches, and because it is designed to be disseminated on a large scale, we have attempted to identify characteristics and qualifications that therapists should have in order to deliver this treatment. In recent years, a large number of studies have tried to identify the therapist-related characteristics that are significantly associated with psychotherapy outcome factors (Mulder et al., 2017). Some of them seem to be common across different psychotherapeutic theoretical backgrounds and methodologies, since they are more related to therapy goals such as motivation to change. Nevertheless, some therapist characteristics are indispensable for the delivery of this intervention, including: (i) motivation and experiences with care with older patients and patients with severe medical comorbidities, (ii) expertise in collaborating with medical professionals (ICU doctors, pneumologists, etc...), and (iii) competency in treating different psychological manifestations in acute or post-acute phases. Moreover, our experience suggests that therapists might face resistance from COVID-19 patients because psychological treatment is not always actively requested by the patients themselves. Given the heterogeneity of psychological and medical complexity among COVID-19 survivors and family members and the customized approach we have developed, we believe that psychiatrists and clinical psychologists are the most suited mental health professionals to be trained on this treatment model.

The goal of this manuscript was to present the development process, the target population, as well as the manualized content of our psychotherapeutic program. This initiative is part of a larger project that will sequentially evaluate acceptability, feasibility, efficacy and effectiveness. A pilot study is currently underway to evaluate the feasibility and preliminary efficacy of this treatment. Interim results seem to indicate good acceptability, with virtually absent attrition rates and high attendance rates from COVID-19 patients and their family members. Clinicians involved in the project found the delivery method highly acceptable and compatible with their work flow. To date, no adverse events have been reported.

We believe that the intervention model described here has great innovation potential in that: (1) it offers immediate psychotherapeutic support to all those who live experiences of psychological suffering associated with COVID-19; (2) helps therapists to operate in acute and subacute settings, overcoming the barriers imposed by public health and prevention measures; and (3) contributes to study and determine the procedures by which tele-psychotherapy can be best implemented.

METHODOLOGICAL SIGNIFICANCE

This manuscript leverages ongoing clinical experiences with COVID-19 survivors and family members to propose a structured 8-week brief psychotherapy program designed to address commonly endorsed mental health symptoms associated with COVID-19.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

AUTHOR CONTRIBUTIONS

BB, SZ, CF, and VG: conceptualization, investigation, methodology, and writing – review and editing. MB and CB: writing – original draft, investigation, methodology, and writing – review and editing. PB: conceptualization, methodology, and writing – review and editing. All authors contributed to the article and approved the submitted version.

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Can We Boost Treatment Adherence to an Online Transdiagnostic Intervention by Adding Self-Enhancement Strategies? Results From a Randomized Controlled Non-inferiority Trial

*Andreea Bogdana Isbăşoiu, Bogdan Tudor Tulbure, Andrei Rusu and Florin Alin Sava**

Department of Psychology, West University of Timişoara, Timişoara, Romania

Background: Internet-delivered psychotherapy represents an impactful large-scale solution for addressing psychological disorders. In spite of its flexibility and scalability, the fact that the ones in need have to initiate and sustain the curse of the treatment by themselves comes with considerable downsides in terms of treatment adherence. One solution could be to increase the ease of use and attractivity of the strategies and assignments from such programs. The present study aims to address this issue by incorporating a series of self-oriented strategies to the validated internet-delivered short version of the Unified Protocol (UP). By this mean we intend to complement the symptom-focused assignments, which may be more suitable in a therapist assisted context, with ones designed for self-enhancement, which may be easier approached as self-initiated. Based on a randomized controlled non-inferiority trial we compared the modified version of the UP with the standard short version.

Method: The trial design was factorial, with two parallel arms and three measurement moments (baseline, post-intervention and 6-months follow-up). A total of 284 participants were randomly assigned to the intervention or the active control groups. The intervention group (baseline $n = 142$) received the self-enhanced nine modules of the UP (Self-enhanced 9UP) while the active control (baseline $n = 142$) received the standard nine modules (9UP). The newly added techniques were inspired by the acceptance and commitment therapy and were specific for self-concepts such as self-compassion or unconditional self-acceptance. Both programs lasted for 9 weeks. The non-inferiority of the Self-enhanced 9UP was tested against a margin of $d = -0.35$, on the following primary outcome measures: Patient Health Questionnaire 9 (PHQ9) – operationalization for depression; Generalized Anxiety Disorder 7 (GAD7) – operationalization for generalized anxiety or worry; Social Phobia Inventory (SPIN) – operationalization for social phobia; and Panic Disorder Severity Scale-Self Report (PDSS-SR) – that showed participants' level of panic. Treatment adherence was assessed through the drop-out analyses and the engagement in completing the

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Cristina Costescu,
Babeş-Bolyai University, Romania

Reviewed by:
Carmen Costea Barlutiu,
Babeş-Bolyai University, Romania
Teresa Pozo-Rico,
University of Alicante, Spain
Matei Silvia Raluca,
Ovidius University, Romania

****Correspondence:***
Florin Alin Sava
florin.sava@e-uvt.ro

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homework assignments. Secondary outcome measures included several self-concept measures: Self-Compassion Scale (SCS); Rosenberg Self-Esteem Scale (RSES); Unconditional Self-Acceptance Questionnaire (USAQ); New General Self-Efficacy Scale (NGSE); and Self-Concept Clarity Scale (SCCS). On the secondary outcomes we explored the potential boost of effectiveness produced by the newly added self-enhancement components.

Results: The dropout rates were similar in both groups (approximately 45%) and high overall. Adherence to treatment assignments was also modest and similar between groups (on average participants completed approximately half of the tasks), without a statistically significant bias toward the self-enhancement ones. Overall, both the intention-to-treat and completers analyses yielded no significant group by time interactions for any of the post-intervention and follow-up measurements, but a few non-inferiority analyses suggested that the Self-enhanced 9UP had a significantly weaker effectiveness than the standard 9UP. Within-group analyses showed significant alleviations on all the primary and secondary outcomes for both groups. The effect size estimates were mainly medium and high, and their magnitude tended to be kept also at 6-months follow-up.

Discussion: We failed to increase treatment adherence, but we found support with some exceptions, for the non-inferiority hypothesis. Hence, the alterations performed to the 9UP protocol, although they did not boost the treatment attractiveness, they also did not decrease the treatment effectiveness as suggested by most non-inferiority analyses. Likewise, the gain on self-concepts was produced by both groups. Hence, the short version of the UP seems to have the potential of effectively alleviating a larger palette of psychological variables associated with mental health symptoms than previously known. Even though our main objective was only partially achieved, these secondary results are insightful and could open new avenues of research.

Clinical Trial Registration: This trial has been registered at ClinicalTrials.Gov (NCT03917550; 17 April 2019; https://clinicaltrials.gov/ct2/show/NCT03917550).

Keywords: transdiagnostic, anxiety, depression, unified protocol, self-enhance, treatment adherence, non-inferiority trial

INTRODUCTION

Anxiety and depression are some of the most common mental disorders among adults. Worldwide, a total of 322 million people live with depression, and an additional 264 million live with anxiety (World Health Organization, 2017). Unfortunately, compared to 10 years before (i.e., 2005) some of the most recent epidemiological estimates (Walker et al., 2015) display an 18.4% increase for depression and 14.9% for anxiety. Such increases are only partially explained by population growth and aging, contributing to significant impairments in health and functional status. The data speak by themselves and point toward the constant need for evidence-based and large-scale strategies that could effectively address anxiety and depression. In this context, the importance of internet interventions as unbounded solutions for offering psychological treatments has never been more momentous. Also, the restrictions imposed in fighting the world-wide COVID-19 pandemic revealed this type of approaches as some of the only means to reach for those in need of psychological assistance. Guided internet-delivered therapy has plenty of advantages regarding its accessibility and flexibility, and has already shown promising results (see Berger et al., 2009; Furmark et al., 2009; Titov et al., 2011; Johansson and Andersson, 2012; Andersson, 2014; Tulbure et al., 2018; to name just a few randomized controlled trials). However, participants' high empowerment over the treatment process translates into self-regulatory effort (Donkin and Glozier, 2012; Zarski et al., 2018), thus impacting their adherence to such treatments (Beatty and Binnion, 2016; Flett et al., 2019; Arndt et al., 2020). Adherence reflects the degree to which participants receive the "active ingredients" of the program (Danaher et al., 2006), and was supported to be a significant mediator toward treatment outcomes (Arndt et al., 2020). Hence, the higher the adherence to the protocol, the higher the resulting mental health alleviation. Therefore, understanding and fostering treatment adherence are necessary and current concerns for the research on internet interventions (Zarski et al., 2018; Arndt et al., 2020).

Likewise, transdiagnostic interventions raised as a response to the issue of alarmingly high comorbidity rates between psychological disorders (Schaeuffele et al., 2021). This class of therapies is being designed to address transdiagnostic processes, i.e., psychological mechanisms which are common sources for the onset and/or development of several types of psychopathologies (Harvey et al., 2004). The Unified Protocol for Transdiagnostic Treatment of Emotional Disorders (UP; Barlow et al., 2011) is such a successful example, and is focused on emotion regulation as a shared mechanism (Sakiris and Berle, 2019). Moreover, recent findings also reported changes in neuroticism following UP (Zemestani et al., 2021), a personality dimension which is associated with the experience of intense negative emotions and a well-documented pathological risk factor (Kalokerinos et al., 2020). The protocol's efficacy, effectiveness and generalizability already rely on a large and robust body of evidence (see Sakiris and Berle, 2019; Cassiello-Robbins et al., 2020 for reviews and meta-analyses). The most recent systematic review (Cassiello-Robbins et al., 2020) identified 77 studies indicating support for the UP's suitability to a wide range of psychological conditions (i.e., 9 types of disorders), and also non-diagnosable problems.

Recently, Tulbure et al. (2018) delivered a shorter version of the UP that consisted of 9 web-based sessions (9UP) and found that relative to the wait-list control group, the intervention yielded medium to large effect sizes for the primary (e.g., anxiety, depression) and secondary (e.g., anxiety sensitivity) outcome measures. The effects were measured immediately after the treatment and 6 months later. Moreover, the intervention was perceived as credible, and participants declared themselves to be satisfied with the program. But in spite of these results, the modest treatment adherence reflected the status quo of internet interventions. For example, from the maximum of homework assignments, on average, participants completed a bit less than 50% of them. This observation occurred in spite of the fact that the program was not entirely self-help, but a therapist guided internet intervention. Importantly, each participant's number of finished assignments correlated negatively with the number of clinical disorders diagnosed at post-treatment (r = –0.23). Therefore, together with previous findings and observations regarding adherence to internet interventions (e.g., Zarski et al., 2018; Arndt et al., 2020), this particular result had a pivotal role in the development of the current study.

The present study aims to increase the adherence to an already validated guided internet-delivered psychological treatment, namely the online version (Tulbure et al., 2018) of the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders (UP; Barlow et al., 2011). Based on a two-armed randomized non-inferiority trial we compared a modified version of the internet-based UP with the protocol as validated by Tulbure et al. (2018). Since treatment adherence to internet interventions can be validly operationalized through the extent in which participants complete their assignments (Tulbure et al., 2018), the modifications that we came up with targeted this part of the program. We altered or replaced some non-critical assignments with newer ones derived from the self-enhancement literature. Through this modification, we tried to complement the mainly symptom-focused assignments of the UP, which may be better suited in a therapist delivered format, with more self-oriented ones, which may be easier approached in a standalone manner. Likewise, such self-enhancement add-on therapeutic techniques could bring the participants in deeper contact with their inner structure and lead to a greater desire to complete homework assignments and to progress further on the path of their own healing.

Since a rather neglected aspect in the transdiagnostic interventions for affective and anxiety disorders is how clients see themselves at a deeper level (their self-concept), the add-ons to the web-based UP protocol were psychotherapeutic techniques which aimed to bring participants in deeper contact with their inner structure. The rationale was that this could lead to a greater desire to achieve their homework and thus to progress further on the path of their own healing. Such self-enhancement strategies could not only improve treatment adherence in the general medical context (Sirois and Hirsch, 2019) and the mental health context (e.g., Uzer-Kremers et al., 2020) but could also be beneficial for the healing progress. Higher levels of self-compassion and self-esteem generally lead to lower levels of stress and burden and more perceived internal resources to cope with stressors. These, in turn, are likely to reduce the symptoms of anxiety and depression. There were 9 modifications to the 9 UP modules, one for each module. As to avoid any impact on the effectiveness of the original program, and not to alter its length and structure, the new assignments only replaced redundant or too extensive explanations from the existing ones or, where the existent exercises were simple and intuitive, replaced the examples from the explanations. Hence, in order to make room for the newer exercises, we altered the original content of the protocol by making the requirements of the existent exercises and assignments more concise.

The idea of "self as a context" was incorporated in Acceptance and Commitment Therapy (ACT; Hayes and Strosahl, 2004), thus the new exercises that we added were inspired and picked from this area (e.g., Lim et al., 2005; Leahy et al., 2011). Moreover, we considered that since self-restructuring represents an integral part of emotion-regulation, enhancing self-concepts within the framework of the UP has the potential to easily mold on the existing protocol, and through the nature of the tasks, to improve treatment adherence. In summary, the new techniques aimed the following constructs: Gratitude and ways to cultivate it – Grounds for gratitude (module 1); Altruism and generosity toward others – Planning acts of generosity (module 2); Self-compassion – Validation of the compassionate self (modules 3 and 4); Unconditional self-acceptance – Diffusion practices for everyday life (modules 5 and 6); Self-esteem – Identify ineffective rules and assumptions (modules 7 and 8); Life after treatment – Recognition of achievements and future plans (module 9). As compared to the mainly symptom focused assignments of the UP, we expected that the more directly the assignments will put participants in contact with their own selves, the more their involvement in the therapeutic process would be, and thus would increase their overall engagement with the protocol of the intervention.

Therefore, since we performed (subtle) alterations to each of the nine modules of the short web based UP protocol, our first aim was to ensure that these modifications will not deteriorate the effectiveness of the intervention. Hence, using a two-armed randomized non-inferiority trial design, the present study compared the modified version (self-enhanced) of the 9UP with the validated internet delivered protocol (Tulbure et al., 2018) as active control. Our main prediction was that both groups produce significant alleviations of the outcomes and that the self-enhanced 9UP is non-inferior to the 9UP on all primary outcomes (i.e., depression and anxiety symptoms). Moreover, due to the newly added self-related assignments, we also expected that participants engage in completing these new tasks to a higher frequency than the original ones. Finally, as a secondary, rather exploratory, objective, we tested if the self-enhanced 9UP produces significantly higher augmentations to the self-concepts targeted by the newly added exercises (e.g., self-esteem, self-compassion) than the standard protocol.

MATERIALS AND METHODS

Trial Design

In order to test if the modified version of the web-based 9UP intervention (which we refer to as the *Self-enhanced 9UP*) is at least as effective as the validated one but with improvements in terms of participants' adherence, the study was designed as a factorial randomized controlled non-inferiority trial (trial registration: ClinicalTrials.gov NCT03917550) with two parallel arms and three measurement moments (i.e., baseline, post-intervention, and 6-months follow-up). Participants were randomized with a 1:1 ratio to either (1) the Self-enhanced 9UP intervention group or (2) the standard 9UP active control. The trial was conducted as designed, without any unmanageable interferences caused by the online framework. In designing and reporting the trial we guided ourselves by the CONSORT standards (Boutron et al., 2017).

Participants

Potential participants were recruited online through nationwide mass-media news and social-media posts (mainly Facebook). The trial was advertised as free of charge and voluntary. General information about the intervention and the university affiliation of the study team was presented on the study's public website. The trial was open for the general public and participants were encouraged to maintain anonymity by creating and using a new (neutral) email account before registration. After reading and approving the informed consent (i.e., by a compulsory checkbox) interested participants registered for the study and received an anonymous ID (e.g., 1234abcd). Afterward, they were invited to complete a number of online self-report questionnaires for the self-assessment of their symptoms. During registration, the email addresses were checked for conformity while participants' mobile phone numbers were collected as part of the screening. Except for the phone interview, conducted before the trial admission, and brief phone reminders during the program (i.e., totalizing about 5 min per participant), there were no other synchronous or face-to-face interactions with the participants.

The inclusion criteria were as follows: (a) to be fluent in Romanian; (b) to be at least 18 years old; (c) to have basic computer/internet literacy, (d) to have at least a clinical diagnosis of major depressive disorder, and/or generalized anxiety disorder, and/or social anxiety disorder, and/or panic anxiety disorder and/or agoraphobia, and/or specific phobia or any combination of these conditions on Structured Clinical Interview for DSM-5® (SCID 5).The exclusion criteria were as follows: (a) presence of suicidal plans; (b) changes in the dosage of psychotropic medication during the last month (if present); (c) presence of bipolar disorder or psychosis (according to medication status); (d) presence of post-traumatic stress disorder or obsessive-compulsive disorder (according to SCID 5 interview); (e) presence of an alcohol or substance abuse and/or dependence disorder; (f) current participation in other psychological programs or treatments; (g) presence of obvious obstacle to participate (i.e., no current Internet access, long travel plans during the treatment period, etc.).

Potential participants who met the inclusion criteria upon completing the web-based measures were further invited to take a phone interview based on SCID 5. After the interview, participants who met all the inclusion criteria were informed about their admission, while those who did not meet the inclusion criteria received a message regarding their status (with the main reason for their exclusion) and additional resources that could be helpful for their situation.

Interventions

The main aim of this study was to directly compare two intervention strategies that comprised the two study arms: the UP for transdiagnostic treatment of anxiety and affective disorders that was originally developed by Barlow et al. (2011), in its short web-based 9 modules version (9UP; Tulbure et al., 2018), and a Self-enhanced 9UP version where enhancement strategies that address self-concepts were added. Both interventions were designed as stand-alone web-based programs that could address clinical symptoms of anxiety and affective disorder.

The central idea behind Barlow's UP is that affective and anxiety disorders are caused by similar underlying mechanisms and that we could jointly address the common vulnerabilities. The UP comprised of the following therapeutic strategies: (1) encouraging emotional awareness by noticing emotional experiences and accepting intense emotions; (2) adopting flexible thinking strategies; (3) recognizing and changing the emotion driven behaviors (EDB); (4) facilitating emotional exposure (to interoceptive and situational threats). This short version of Barlow's UP (9 web-based modules or the 9UP) that retained the essential ingredients of Barlow's protocol was previously proven effective (see Tulbure et al., 2018; for details regarding this web-based intervention).

The ***9UP self-enhanced*** intervention also retained the essential components and homework tasks originally included in the UP but replaced the redundant tasks or reduced some extensive

TABLE 1 | Overview of the newly added self-enhancement applications.

Module	Self-enhancement add-on	Application (assignment)	Source of the application
1	Gratitude and ways to cultivate it	Grounds for gratitude – finding reasons for being grateful in everyday life.	Leahy et al., 2011
2	Altruism and generosity towards others	Planning acts of generosity towards the others.	Leahy et al., 2011
3	Self-compassion and how can we improve it (part 1)	Imagining your compassionate self – description of the experience in a pleasant and relaxing place.	Leahy et al., 2011
4	Self-compassion and how can we improve it (part 2)	A letter of self-compassion – for the validation of the compassionate self.	Leahy et al., 2011
5	Unconditional self-acceptance and how can we improve it (part 1)	Diffusion practices for everyday life – a journal of behaviors based on unconditional acceptance and goodwill.	Leahy et al., 2011
6	Unconditional self-acceptance and how can we improve it (part 2)	Breaking identification with thoughts – keeping a diary of the daily "monsters."	Leahy et al., 2011
7	Self-esteem and how can we improve it (part 1)	Journal of unrealistic and exaggerated expectations.	Lim et al., 2005
8	Self-esteem and how can we improve it (part 2)	Identifying the ineffective rules and assumptions.	Lim et al., 2005
9	Life after treatment. Recognition of achievements and future plans	Putting events in perspective: what could I still do?	Leahy et al., 2011

explanations with new homework tasks designed to address self-concepts such as self-esteem, self-compassion, or unconditional self-acceptance. The intervention strategies for enhancing self-concepts were based on previous literature (i.e., Lim et al., 2005; Leahy et al., 2011). An overview of the newly added applications is presented in **Table 1**.

For both treatment arms the order of the sessions was retained form the original UP and the intervention content remained unchanged during the whole program, as no revisions or updates were provided during the trial. All participants were encouraged to be actively involved in the treatment by reading the information and completing the homework tasks for each week (as the optimal pace for the program). The amount of text per page was generally designed to fit an average laptop screen, requiring minimal scrolling. Both intervention arms consisted of nine modules (or web-based sessions) that were made available on a weekly basis, thus the 9-week total duration of the trial. Participants could access the intervention content whenever they decided to, and all previous modules remained activated and could be consulted at any time.

At the end of each week participants who completed their homework tasks received personalized feedback regarding the content of their homework. The feedback was delivered through an asynchronous internal email system that was designed to keep all messages within the secure web space of the therapy platform. If no homework was completed, participants received the following succession of messages starting from mid-week until they managed to complete or partially complete the tasks: two email reminders, two SMS reminders, and a short phone call (i.e., 5 min). Twelve graduate psychology students undergoing CBT training supervised by an experienced clinician assisted the participants throughout the study. Each graduate student was responsible for monitoring the evolution of a comparable number of participants from both treatment arms. We estimate that a graduate student spent on average 45 min per participant weekly. The written feedbacks were provided under the supervision of the experienced clinician who suggested response models and intervention strategies. If these web-based programs would be offered as routine programs in a clinical setting outside the university, we estimate that clinicians with average expertise would need about 20–25 min per participant per week.

Outcomes

All primary and secondary outcome measures were administered online at pre-treatment, post-treatment, and at 6-months follow-up. A number of studies have shown that online questionnaires produce similar results as the classical pen-and-paper format (Hollandare et al., 2010). Moreover, the anxiety and depression measures were successfully used in previous web-based interventions implemented by our team (e.g., Tulbure et al., 2015, 2018).

Treatment adherence (the intensity or dosage of treatment use) was monitored by the sum of homework assignments completed by each participant. We used this operationalization since it correlated with the treatment effectiveness in the previous trial of the online 9UP (Tulbure et al., 2018). Moreover, we complemented these results with the drop-out analysis and participants' feedback obtained through the online questionnaire at post-treatment (i.e., treatment satisfaction).

Primary Outcome Measures

Patient Health Questionnaire 9 (PHQ9; Kroenke et al., 2001) was designed to measure participants' level of depression reflecting the diagnostic criteria. The scale is one-dimensional and the total score ranges from 0 to 27. High scores are associated with elevated levels of depression. Reliability on our sample was at least optimal at each of the three measurement moments ($\alpha = [0.85,0.91]$).

Generalized Anxiety Disorder 7 (GAD7; Spitzer et al., 2006) was designed to measure participants' level of generalized anxiety or worry also reflecting the diagnostic criteria. The scale is unidimensional and the total score ranges from 0 to 21. High scores reflect higher levels of worry. Reliability on our sample was at least optimal at each measurement moment ($\alpha = [0.88,0.94]$).

Social Phobia Inventory (SPIN; Connor et al., 2000) was designed to measure participants' level of social phobia. The scale is unidimensional and the total score ranges from 0 to 68. High scores are associated with high levels of social phobia. Reliability on our sample was excellent at each measurement moment (α = [0.93,0.95]).

Panic Disorder Severity Scale-Self Report (PDSS-SR; Shear et al., 2001) was designed to measure participants' level of panic. The scale is unidimensional and the total score rages from 0 to 28. High scores are associated with elevated levels of panic. Reliability on our sample was excellent at each measurement moment (α = [0.92,0.93]).

Secondary Outcome Measures

Self-Concept Clarity Scale (SCCS; Campbell et al., 1996) was designed to measure participants' Self-Concept Clarity. The scale is unidimensional and the total score rages from 12 to 60. High scores are associated with high levels of Self-Clarity. Reliability on our sample was at least optimal at each measurement moment (α = [0.88,0.91]).

New General Self-Efficacy Scale (NGSE; Chen et al., 2001) was designed to measure participants' General Self-Efficacy. The scale is unidimensional and the total score rages from 8 to 40. High scores are associated with high levels of Self-Efficacy. Reliability on our sample was excellent at each measurement moment (α = [0.92,0.94]).

Unconditional Self-Acceptance Questionnaire (USAQ; Chamberlain and Haaga, 2001) was designed to measure participants' level of Unconditional Self-Acceptance. The scale is unidimensional and the total score rages from 20 to 140. High scores are associated with high levels of unconditional Self-Acceptance. Reliability on our sample was at least optimal at each measurement moment (α = [0.86,0.88]).

Rosenberg Self-Esteem Scale (RSES; Rosenberg, 1965) was designed to measure participants' level of Self-Esteem. The scale is unidimensional and the total score rages from 10 to 40. High scores are associated with high levels of Self-Esteem. Reliability on our sample was excellent at each measurement moment (α = [0.90,0.93]).

Self-Compassion Scale (SCS; Neff, 2003) was designed to measure participants' level of their Self-Compassion. The scale is multidimensional and the total score ranges from 26 to 130. For the mainly exploratory purpose for this study, we used only the total self-compassion score. Low values are associated with low levels of Self-Compassion, while high scores are associated with high levels of Self-Compassion. Reliability on our sample was at least optimal at each measurement moment (α = [0.89,0.95]).

Besides the aforementioned measures, the list of secondary outcomes also included the Work and Social Adjustment Scale (WSAS; Mundt et al., 2002), which measures symptom interference; Beck Depression Inventory-II (BDI-II; Beck et al., 1996), and Overall Depression Severity and Impairment Scale (ODSIS, Bentley et al., 2014), also as measures of depression; Overall Anxiety Severity and Impairment Scale (OASIS; Norman et al., 2006), and Penn State Worry Questionnaire (PSWQ; Meyer et al., 1990), as operationalizations of anxiety symptoms; and Anxiety Sensitivity Index 16 (ASI16; Reiss et al., 1986). These data are not in the main focus of the current manuscript and will serve secondary analyses (e.g., mechanisms of change) which will be reported in future manuscripts. However, for transparency, we tested the intervention effects also on these secondary outcomes and reported them as **Supplementary Material**.

Treatment Credibility

Treatment credibility inquired participants' expectations regarding treatment and was measured at baseline with five items previously used on RCTs for internet interventions (e.g., Tulbure et al., 2018). The items were: *How much sense do you think it makes the method of delivering a psychological treatment over the internet?; How confident are you that the program will help you to better manage your emotions?; Would you recommend this program to a friend with the same emotional difficulties?; How effective will this program be in managing other uncomfortable emotions?; How confident are you that you will make improvements at the end of this program?* The response format was based on a 10-point Liker scale (e.g., *0 – not at all vs. 10 – to a great extant*). Internal consistency of the five items was α = 0.88. Credibility scores could have ranged between 0 and 50, higher scores represent greater credibility.

Sample Size

Our main goal was to test the non-inferiority hypothesis, namely that altering the content of 9UP in order to fit the extra self-related assignments will not decrease its effectiveness. Hence, we conducted the sample size estimation for a non-inferiority trial with continuous outcomes. Based on the online calculator (Sealed Envelope Ltd., 2012) developed after the recommendations of Julious (2004), for a 5% significance level, 80% power and a non-inferiority margin of Cohen's $d = 0.35$, the sample size required per group is of 101 participants (total $N = 202$). Considering a 20% attrition rate, the sample aimed to be recruited was of 222 participants.

Randomization and Blinding

Before starting the interventions, all included participants were randomly assigned by one of the authors (BTT), using a 1:1 ratio *via* a true random number generator[1]. No randomization restrictions were used. Included participants were then assigned to their intervention group by volunteering graduate students. Participants were the only actors blinded regarding the specific nature of the comparison (the non-inferiority hypothesis) as they were informed about the two treatments, but they were unaware which they will be receiving.

Statistical Methods

In order to test our predictions, we applied several sets of analyses. With the aid of linear mixed model effects (LMM) we first tested for any significant differences between the two groups at post-intervention or follow-up (group by time interactions). The interaction between factors was treated as fixed effect and the varying intercept of participants was set as random. Also based on LMM we tested the within-group modifications (for each separate

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[1] http://www.random.org

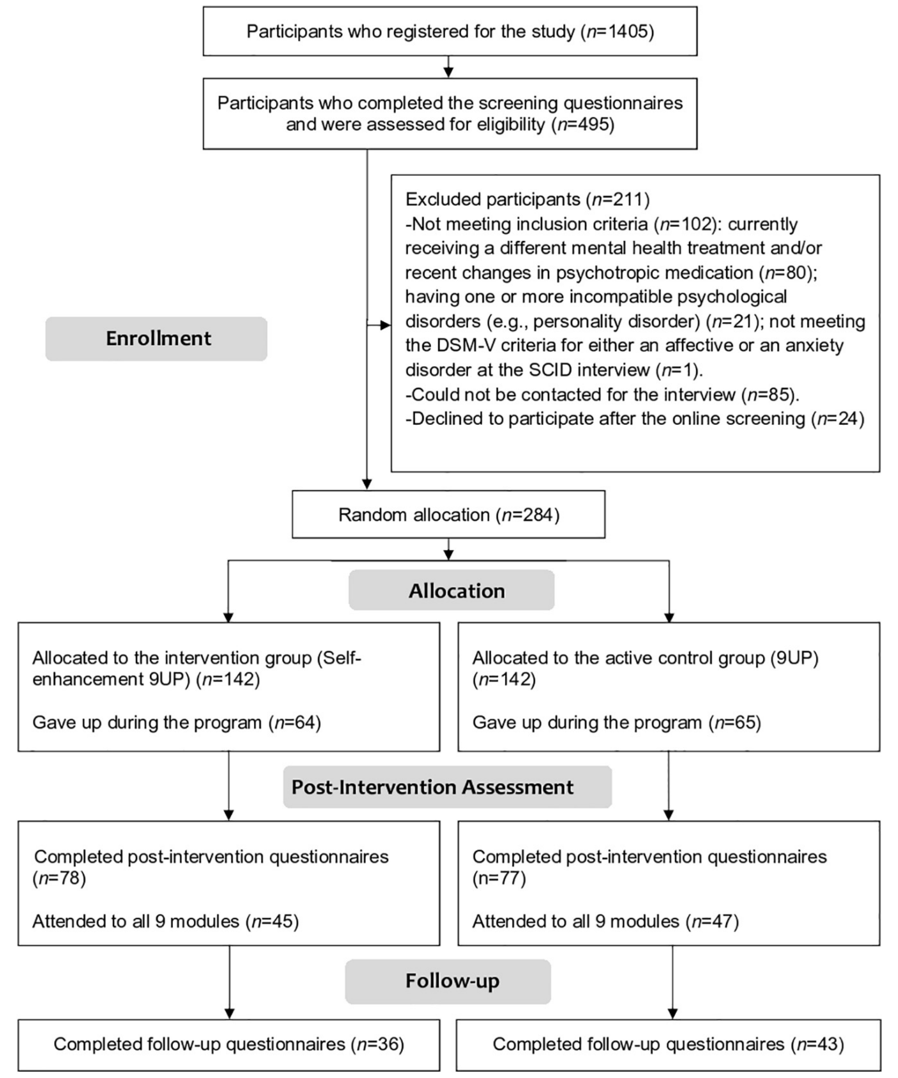

FIGURE 1 | The flowchart displaying participants' cycle throughout the study.

models). In this case we tested the baseline to post-intervention, and baseline to follow-up modifications in outcomes. As in the previous trial on 9UP (Tulbure et al., 2018), we included age, gender, and treatment credibility (which was assessed at baseline) as covariates in all LMM models. Also, these analyses were performed on all primary and secondary outcome measures and were conducted on the Intent-to-treat (ITT) principle. For each between or within comparison we reported the Cohen's *d* effect size estimate and its 95% confidence interval.

Since statistically non-significant differences between two groups are not implying equivalence (or non-inferiority, as in our case), there are dedicated tests developed for investigating such effects. Basically, a non-inferiority analysis tests if a new intervention is not worse than the standard one by more than a pre-specified extent, which is called the 'non-inferiority margin'. On continuous outcomes this bound can be specified as the smallest acceptable effect size. The standards for controlled trials developed by regulators (e.g., Committee for Medicinal Products for Human Use, 2005) suggest selecting the non-inferiority margin based on existing meta-analytical evidence from effectiveness trials on the active comparator and considering the lower limit of the 95% CI of the effect. However, this value should also be scrutinized by expert opinion as to ensure its clinical significance. In our case, we only had the previously conducted effectiveness trial on the web-based 9UP and the general meta-analyses on the unified protocol. The lower limit of the 95% CI for the effect size estimates on depression and anxiety outcomes was in the range of (0.30,0.40). Hence, we selected $d = 0.35$ (the mid-point between a small and medium effect) as the non-inferiority margin. We conducted the actual non-inferiority analyses based on equivalence *t*-tests for independent samples and reported if the observed data is significantly lower than the non-inferiority margin.

The analyses were carried out in R version 4.0.5 (R Core Team, 2021), with package *lme4* (Bates et al., 2015) to perform linear mixed model analyses, package *emmeans* (Lenth, 2020) to extract Estimated Marginal Means, and package *TOSTER* (Lakens, 2018) for the non-inferiority analysis.

Ethics

Study ethical approval was granted by the University Ethics Committee (5792/28.02.2019) before study initiation.

RESULTS

Participant Flow and Treatment Adherence

As illustrated in **Figure 1**, after mass-promoting the program, 1405 individuals manifested interest in participating. Out of them, 495 took part in the screening phase and 284 were found to be eligible and randomly allocated to the two arms of the study (n = 142 in each arm). During the 9 weeks of the program, both arms lost a similar number of people. Namely, from the intervention group 64 participants abandoned the program (45.07% dropout rate at post-intervention), and from the active control 65 participants (45.77% dropout rate at post-intervention). These numbers fail to meet our expectations (20% anticipated dropout), representing a more dramatic abandon rate than previously recorded in our internet interventions. Moreover, at six-moths follow-up responded only 36 of those who benefited of the Self-enhanced 9UP (74.65% dropout rate), and only 43 of participants from 9UP (69.72% dropout rate).

Moreover, since it is required for the non-inferiority analysis, we also isolated the data per protocol (PP). Based on a more permissive approach, we considered all participants who took part to the entire intervention – all nine modules – by completing at least one homework assignment per module. There were 45 participants who completed at least one assignment per module of the Self-enhancement 9UP (31.69% protocol adherence), and 47 participants from the 9UP (33.09% protocol adherence).

Finally, as previously mentioned, our main operationalization for treatment adherence was the overall number of homework assignments completed by participants. Participants in the 9UP active control had 36 assignments while those from the Self-enhanced 9UP intervention had 45 (36 + 9 self-related tasks). On average, participants from the control condition completed 56.3% of their homework (SD = 35.0), and those who received the self-enhanced 9UP completed 61.8% of their homework (SD = 32.2). The difference between the two groups was not statistically significant, [$t_{(282)} = 1.38$, $p = 0.084$, one-tailed]. Hence, on average, participants of both groups managed to work only on approximately half the assignments (as also in the previous validation of the web-based 9UP; Tulbure et al., 2018). Most importantly, contrary to our prediction, participants from the Self-enhanced 9UP did not seem to be more attracted by the newly added tasks, manifesting a similar elaboration rate as for assignments of the active control group.

Baseline Characteristics

Included participants (N = 284) had a mean age of 33.20 years old (SD = 10.09, age range 19–67) and most of them were women (n = 240, 84.5%). All participants had at least one clinical disorder (based on SCID I for DSM-5), and 32.04% of them received psychotherapy in the previous 4 years. On average, participants rated the treatment as rather credible (M = 39.05, SD = 7.65, range: 11–50). There were no statistically significant differences between the two groups on any of the recorded variables. Complete details regarding the screening characteristics of participants can be found in **Table 2**.

Intervention Effects on Primary Outcomes

On the one hand, the LMM analyses revealed no significant group by time interactions on any of the primary outcomes, neither on baseline to post-intervention change nor on baseline to follow-up change (see **Table 3** for detailed results). Hence, from this point of view, none of the two interventions were significantly more effective than the other (which should not be treated as non-inferiority). On the other hand, the decrease in symptoms within each group was statistically significant (all ps < 0.001; see **Table 4** for detailed results). Both intervention programs (the 9UP and the Self-enhanced 9UP version) produced alleviations on all four primary outcomes, with effects size indices ranging from small to medium (for the Self-enhanced 9UP) and medium to large (for the 9UP active control) with overlapping confidence intervals between the two groups. Importantly, the effects kept a similar magnitude at follow-up.

Non-inferiority Analysis

We conducted the non-inferiority analyses on the primary outcomes based on three scenarios: (1) data per protocol (PP; only on those participants who took part to the entire intervention – all modules), (2) intent-to-treat (ITT; all randomized participants, with the last observation carried forwards), and also on (3) completers (participants who completed any number of sessions or modules and also the post-intervention assessment). Even though the comparative reporting of PP and ITT results represent the recommended practice (e.g., Committee for Medicinal Products for Human Use, 2005), because of the large difference between the PP population (max n = 92) and the ITT one (max n = 284) we decided to also include a group with intermediate level of treatment adherence (completers max n = 155).

As can be seen from **Table 5**, the non-inferiority t-tests on PP data suggest that the self-enhanced 9UP program was non-inferior on most analyses based on the four main outcomes (ps < 0.025). The ITT data support the non-inferiority hypothesis in all cases, whereas the PP and completers data support the non-inferiority hypothesis on the majority of outcomes and occasions. Hence, with a cautionary note in mind because of the few results which departs from a non-inferiority scenario, we incline toward concluding that the non-inferiority of the self-enhanced 9UP program is supported by the data.

TABLE 2 | Baseline characteristics of the participants in the two groups and the entire sample.

Variable	Self-enhanced 9UP intervention (*n* = 142)	9UP active control (*n* = 142)	All participants (*n* = 284)	Statistic (df)	*p*
Age (years)				*t* = 0.23 (282)	0.81
Mean (*SD*)	33.34(10.20)	33.06 (10.02)	33.20 (10.09)		
Gender, *n* (%)				χ^2 = 0.43 (1)	0.51
Male	24 (16.9)	20 (14.1)	44 (15.5)		
Female	118 (83.1)	122 (85.9)	240 (84.5)		
Educational level, *n* (%)				χ^2 = 0.94 (1)	0.53
Higher education	103 (72.53)	105 (73.94)	208 (73.24)		
High school or lower	39 (27.47)	37 (26.06)	76 (26.76)		
Marital status, *n* (%)				χ^2 = 5.02 (4)	0.28
Never married	56 (39.43)	49 (34.5)	105 (36.97)		
In a relationship	29 (20.42)	24 (16.9)	53 (18.66)		
Married	40 (28.16)	54 (38.02)	94 (33.09)		
Divorced	15 (10.56)	15 (10.56)	30 (10.56)		
Widowed	2 (1.4)	0 (0.0)	2 (0.7)		
Primary diagnostic, *n* (%)				χ^2 = 10.94 (9)	0.28
GAD	21 (14.78)	322(2.53)	53 (18.66)		
SAD	8 (5.63)	8 (5.63)	16 (5.63)		
MDD	41 (28.87)	38 (26.76)	79 (27.81)		
PD/A	26(18.3)	18(12.67)	44 (15.49)		
PDD	42(29.57)	43(30.28)	85 (29.92)		
Other	4 (2.81)	3 (2.11)	7 (2.46)		
Secondary diagnostic, *n* (%)				χ^2 = 20.68(17)	0.24
GAD	46 (32.39)	38 (26.76)	84 (29.57)		
SAD	9 (6.33)	23 (16.19)	32 (11.26)		
MDD	7 (4.92)	14 (9.85)	21 (7.39)		
PD/A	28 (19.71)	24 (16.9)	52 (18.3)		
SP	1 (0.7)	1 (0.7)	2 (0.7)		
PDD	24 (16.9)	17 (11.97)	41 (14.43)		
Other	15 (10.56)	14 (9.85)	29 (10.21)		
Comorbid diagnostic, *n* (%)				χ^2 = 55.71(19)	0.49
GAD	23 (16.19)	21 (14.78)	44 (15.49)		
SAD	12 (8.45)	12 (8.45)	24 (8.45)		
MDD	8 (5.63)	8 (5.63)	16 (5.63)		
PD/A	9 (6.33)	8 (5.63)	17 (5.98)		
PDD	9 (6.33)	7 (4.92)	16 (5.63)		
Other	8 (5.63)	12 (8.45)	20 (7.04)		
Previous psychotherapy (in the last 4 years), *n* (%)				χ^2 = 0.14 (1)	0.70
Yes	47 (33.09)	44 (30.98)	91 (32.04)		
No	95 (66.9)	98 (69.01)	193 (67.95)		
Previous psychiatric diagnostic, *n* (%)				χ^2 = 0.15 (1)	0.69
Yes	40 (28.16)	43 (30.28)	83 (29.22)		
No	102 (71.83)	99 (69.71)	201 (70.77)		
Currently under medication, *n* (%)				χ^2 = 0.94 (1)	0.33
Yes	15 (10.56)	20 (14.08)	35 (12.32)		
No	127 (89.43)	122 (85.91)	249 (87.67)		
Time spent online (hours/day)				*t* = 1.17 (282)	0.24
Mean (*SD*)	4.67 (3.21)	4.26 (2.71)	4.46 (2.69)		
Treatment credibility					
Mean (*SD*)	38.91 (7.79)	39.19 (7.52)	39.05 (7.65)	*t* = 0.29 (279)	0.77

GAD, generalized anxiety disorder; SAD, social anxiety disorder; MDD, major depressive disorder; PD/A, panic disorder/agoraphobia; PTSD, post-traumatic stress disorder; OCD, obsessive compulsive disorder; PDD, persistent depressive disorder.

TABLE 3 | Estimated differences in mean change between baseline and post intervention, respectively, follow-up, for the intervention versus the control group (group by time interactions).

Variable	Group × Time	b [95% CI]	t* (df)†	d [95% CI]
Primary outcomes				
PHQ9	Post-intervention	0.47 [–1.37, 2.31]	0.50 (418)	–0.04 [–0.18, 0.11]
	Follow-up	1.45 [–1.27, 4.17]	1.05 (338)	–0.10 [–0.29, 0.09]
GAD7	Post-intervention	1.26 [–0.47, 2.99]	1.43 (415)	–0.10 [–0.24, 0.04]
	Follow-up	0.51 [–1.80, 2.83]	0.43 (336)	–0.04 [–0.21, 0.14]
SPIN	Post-intervention	2.96 [–0.91, 6.83]	1.50 (421)	–0.11 [–0.26, 0.03]
	Follow-up	3.80 [–1.67, 9.28]	1.36 (343)	–0.13 [–0.32, 0.06]
PDSS-SR	Post-intervention	1.30 [–0.20, 2.80]	1.70 (417)	–0.13 [–0.28, 0.02]
	Follow-up	0.76 [1.69, 3.22]	0.61 (338)	–0.06 [–0.27, 0.14]
Secondary outcomes				
SCCS	Post-intervention	–1.13 [–4.30, 2.04]	– 2.70 (414)	–0.05 [–0.09, –0.19]
	Follow-up	–1.29 [–5.36, 2.78]	– 0.62 (336)	0.06 [–0.13, 0.26]
NGSE	Post-intervention	–1.59 [–3.88, 0.69]	– 1.37 (414)	0.10 [–0.05, 0.25]
	Follow-up	–0.09 [–3.42, 3.24]	– 0.05 (334)	0.01 [–0.20, 0.21]
USAQ	Post-intervention	0.75 [4.18, 5.68]	0.30 (414)	–0.02 [0.17, –0.12]
	Follow-up	–3.09 [–10.34, 4.16]	– 0.83 (333)	0.08 [–0.11, 0.28]
RSES	Post-intervention	–1.10 [–2.66, 0.46]	– 1.38 (418)	0.10 [–0.04, –0.25]
	Follow-up	–1.41 [–3.62, 0.79]	– 1.26 (336)	0.13 [–0.08, 0.34]
SCS	Post-intervention	–1.73 [–8.05, 4.58]	– 0.54 (414)	0.04 [0.10, –0.17]
	Follow-up	–1.36 [–9.63, 6.90]	– 0.32 (333)	0.03 [–0.14, 0.19]

**All ps > 0.05*

†Degrees of freedom vary between measures because participants were not forced to fill-in the entire set of scales (hence, some were occasionally skipped). All models were adjusted for three covariates (age, gender, and treatment credibility).

b, Mean change difference in treatment versus control group estimate; d, Cohen's d for between-groups effects; PHQ9, Patient Health Questionnaire 9; GAD7, Generalized Anxiety Disorder 7; SPIN, Social Phobia Inventory; PDSS-SR, Panic Disorder Severity Scale-Self Report; SCCS, Self-Concept Clarity Scale; NGSE, New General Self-Efficacy Scale; USAQ, Unconditional Self-Acceptance Questionnaire; RSES, Rosenberg Self-Esteem Scale; SCS, Self-Compassion Scale.

Intervention Effects on Secondary Outcomes

The LMM analyses found no significant group by time interaction (all *p*s > 0.05) for any of the secondary outcomes. Again, the non-significant differences in changes between the two intervention groups were both for baseline to post-intervention and baseline to follow-up data (**Table 3**). When it comes to within-group comparisons, both the baseline to post-intervention and baseline to follow-up alleviations were statistically significant (all *p*s < 0.001) for both groups (**Table 4**).

Even though our second direction of analyses – to test whether the use of self-oriented exercises lead to increases in the self-concept – was rather exploratory, the data seem not to support it. Not only that the differences between the two groups were not significant, but both produced positive modifications. In addition, the effect sizes on secondary outcomes for the self-enhanced 9UP program were on average smaller with $d = 0.11$ than the effect sizes for the 9UP program.

Treatment Satisfaction

Treatment satisfaction was operationalized through nine questions addressed at post-intervention (see the complete list in **Table 6**). There were no significant differences between participants' answers on any of the items. Overall, participants declared to be satisfied with the program. On the majority of the items the mean responses were close to the positive end of the scale. Notably, participants reported to have understood approximately 7 out of 9 modules (in both programs), spent almost 5 h per week on the program, and the activity was somehow demanding. These suggest that the level of difficulty of both programs is elevated and may be one of the reasons behind the dramatic drop-out/reduced treatment adherence.

DISCUSSION

Conceptually the UP offers a solid third-wave cognitive-behavioral framework that seemed inviting for other researchers to test additional hypothesis (Sauer-Zavala et al., 2019). Our main goal in this study was to explore some alternative modalities to foster treatment adherence by introducing a new set of tasks derived from the self-enhancement literature. We compared the 9UP (active control arm) with a self-enhanced version of it (intervention arm) that included explicit intervention strategies designed for self-enhancement. More specifically, we hypothesized that the self-enhanced 9UP version will provide ampler space for self-talk, and therefore participants will adhere more to the treatment and maybe will be more satisfied by it compared to the 9UP. At the same time, we wanted to be assured that the modifications that we made to the 9UP protocol in order to fit the newer elements (some content elimination from the 9UP program to compensate for one new assignment for each

TABLE 4 | Estimates of mean differences between baseline and post intervention, respectively, follow-up (within-group effects).

Variable	Baseline vs. Time	Self-enhanced 9UP intervention			9UP active control		
		***b* [95% CI]**	***t* (df)***†	***d* [95% CI]**	***b* [95% CI]**	***t* (df)***†	***d* [95% CI]**
Primary outcomes							
PHQ9	Post-intervention	–6.31 [–7.52, –5.10]	– 10.23 (243)	0.74 [0.55, 0.93]	–5.89 [–7.23, –4.56]	– 8.66 (238)	0.93 [0.71, 1.14]
	Follow-up	–7.75 [–9.36, –6.13]	– 9.41 (243)	0.56 [0.38, 0.74]	–6.34 [–8.21, –4.48]	– 6.68 (238)	0.84 [0.64, 1.04]
GAD7	Post-intervention	–6.09 [–7.27, –4.90]	– 10.08 (240)	0.72 [0.91, 0.53]	–4.78 [–5.91, –3.64]	– 8.26 (237)	0.86 [0.67, 1.06]
	Follow-up	–6.23 [–7.81, –4.65]	– 7.74 (240)	0.56 [0.37, 0.74]	–5.25 [–6.83, –3.66]	– 6.50 (237)	0.65 [0.47, 0.83]
SPIN	Post-intervention	–11.31 [–13.68, –8.94]	– 9.34 (245)	0.49 [0.31, 0.68]	–8.17 [–11.02, –5.32]	– 5.62 (243)	0.83 [0.63, 1.03]
	Follow-up	–14.88 [–17.99, –11.78]	– 9.40 (245)	0.46 [0.28, 0.64]	–10.68 [–14.61, –6.75]	– 5.33 (243)	0.83 [0.63, 1.03]
PDSS-SR	Post-intervention	–3.53 [–4.60, –2.46]	– 6.47 (243)	0.40 [0.21, 0.58]	–2.24 [–3.25, –1.22]	– 4.33 (238)	0.60 [0.40, 0.79]
	Follow-up	–4.31 [–5.71, –2.90]	– 5.99 (243)	0.45 [0.26, 0.64]	–3.57 [–4.99, –2.15]	– 4.92 (238)	0.55 [0.36, 0.74]
Secondary outcomes							
SCCS	Post-intervention	8.01 [6.08, 9.93]	8.16 (239)	0.50 [0.31, 0.68]	6.83 [4.48, 9.19]	5.68 (237)	0.72 [0.52, 0.91]
	Follow-up	10.45 [7.89, 13.01]	8.00 (239)	0.47 [0.29, 0.65]	9.23 [5.93, 12.52]	5.49 (237)	0.70 [0.51, 0.89]
NGSE	Post-intervention	6.51 [4.82, 8.20]	7.56 (238)	0.60 [0.40, 0.79]	4.87 [3.42, 6.33]	6.56 (236)	0.68 [0.48, 0.88]
	Follow-up	5.22 [2.96, 7.48]	4.53 (238)	0.44 [0.25, 0.62]	5.03 [2.97, 7.10]	4.78 (236)	0.39 [0.22, 0.57]
USAQ	Post-intervention	13.84 [10.42, 17.26]	7.93 (238)	0.74 [0.54, 0.94]	14.60 [11.16, 18.04]	8.32 (232)	0.71 [0.52, 0.91]
	Follow-up	17.30 [12.67, 21.93]	7.32 (238)	0.50 [0.31, 0.68]	14.57 [9.50, 19.64]	5.63 (232)	0.65 [0.46, 0.85]
RSES	Post-intervention	5.08 [4.01, 6.15]	9.32 (238)	0.67 [0.47, 0.87]	4.02 [2.95, 5.08]	7.39 (236)	0.84 [0.63, 1.05]
	Follow-up	5.87 [4.42, 7.32]	7.94 (238)	0.52 [0.33, 0.71]	4.68 [3.10, 6.25]	5.82 (236)	0.71 [0.52, 0.91]
SCS	Post-intervention	19.67 [15.52, 23.82]	9.30 (238)	0.70 [0.51, 0.88]	18.14 [13.83, 22.45]	8.25 (235)	0.80 [0.60, 0.99]
	Follow-up	20.65 [15.08, 26.22]	7.27 (238)	0.52 [0.35, 0.69]	20.03 [13.85, 26.21]	6.36 (235)	0.61 [0.43, 0.79]

**All ps > 0.05.*

†*Degrees of freedom vary between measures because participants were not forced to fill-in the entire set of scale (hence, some were occasionally skipped). All models were adjusted for three covariates (age, gender, and treatment credibility).*

d, Cohen's d for within-group effects; PHQ9, Patient Health Questionnaire 9; GAD7, Generalized Anxiety Disorder 7; SPIN, Social Phobia Inventory; PDSS-SR, Panic Disorder Severity Scale-Self Report; SCCS, Self-Concept Clarity Scale; NGSE, New General Self-Efficacy Scale; USAQ, Unconditional Self-Acceptance Questionnaire; RSES, Rosenberg Self-Esteem Scale; SCS, Self-Compassion Scale.

module in the self-enhancement 9UP) will not significantly worsen the program.

Overall, both groups produced significant increases on each primary and secondary outcomes, with effect size estimate generally ranging from medium to high, and these positive effects preserved also at 6-months follow-up. However, when it comes to the particular objectives which we aimed through this study, the data were not in their favor. We were unable to find differences between the two groups in terms of treatment adherence. Specifically, the dropout rate recorded in our study was higher than previously recorded on 9UP (Tulbure et al., 2018) and similar for both groups (i.e., almost half the sample was lost at post-intervention and another 20% at follow-up). Also, adherence to assignments din not increase, participants completed on average a bit more than 50% of the tasks, without a predilection to complete the self-related ones. A possible explanation of the high drop-out rate comes from the treatment satisfaction items. Even though participants of both groups reported to be satisfied with the programs, they also suggested that these are rather difficult and demanding. As already pointed out in the literature on internet-interventions, the high self-regulatory effort needed from behalf of the participants is one key hindering factor when it comes to their adherence to such treatments (Donkin and Glozier, 2012; Beatty and Binnion, 2016; Zarski et al., 2018; Flett et al., 2019; Arndt et al., 2020). On this line of thought, it may be that adding the extra 9 add-ons to the UP, even though presumably more attractive and easily to follow, only increased the program's complexity and participants' workload. Another speculative explanation for the reduced treatment adherence is the dual (paradoxical) effect of self-enhancement. On the one hand, such exercises could increase participants' comfort with the task and themselves, increasing the likeability of the training. On the other hand, self-boosting could increase individuals' beliefs that they can handle day-to-day tasks without needing to rely on all prescribed exercises. Recent evidence (Harrell et al., 2021) supports this view, suggesting that people with low self-efficacy feel less equipped to face the burden they encounter. Therefore, they are more willing to engage in the training they could benefit from compared to people with high levels of self-efficacy. However, this result is discrepant from other findings (e.g., Sainsbury et al., 2018) that associated self-efficacy to better adherence in a different health context, dieting. Future studies should focus more on disentangling the role of various self-concepts such as self-esteem, self-efficacy, or self-compassion in treatment adherence. Likewise, future studies could also focus on the differential role of general and specific self-concepts. For instance, it might be the case that high levels of general self-efficacy and self-compassion could play a minor role in increasing treatment adherence, as the current research

TABLE 5 | Between-groups *t*-test comparisons for non-inferiority on all primary outcomes against the non-inferiority margin of *d* = –0.35.

Variable	*Baseline vs. Time*	*t (df)*	*P**	95% CI
PP				
PHQ9	Post-intervention	1.86 (89)	0.033	[–0.37,0.45]
	Follow-up	1.96 (46)	0.028	[–0.35,0.78]
GAD7	Post-intervention	3.26 (89)	< 0.001	[–0.08,0.75]
	Follow-up	1.79 (46)	0.040	[–0.40,0.73]
SPIN	Post-intervention	3.43 (90)	< 0.001	[–0.05,0.77]
	Follow-up	2.46 (48)	0.009	[–0.22,0.90]
PDSS-SR	Post-intervention	2.85 (88)	0.003	[–0.16,0.66]
	Follow-up	1.28 (47)	0.103	[–0.55,0.58]
ITT				
PHQ9	Post-intervention	2.79 (275)	0.003	[–0.25,0.22]
	Follow-up	3.31 (275)	< 0.001	[–0.19,0.28]
GAD7	Post-intervention	3.74 (274)	< 0.001	[–0.11,0.37]
	Follow-up	3.98 (274)	< 0.001	[–0.11,0.37]
SPIN	Post-intervention	4.05 (276)	< 0.001	[–0.10,0.37]
	Follow-up	4.43 (276)	< 0.001	[–0.05,0.42]
PDSS-SR	Post-intervention	4.13 (274)	< 0.001	[–0.09,0.38]
	Follow-up	3.98 (274)	< 0.001	[–0.11,0.37]
Completers				
PHQ9	Post-intervention	1.87 (146)	0.032	[–0.37,0.28]
	Follow-up	2.88 (67)	< 0.001	[–0.13,0.82]
GAD7	Post-intervention	3.16 (144)	< 0.001	[–0.15,0.49]
	Follow-up	1.97 (66)	0.027	[–0.35,0.60]
SPIN	Post-intervention	3.42 (148)	< 0.001	[–0.11,0.53]
	Follow-up	2.95 (71)	0.002	[–0.12,0.80]
PDSS-SR	Post-intervention	3.39 (145)	< 0.001	[–0.12,0.53]
	Follow-up	1.77 (68)	0.041	[–0.39,0.55]

**Reference p-value for rejecting the null hypothesis = 0.025.*
PP, per protocol; ITT, intent-to-treat; Completers (participants who provided post-intervention data); PHQ9, Patient Health Questionnaire 9; GAD7, Generalized Anxiety Disorder 7; SPIN, Social Phobia Inventory; PDSS-SR, Panic Disorder Severity Scale-Self Report.

TABLE 6 | Descriptive statistics for the treatment satisfaction items.

No.	Outcome	Self-enhanced 9UP intervention *M(SD)*	9UP active control *M(SD)*	*t (df)*	*p*
1	Overall, how satisfied are you with the treatment you received? (*1-very unsatisfied vs. 5-very satisfied*)	4.35 (0.75)	4.40 (0.70)	– 0.42 (139)	0.67
2	How would you evaluate the quality of the information that was provided? (*1-very weak vs. 5-very good*)	4.60 (0.92)	4.52 (0.97)	0.53 (139)	0.59
3	How satisfied were you with the timing of the treatment program? (*1-too short, 3-appropriate, 5-too long*)	2.54 (0.83)	2.58 (0.84)	– 0.29 (139)	0.76
4	How many modules did you fully understood? (*out of 9*)	7.01 (1.88)	7.16 (1.88)	– 0.47 (139)	0.63
5	Please, estimate the average number of hours you spent in a week on the program.	4.79 (4.29)	4.95 (4.98)	– 0.20 (133)	0.83
6	How demanding were the activities? (*1-very little vs. 4-very much*)	2.78 (0.65)	2.77 (0.75)	0.06 (139)	0.94
7	The program helped me approach my problems more effectively. (*1-not at all vs. 4-to a great extant*)	3.47 (0.55)	3.38 (0.63)	0.85 (139)	0.39
8	How logical seemed to you the method that we used? (*0-not at all vs. 10-very logical*)	8.25 (1.89)	8.08 (2.07)	0.50 (139)	0.61
9	How confident would you be to recommend this method of treatment? (*0-not at all vs. 10-very confident*)	8.52 (1.77)	7.94 (2.67)	1.52 (113)	0.13

suggests. However, the situation would have been different if the focus were on specific self-concepts such as technology self-efficacy, self-regulatory self-efficacy, or specific self-compassion. These constructs seem highly relevant for internet-delivered treatments, demanding homework, and instances of adherence failure, respectively.

Moreover, since to some extent we altered the original UP protocol, we wanted to test whether these modifications will maintain its clinical impact (the non-inferiority hypothesis). The linear mixed model analyses revealed no significant differences between the two treatment arms. The specific non-inferiority analyses support these findings in all cases when conducting ITT analyses and in most cases when conducting data per protocol and completers analyses. We should take these results with caution, considering that the margin (d = 0.35) was not set on strong empirical grounds. If we accept the evidence supporting the non-inferiority hypothesis found in most cases, it appears that we were successful in making the 9UP more concise in order to add the new techniques in the self-enhancement arm, because its effectiveness was indeed not altered. The longer and sometimes redundant explanations in the standard 9UP program could have been eliminated to leave room for some self-enhancement exercises. Unfortunately, the non-inferiority gain was not associated with an increase in treatment adherence, making less useful our entire approach of altering the 9UP.

Finally, our second objective, which was rather exploratory, revealed not only that the self-enhancement strategies added to the 9UP did not improve or augmented the self-related constructs beyond the active control intervention, but also that the 9UP alone was quite successful in this regard. The data revealed that both interventions were able to improve participant's self-concepts effectively, with medium to large ES, but the 9UP displayed slightly higher overall effects (with a couple of exceptions). These results are somehow surprising, considering that the 9UP does not explicitly address such self-concepts during the intervention and despite this fact, participants following the program were able to significantly improve them. It may be that an effective psychotherapy program like the UP and its shorter version (9UP) is able to positively impact participant's self-concepts simply by developing cognitive flexibility skills and promoting avoidance reduction through exposure techniques. Due to its flexibility and focus on the functional nature of emotions, the UP could be used beyond the original purpose (symptoms reduction), being also beneficial for other purposes (e.g., personal development, self-enhancement). This aspect is important for the work of clinical psychologists. It seems it would be enough to correctly deliver the therapy protocol for the patients' clinical condition. The self-constructs will follow the ascending path of the patient's progress. Our role as psychotherapists remains to accompany the patient on this path of inner healing. Future research should investigate the mediators (processes) through which a 9UP transdiagnostic intervention also impacts on self-concepts and self-structures. It might be the case that cognitive restructuring and cognitive diffusion reduce self-criticism tendencies (Levin et al., 2018), which, in turn, facilitate self-enhancement.

Although taken separately the self-concepts demonstrated some improvements in specific intervention studies (Kirby et al., 2017; Wilson et al., 2018; Ferrari et al., 2019), when we addressed them simultaneously with the 9UP by means of brief, non-repetitive homework tasks, their potential prove to be less than we have hoped for. Probably the more consistent and better focused approach of the 9UP program was able to keep participants on track and lead them to deeper and more coherent changes, while the dual approach of the Self-enhanced 9UP program, although overall effective, was unable to go beyond its active control golden standard. Thus, our "self-enhanced" program proved to be less worthy of proudly wearing such a name. Finally, we should consider that, on the state-trait continuum, self-concepts lay closer to the less malleable trait extreme compared to the emotional symptoms, that characterize affective and anxiety disorders, that lay closer the more malleable state extreme.

Study Limitations

The results presented above should be considered in the context of the study limitations.

First of all, by design the intervention content of the two study arms (the 9UP and the self-enhanced 9UP) were significantly overlapping (about 80%). This makes more difficult to highlight eventual differences between the two programs. We had little room for decreasing the level of overlapping between the two programs because of ethical reasons. Evidence-based interventions (i.e. a previously tested 9UP program) are required as active controls when dealing with a clinical sample.

Working with a clinical sample might also explain why we failed in enhancing treatment adherence. When people are confronted with a high level of distress, as in our clinical sample, participants focus heavily on symptoms reduction. In other contexts, such as personal development or working with subclinical samples, the focus would be less on symptoms' levels, but on participants' level of well-being and perceived self-enhancement. Therefore, maybe when working with a different sample (i.e., subclinical), participants' focus would lean toward self-enhancement than on reducing the emotional burden, given that such participants do not face intense emotional burden. For clinical samples, instead, our results suggest that there is no reason to alter the 9UP program, and no need to add self-enhancement modules.

Another relevant limitation of the current study refers to the high degree of observed dropout, which was double than expected and affected statistical power for our hypotheses. Overall, participants who did not dropout spent almost 5 h per week on the program, and perceived the activity as rather demanding, but useful. However, such a high workload might also have affected the willingness of participants for doing more homework assignments, therefore influencing the level of treatment adherence in both groups. Future studies could tackle this issue of the workload amount for internet-delivered studies. Maybe another protocol that will prolong the duration of the same program with 50% (e.g., a 14-session UP instead of 9-UP), would decrease the homework assignment workload per week will lead to different results with regards to the potential benefits of adding self-enhancement content.

CONCLUSION

Both 9UP programs are reliable and very useful internet-delivered transdiagnostic treatments. There were no statistically significant differences between the two intervention groups for any of the 17 outcome measurements, neither at post-test, nor at follow-up. All statistically significant differences existed only within each treatment group, showing the progress made by all participants throughout the therapeutic program. The beneficial effects on their mental state, the decrease of the symptoms from anxiety and depression and the raising of the self-parameters were preserved even at 6 months after the end of the interventions, for both groups. These conclusions are weakened by the study limitations mentioned above. However, despite multiple signs of non-inferiority, there are no reasons to alter the existing 9UP program because the introduction of the self-enhancement modules did not lead to the expected increase in treatment adherence. Moreover, improvements in secondary outcomes referring to self-structures were also found in the arm that did not include self-enhancement tools. This happens because after any correctly implemented psychological intervention, the patients will adapt to new life situations helped by the process they went through. These beneficial changes reflect the process of inner healing and adaptive functioning to the outside world.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the University Ethics Committee (5792/28.02.2019). The participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

AI, FS, and BT contributed to the study design. AI developed the intervention program and supervised the study implementation. AR, BT, AI, and FS wrote the manuscript. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyg.2021.752249/full#supplementary-material

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Screening Social Anxiety in Adolescents Through the Eyes of Their Carers

Luis-Joaquin Garcia-Lopez[1]*, Lourdes Espinosa-Fernandez[1], Jose-Antonio Muela-Martinez[1] and Jose Antonio Piqueras[2]

[1] Department of Psychology, University of Jaén, Jaén, Spain, [2] Department of Health Psychology, Miguel Hernández University, Elche, Spain

Despite the availability of efficacious treatment and screening protocols, social anxiety disorder (SAD) in adolescents is considerably under-detected and undertreated. Our main study objective was to examine a brief, valid, and reliable social anxiety measure already tested to serve as self-report child measure but administered *via* Internet aimed at listening to the ability of his or her parent to identify social anxiety symptomatology in his or her child. This parent version could be used as a complementary measure to avoid his or her overestimation of children of social anxiety symptomatology using traditional self-reported measures. We examined the psychometric properties of brief and valid social anxiety measure in their parent format and administered *via* the Internet. The sample included 179 parents/legal guardians of adolescents (67% girls) with a clinical diagnosis of SAD (mean age: 14.27; *SD* = 1.33). Findings revealed good factor structure, internal consistency, and construct validity. Data support a single, strength-based factor on the SPAIB-P, being structure largely invariant across age and gender. The limited number of adolescents with a performance-only specifier prevented examining the utility of scale to screen for this recently established specifier. It is crucial to evaluate if these results generalize to different cultures and community samples. The findings suggest that the SPAIB-P evidences performance comparable with child-reported measure. Parents can be reliable reports of the social anxiety symptomatology of the adolescent. The SPAIB-P may be useful for identifying clinically disturbed socially anxious adolescents.

Keywords: adolescence, anxiety, assessment, carers, online, psychometrics, social anxiety disorder

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Jose Miguel Mestre,
University of Cádiz, Spain
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Babeş-Bolyai University, Romania

***Correspondence:**
Luis-Joaquin Garcia-Lopez
ljgarlo@cop.es;
ljgarcia@ujaen.es

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INTRODUCTION

Social anxiety disorder is one of the most prevalent childhood psychiatric disorders and tends to be a chronic, stable condition that severely disrupts social and academic functioning (Lijster et al., 2018; Chiu et al., 2021). Despite this, social anxiety disorder (SAD) is under-recognized and undertreated (Jefferies and Ungar, 2020). Without accurate early detection of SAD, youth cannot access to evidence-based interventions (Garcia-Lopez et al., 2015). Brief social anxiety measures can screen for at-risk anxious adolescents (Fuentes-Rodriguez et al., 2017). Parents are in a key position to identify and screen mental health problems early and to provide a link to appropriate services (Mautone et al., 2020). A major advantage of parent-report measures is that they draw on the extensive knowledge parents have about their children and offer a more comprehensive perspective of SAD symptomatology (Garcia-Lopez et al., 2005). Unfortunately, the role of parents as informants of screening for emotional problems in their children has been ignored. This may be partially due to the large discrepancies in social anxiety symptomatology found between parents and adolescents (Becker-Haimes et al., 2018; Deros et al., 2018). Despite this, preliminary findings in early 2000s suggested that parents can be reliable reports of the social anxiety symptomatology of the adolescent (La Greca et al., 2001; Perez et al., 2001). In addition, some authors have argued that, given that adolescents with social anxiety disorder often try to make a good impression to mental health providers, the inclusion as informants of parents, teachers, or significant others might contribute to the correct identification of subjects (Garcia-Lopez et al., 2010). Despite this, no paper has been published to address the psychometric properties of the parent version of a well-established child-report social anxiety measure. Thus, our main study objective was to examine psychometric properties of the parent-report version of Social Phobia and Anxiety Inventory-Brief form (SPAI-B; Garcia-Lopez et al., 2008) in a clinical sample of adolescents with SAD.

First, this paper was aimed at testing whether SPAI-B/P would retain the good psychometric properties evidenced by the original scale in an online format (factor structure, internal consistency, and construct validity) (Garcia-Lopez et al., 2008, 2014, 2015, 2018; Piqueras et al., 2012; Vieira et al., 2013; Moran et al., 2018). Second, it was evaluated whether parent version was invariant for gender and age of his or her child.

To the best of our knowledge, this was the first paper analyzing the role of parents as informants of social anxiety symptomatology of their adolescents using a parent-report measure stemming from a well-established child-reported scale.

MATERIALS AND METHODS

Participants

The participants were 179 adolescents (67% girls) in Grades 8 to 12 (aged 12–18 years; *M* = 14.27; *SD* = 1.33) and parents or legal guardians. The ethnicity of the adolescents was 76% European-Spaniards, 19% Hispanic-American, and 5% Central-European. These data are consistent with the social reality in the country according to INE data (National Statistics Institute, 2020). To code the socioeconomic status of the participating subjects, the profession held by the most socioeconomically advantaged parent at the time of study was selected. Socioeconomic status for this sample was predominantly middle class, as categorized by Hollingshead Social Class (Hollingshead, 1975; Level I: 6.3%; Level II: 5.%; Level III: 16.7%; Level IV: 21%; Level V: 13.5%).

Measures

Adolescents completed the SPAI-B. Parents or legal guardians completed the SPAIB-Parent form and SAS-A/Parent form. For a review of the psychometric properties of the instruments listed below, see Garcia-Lopez et al. (2015).

Social Anxiety Scale for Adolescents (SAS-A; La Greca and Lopez, 1998). This questionnaire contains 18 items (plus four filler items) and includes three subscales: Fear of Negative Evaluation (FNE; eight items), Social Avoidance and Distress specific to new situations or unfamiliar peers (SAD-New; six items), and Social Avoidance and Distress that is experienced more generally in the company of peers (SAD-General; four items). Items are rated on a five-point Likert scale (1-5) and summed across relevant items to obtain total SAS-A scores and scores for each of the three subscales. A parent version (SAS-P) has also been developed, with promising preliminary results (La Greca et al., 2001; Perez et al., 2001).

The Social Phobia and Anxiety Inventory, Brief form (SPAI-B; Garcia-Lopez et al., 2008) consists of 16 items using a five-point Likert scale (1-5). It assesses the cognitive, somatic, and behavioral symptoms (triple-response system) and captures interactional and performance-provoking socially anxious situations. However, the brief form is different from the original form in terms of the Likert scale format used, the number of items, and avoidance of heterocentric language. Items 15 and 16 are comprised of subitems related to somatic and cognitive symptoms; hence, item 15 is scored as the average of four subitems, and item 16 as the average of five subitems. Therefore, decimals can be obtained. The SPAI-B score is the sum of item ratings minus 16. As a result, a total score can be computed (range: 0–64). The SPAI-B Parent version includes the same items but reworded to reflect views of a parent on the symptomatology of his or her child.

The Anxiety Disorders Interview Schedule for DSM-5–Child and Parent Versions (ADIS5-C/P); Albano and Silverman, in press) assesses anxiety disorders in youth aged six to 17 years and is organized according to anxiety disorders included in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition [(DSM-5); American Psychological Association [APA], 2013]. The ADIS-5-C/P consists of comparable yet separate child and parent interviews. A Spanish translation by authors was administered subsequent to obtaining approval of Oxford University Press for the ADIS5-C/P to be used for research purposes.

Procedure

The study was approved by the School District and the University Research Ethics Committee in compliance with the Code of Ethics of the World Medical Association (Declaration of Helsinki of 1975, revised in 2013) and the Charter of Fundamental Rights of the European Union.

Adolescents were screened for social anxiety in their schools. Those who screened positive as being at risk for SAD and a percentage of those who screened negative for SAD were invited to participate in a comprehensive, individualized assessment (ADIS5-C/P, see above) to determine the presence or absence of a clinical diagnosis of SAD. After the diagnostic interview was administered, 227 (6% of the original sample, consistent with prevalence reported by other studies (e.g., Garcia-Lopez et al., 2009, 2014, 2015) were diagnosed with a clinical diagnosis of social anxiety disorder (15% criteria for the performance-only specifier). About 79% of parents (*N* = 179 out of 227) also participated in the study and signed the consent forms online. Completion of the measures took approximately 20 min.

Statistical Analyses

Cronbach's alpha, the greatest lower bound (glb), and the omega total coefficient were used to examine the internal consistency of the SPAIB-P. Age and gender differences were tested by means of ANOVA. Construct validity was examined by calculating Pearson product-moment correlation coefficients. Correlation coefficients between 0.10 and 0.29 are indicative of a weak association, between 0.30 and 0.49 of a moderate association, and 0.50 or higher of a strong association (Cohen, 1988). To examine whether gender moderated the degree of adolescent-parent agreement, additional correlations between adolescent and parent reports were computed for boys and girls.

To obtain evidence of the construct validity of the instrument, we tested the original unidimensional model proposed by the original study using the confirmatory factor analysis (CFA) procedure. Analyses were conducted using the robust maximum likelihood (robust ML) method. The following indices were reported: Satorra Bentler's chi-square (S-B $\chi 2$), robust root mean square error approximation (RMSEA), comparative fit index (CFI), non-normalized fit index (NNFI). For RMSEA, values below 0.05 indicate a good fitting model and below 0.008 acceptable (Schumacker and Lomax, 2004). CFI and NNFI values indicate a good fit with values greater than or equal to 0.95 and an acceptable fit when greater than or equal to 0.90 (Bentler, 1990). The factorial invariance of the model (FI) was analyzed following the procedure suggested by Byrne (2006), according to which measurement invariance applies to) the base model, equivalence of factor loadings, the equivalence of intercepts, and equivalence of variance errors. According to the methodology proposed by Cheung and Rensvold (2002), we report the CFI, ΔCFI, ΔNNNFI, and ΔRMSEA. For ΔCFI increments less than or equal to −0.01 indicate that the null hypothesis of invariance should not be rejected; for the rest, the critical values are −0.001.

RESULTS

Internal Consistency

Internal consistency (Cronbach's alpha) of the SPAIB-P scale was found to be 0.98, the glb was 0.99, and the omega total coefficient was 0.98 (CI, 95%; 0.92–0.99).

Gender and Age Differences

SPAIB-P mean was 21.02 (*SD* = 17.74). The ANOVA showed that parents did not differ significantly in SPAIB-P scores provided for their boys (*M* = 20.24; *SD* = 15.18) and girls (*M* = 21.38; *SD* = 18.87) ($p > 0.05$). No significant main effects of age or interaction effects of gender and age were found.

Construct Validity

Pearson product-moment correlations were computed between the SPAIB-P score and conceptually related social anxiety measures answered by adolescents and parents. The SPAIB-P correlated strongly with the FNE, SAD-N, SAD-G subscales, and Total score of the SAS-P (0.81, 0.90, 0.87, and 0.90, respectively). These high correlations (above 0.50) suggest that these parent versions of SPAIB and SAS-P scales are highly correlated. The correlation coefficients were statistically significant in all cases ($p < 0.01$). However, correlations between SPAIB-P and children-reported social anxiety measures, such as the SPAI-B and the FNE, SAD-N subscales, and Total score of the SAS-P were weak and non-significant (0.04, 0.05, 0.02, 0.03, and 0.05, respectively). Based on gender, parent-youth correlations were −0.10 for boys and 0.13 for girls. Agreement was significantly higher for girls ($p < 0.01$). It must be noted that the highest level of agreement was obtained from one of the most observable Item 10 (SAD-N subscale), "My child get nervous when s/he talks to peers s/he doesn't know very well" to the lowest agreement in item 16 (filler item).

Confirmatory Factor Analysis

We employed robust maximum likelihood estimators (MLM) for the model parameters. All items in CFA were loaded 0.75 or greater, ranging between 0.77 (item 9) and 0.82 (item 2). According to the results, the one-factor model fit the data very well: $\chi 2$/df ratio = 200.894, RMSEA = 0.80, SRMR, CFI = 0.97, and NNFI = 0.97.

Testing Measurement Invariance (Gender and Age)

According to **Table 1**, data related to gender revealed the adequacy of the model fit to data (configural invariance), with CFI = 0.97 and RMSEA = 0.09. Furthermore, the ΔCFI between this model and the baseline 1 was < 0.01, below the cut point 0.01 proposed by Cheung and Rensvold (2002), so factor loadings were considered equivalent across gender (weak invariance). Finally, items were forced to be equal across gender groups (strong invariance). The ΔCFI with respect to the previous model was 0.004, so intercepts may also be considered equivalent across gender. Finally, the ΔCFI with respect to the previous model was 0.010, so there was equivalence of residuals of items, concluding total invariance.

Similarly, analyses for age were conducted to determine whether the unidimensional structure of SPAIB-parent form was invariant across two age groups: middle adolescents (12–14 years old) and late adolescents (15-18 years old). CFI = 0.97 and RMSEA = 0.08 reflected an adequate fit of the baseline model (configural invariance). Then, weak, strong, and total invariance hypotheses were accepted, since ΔCFI was lower than 0.010 in all comparisons.

DISCUSSION

Our objective was to examine a brief, valid, and reliable parent version administered *via* Internet of a well-established social anxiety child measure. Our data confirmed SPAIB-P score was not significantly different between adolescent and parent reports: SPAIB score was 29.43 (*SD* = 10.70) based on an adolescent report, and 21.02 (*SD* = 17.74) based on SPAIB-P. In addition, parents were reliable for identifying the social

TABLE 1 | CFA: Gender and age invariance.

1.1.CFA and *gender* invariance									
	Overall Fit Indices					**Comparative Fit Indices**			
	S/B χ 2	**df**	**CFI**	**NNFI**	**RMSEA [90% CI]**	**Model comparison**	**Δ CFI**	**Δ NNFI**	**Δ RMSEA**
Baseline									
Unidimensional structure	200.89	104	0.97	0.97	0.08 [0.06–0.10]		–		
Boys	153.33	104	0.94	0.93	0.10 [0.06–0.13]				
Girls	179.06	104	0.98	0.97	0.08 [0.06–0.11]				
Multigroup measurement invariance (sex)									
1. Configural	333.27	240	0.97	0.96	0.09 [0.07–.011]				
2. Metric (weak invariance)	355.09	223	0.97	0.96	0.09 [0.07–0.11]	1 vs. 2	−0.002	0	−0.001
3. Scalar (strong invariance)	377.6	239	0.96	0.96	0.09 [0.07–0.10]	2 vs. 3	−0.004	−0.007	−0.001
4. Total (strict/invariant uniqueness)	366.65	255	0.97	0.97	0.08 [0.06–0.10]	3 vs. 4	0.01	0.012	−0.006
1.2.CFA and *age* invariance (12–14year vs. 15–18 year)									
	Overall Fit Indices					**Comparative Fit Indices**			
	SB χ 2	**df**	**CFI**	**NNFI**	**RMSEA [90% CI]**	**Model comparison**	**Δ CFI**	**Δ NNFI**	**Δ RMSEA**
Baseline									
Unidimensional structure	200.89	104	0.97	0.97	0.08 [0.06–0.10]				
12–14	164.33	104	0.97	0.96	0.09 [0.06–0.11]				
15–18	159.71	104	0.97	0.97	0.09 [0.06–0.11]				
Multigroup measurement invariance (sex)									
1. Configural	319.48	206	0.97	0.97	0.09 [0.07–0.10]				
2. Metric (weak factorial)	335.94	221	0.97	0.97	0.08 [0.07–0.10]	1 vs. 2	0	0.002	−0.002
3. Scalar (strong factorial)	385.2	255	0.97	0.96	0.09 [0.07–0.10]	2 vs. 3	−0.005	−0.008	0.004
4. Total (strict/invariant uniqueness)	370.69	256	0.96	0.96	0.09 [0.07–0.11]	3 vs. 4	−0.002	−0.002	0.004

Models: 1. Configural invariance (M1, baseline model; equivalence of model form); 2. Metric invariance (equivalence of factor loadings), M2: M1+ factor loadings; 3. Scalar invariance (equivalence of item intercepts or thresholds), M2+ intercepts, and (d) 4. Total or residual invariance (equivalence of items' residuals or unique variances) (M4: M3+ items' residuals).

anxiety symptomatology of their children, but a higher agreement was found for girls. This is consistent with authors who also found parents can be reliable reporters of social anxiety of their adolescents (La Greca et al., 2001), with higher parent-teen correlations for girls (Perez et al., 2001; Garcia-Lopez et al., 2010). As far as the correspondence between the adolescent and parent reports is concerned, an interrater agreement was low. This is also aligned with the work of Perez et al. (2001), who indicated low-to-medium agreement but lower than parent and child responses to anxiety measure (Runyon et al., 2018). Furthermore, confirmatory factor analysis of the parent-report version of the SPAIB-P yielded essentially the unifactorial structure as the adolescent report version (for a review, please see Garcia-Lopez et al., 2008).

Good measurement invariance was found across gender and age, consistent with child-version SPAIB (Olivares et al., 2004; Vieira et al., 2013). Thus, our findings demonstrate that the factor loading and factor invariances and covariances were equivalent across gender and age groups of Spanish adolescents. Therefore, it may be recommended administering SPAIB-P for identifying of social anxiety symptomatology of children. Multi-method and multi-informant are crucial. This parent version could be used as a complementary measure to avoid the overestimation of the social anxiety symptomatology of his or her child.

Limitations

Some limitations must be noted. Even though our study was strengthened by the use of a sample of adolescents with a primary clinical diagnosis of SAD according to DSM-5, the limited number of performance-only SAD-specifier adolescents is a drawback of this study, which might have affected findings. Similar to other studies, our sample was composed by a limited number (15%) of performance-specifier individuals (Burnstein et al., 2011; Kerns et al., 2013; Garcia-Lopez et al., 2016, 2018). Uniqueness of a performance-only specifier (lower social anxiety scores and comorbidity rates) appears to be consistent with findings from other researchers (Bögels et al., 2010; Garcia-Lopez et al., 2018), who have suggested that the specifier presents a different pattern than a full spectrum of SAD. Therefore, future studies should look at examining the discriminative validity of the SPAIB-P to differentiate the presence of specifier in their children. In addition, it is crucial to examine if our results generalize to different cultures, community samples, and paper-and-pencil format. As a sample was composed by socially anxious adolescents and no control condition was available, future studies should focus on providing cut-off scores. Finally, the high-consistency value suggests future studies could explore the reduction of the number of items by eliminating redundancy or poorly performing items.

Although efficacious treatments for pediatric SAD are available, underdiagnosis is associated with undertreatment and poorer outcomes. Due to difficulties in detecting mental health emotional disorders in their early stages and overestimation of adolescents of their symptomatology, it is crucial to complement it with our resources. Parents may provide useful information about their perception of the social anxiety levels of their children. Our findings suggest this parent-based measure provided similar information for their children who are clinically diagnosed with social anxiety.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Bioethical Commitee, University of Jaen. Written informed consent to participate in this study was provided by the participants' legal guardian/next of kin.

AUTHOR CONTRIBUTIONS

L-JG-L contributed to data collection and data analysis and wrote the manuscript. LE-F coordinated data collection and wrote the manuscript. J-AM-M contributed to data collection and manuscript revision and wrote part of the results section. JP performed part of the statistical analysis, wrote part of the results section, and contributed to manuscript revision. All authors contributed to the article and approved the submitted version.

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Remote Assessment of Depression Using Digital Biomarkers From Cognitive Tasks

Regan L. Mandryk[1]*, Max V. Birk[2], Sarah Vedress[1], Katelyn Wiley[1], Elizabeth Reid[1], Phaedra Berger[1] and Julian Frommel[1]

[1] Interaction Lab, Department of Computer Science, University of Saskatchewan, Saskatoon, SK, Canada, [2] Systemic Change Group, Department of Industrial Design, Eindhoven University of Technology, Eindhoven, Netherlands

We describe the design and evaluation of a sub-clinical digital assessment tool that integrates digital biomarkers of depression. Based on three standard cognitive tasks (D2 Test of Attention, Delayed Matching to Sample Task, Spatial Working Memory Task) on which people with depression have been known to perform differently than a control group, we iteratively designed a digital assessment tool that could be deployed outside of laboratory contexts, in uncontrolled home environments on computer systems with widely varying system characteristics (e.g., displays resolution, input devices). We conducted two online studies, in which participants used the assessment tool in their own homes, and completed subjective questionnaires including the Patient Health Questionnaire (PHQ-9)—a standard self-report tool for assessing depression in clinical contexts. In a first study ($n = 269$), we demonstrate that each task can be used in isolation to significantly predict PHQ-9 scores. In a second study ($n = 90$), we replicate these results and further demonstrate that when used in combination, behavioral metrics from the three tasks significantly predicted PHQ-9 scores, even when taking into account demographic factors known to influence depression such as age and gender. A multiple regression model explained 34.4% of variance in PHQ-9 scores with behavioral metrics from each task providing unique and significant contributions to the prediction.

Keywords: depression, digital biomarkers, digital phenotyping, assessment, mental health

Edited by:
Ioana Roxana Podina,
University of Bucharest, Romania

Reviewed by:
Silviu Matu,
Babeç-Bolyai University, Romania
Ana Cosmoiu,
University of Bucharest, Romania

***Correspondence:**
Regan L. Mandryk
regan@cs.usask.ca

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1. INTRODUCTION

Depression is currently the leading cause of disability around the world (Friedrich, 2017) and contributes heavily to the estimated US $2.5–8.5 trillion in lost output globally from mental, neurological, and substance use disorders (Wykes et al., 2015). Diagnosing depression involves clinicians who employ interview techniques, questionnaires, and test batteries that follow standardized manuals, such as the DSM-V (American Psychiatric Association, 2013). As a complement to these techniques, digital biomarkers of depression—that is, measurable responses gathered from digital devices and used to reliably predict the incidence of depression—could help inform clinician assessment, particularly when they can be gathered easily, unobtrusively, and outside of the clinical context. Digital biomarkers of depression could enhance clinical treatment (Mohr et al., 2017), including through timely identification for early intervention, ongoing assessment during treatment, and by reducing disparities in access to assessment due to factors such as geography or income (Kumar and Phookun, 2016; Naslund et al., 2017). Digital biomarkers additionally support assessment for subclinical populations—that is, people who live with symptoms of depression that may not meet criteria for a DSM-V diagnosis, but who are prevented from achieving their potential, leading their fullest lives, and for whom symptoms may escalate in severity if left untreated. Further, digital biomarkers of depression deployed at a large scale could be used for population screening or prevalence estimations that are not currently possible with traditional clinician-intensive approaches (Gillan and Daw, 2016).

Previous approaches in the design of digital biomarkers for assessing depression have harnessed data from a variety of digital sources, including from smartphones and social media use. For example, Saeb et al. (2015) showed that location features drawn from 2 weeks of mobile phone use (e.g., location variance, location entropy, and regularity over 24-h) along with phone usage metrics (e.g., duration, frequency of use) were related to depressive symptoms. The authors argued that predicting depression through passively sensing daily behaviors is feasible in principle, as daily routines include behaviors that mark presence of depression (e.g., social behaviors or sleep behaviors), which can be sensed by smartphones. Using various features extracted from mobile phones (e.g., location, physical activity, phone calls, text messages, WiFi), researchers have trained machine learning models to predict aspects of self-reported depression or depressive symptoms (Canzian and Musolesi, 2015; Farhan et al., 2016; Wahle et al., 2016; Wang et al., 2018). For example, using a variety of smartphone sensors (e.g., bluetooth, screen status, call logs, location sensing) over the course of a college semester, Xu et al. (2019) were able to predict whether students were likely to report high scores on Beck's Depression Inventory (BDI-II: Beck et al., 1996) at the end of the semester. Further, Chikersal et al. (2021) showed that this prediction could be accurately made 11–15 weeks before the end of the semester, allowing time for preventative interventions. Passively sensing explicit behaviors through smartphone use has been shown as a promising approach for augmenting the detection of depression.

In addition to passively detecting behaviors, researchers have investigated passively detecting communications for features that mark depression. In particular, social media posts contain content that has been used to predict the presence of major depression (De Choudhury et al., 2013) from sources such as Twitter (e.g., Tsugawa et al., 2015), Reddit (e.g., Aladağ et al., 2018), Facebook (e.g., Park et al., 2013), Sina Weibo (e.g., Cheng et al., 2017), and Instagram (e.g., Reece and Danforth, 2017). And as with smartphone sensing approaches, social media posts are also used to predict the presence of symptoms associated with depression, such as suicidal ideation (e.g., Burnap et al., 2015; Shing et al., 2018), and the severity of the mental illness (e.g., Chancellor et al., 2016). Although semantic analysis of the posts themselves are often used as a feature in sensing depression, other metrics derived from behavior (e.g., activity, followers, networks), posted images, or sentiment analysis have also contributed to machine learning models using social media data (De Choudhury et al., 2013).

What these methods have in common is that they use computational approaches to identify ways in which people with depression communicate or behave differently than those without depression (Mandryk and Birk, 2019). Researchers generally employ a "bottom-up" machine learning (LeCun et al., 2015) approach that is naive to known effects of depression on cognition or behavior, but instead harnesses activity traces left behind by natural interactions with the world to build blackbox models that classify people, using ground truth labels of depression, such a clinical diagnosis or self-report scales. However, when behavioral or cognitive correlates of depression are already known, a contrasting approach (Mandryk and Birk, 2019) is to develop custom software tools that monitor people's responses (e.g., reaction time, performance, decisions), and then use statistical approaches to predict the likelihood of depression. For example, this custom tool approach has been successfully used to assess dementia on a large scale https://glitchers.com/project/sea-hero-quest/.

In the domain of depression, there has been significant research investigating behavioral and cognitive differences of people with a diagnosis of depression, with remitted depression, or with medicated treatment of depression, as compared to healthy control groups. For example, studies demonstrate that people with depression exhibit reduced visual contrast acuity or sensitivity (Bubl et al., 2009, 2010; Fam et al., 2013). Studies have suggested that people with depression have a recall bias that preferences negative autobiographical recall (Brittlebank et al., 1993) and an attention maintenance bias toward dysphoric images and sad faces (Suslow et al., 2020). Further, a significant body of work has focused on cognitive differences between people with depression and healthy controls and has found deficits, especially on measures of attention, executive function, memory, and psychomotor speed (Tavares et al., 2003; Chamberlain and Sahakian, 2006). Additionally, some of these attentional deficits have been shown to persist, even when patients have recovered fully, according to clinical diagnosis (Silverstein et al., 1994; Chamberlain and Sahakian, 2006). A diagnostic criterion for major depressive disorder is a "diminished ability to think or concentrate" (American Psychiatric Association, 2013), which can include difficulties with all types of attention. Depression has been linked to impairments in selective attention (the ability to attend to relevant information and ignore irrelevant stimuli), sustained attention (the ability to focus on something for a continuous amount of time) and divided attention (the ability to attend to multiple things at once) (American Psychiatric Association, 2013). Studies have also shown that people with depression demonstrate attentional biases toward negative information (MacLeod et al., 1986; Peckham et al., 2010).

Traditionally, measuring attention has been done using cognitive tasks in which participants are shown stimuli and asked to respond in different ways, while their reaction times and accuracy are measured. A variety of cognitive tasks rely on attention, such as the Stroop task (selective attention) (Kertzman et al., 2010; Keller et al., 2019), Continuous Performance Task (sustained attention) (Shalev et al., 2011; Conners, 2014), and bimodal tasks (divided attention) (Thomas et al., 1998). When comparing participants with depression to healthy controls on these cognitive tasks, those with depression generally demonstrate slower response times. Some of these differences may be due to psychomotor slowness or low mood rather than impairments specific to attention (Kertzman et al., 2010; Keller et al., 2019), though further research correlates depression with impairments specific to attentional control and executive functions (Snyder, 2013; Rock et al., 2014). These studies have found impairments correlated with updating (the ability to take new information into working memory), shifting (the ability to allocate attention to whatever is most relevant at the time), and inhibition (the ability to prevent irrelevant stimuli from impairing performance) (Snyder, 2013). For example, meta-analyses have found that depressed participants show significant deficits compared to healthy controls on the D2 Test of Attention, Delayed Matching to Sample Task, and Spatial Working Memory Task (Rock et al., 2014; Wang et al., 2020).

Although previous research has shown a variety of differences in measures of attention between people with depression and healthy controls, using these tasks for assessment can be complex. In particular, cognitive tasks that have traditionally produced robust experimental effects may not reliably correlate with individual differences, an effect that Craig, Hedge, and Sumner call 'the reliability paradox' (Hedge et al., 2018b). For this reason, some tasks traditionally associated with depression may not be suitable for assessment, such as emotional Stroop tasks (Eide et al., 2002) or other tasks based on attentional biases (MacLeod et al., 2019; Gladwin et al., 2020).

There are also challenges with gathering data related to attention *in situ* for remote assessment. Gathering data *in situ*—rather than in controlled laboratory contexts—presents challenges to researchers. For example, differences in hardware (e.g., screen size, display resolution, visual angle, refresh rate) make conducting research that relies on visual stimuli less controlled than experimenters are accustomed to. Differences in software settings (e.g., control-display gain, cursor acceleration) make conducting research on psychomotor tasks less controlled than in a laboratory. Although progress has been made in the last decade in research methods that support online experiments (Buhrmester et al., 2011, 2018; Mason and Suri, 2012), particularly for challenging psychomotor tasks, e.g., Peirce, 2007, the lack of control *in situ* still raises challenges for gathering data related to human attention. The lack of control over the auditory environment (e.g., sirens, construction outside, television or music playing), the interruptions of family members or pets, the presence of children, and the propensity to multitask—both on and off the computer—all make the assessment of attention *in situ* a challenging task. However, there are consistent and persistent associations of depression with error measures from tests of attention that we propose may be more robust to *in situ* assessment than measures related to reaction time, response latency, or speed of performance, as timing measures may be susceptible to variations in computing systems, like display latency or input lag.

In this paper, we harness depression-related differences in errors within attention tasks to design and evaluate a sub-clinical digital assessment tool that integrates digital biomarkers of depression. Based on three standard cognitive tasks (D2 Test of Attention: Brickenkamp, 1962; (Brickenkamp and Zillmer, 1998), Delayed Matching to Sample Task: Ferster, 1960; Sahakian et al., 1988; Robbins et al., 1997; Jäkälä et al., 1999, Spatial Working Memory Task: Owen et al., 1990; De Luca et al., 2003) on which people with depression have been known to perform differently than a control group (Rock et al., 2014; Wang et al., 2020), we designed a digital assessment tool that can be deployed outside of laboratory contexts, in uncontrolled home environments on computer systems with widely varying system characteristics (e.g., display resolution, input devices). We evaluated the assessment tool in two online studies—with participants in their own homes completing the task on their own digital devices—to show that the assessment tool can significantly predict scores from the Patient Health Questionnaire (PHQ-9: Kroenke et al., 2001)—a standard self-report tool for assessing depression in clinical contexts.

2. MATERIALS AND METHODS

2.1. The Digital Assessment Tool

Our digital tool embeds three standard tests of attention in a single assessment.

The *D2 Test of Attention* Brickenkamp, 1962; (Brickenkamp and Zillmer, 1998) measures sustained and selective attention. It uses rows of hard-to-distinguish stimuli—historically consisting of the letters d and p with 1–4 markings at the top or bottom. People are instructed to mark each item that fits a certain description. The test has been developed and is mostly used in pen-and-paper form. Our implementation used shapes with notches on the left or right and 1 to 4 dots in a 7 by 6 grid (see **Figure 1**, left). The correct stimulus was defined as those with 2 dots and a notch on the left side. Participants navigated between the stimuli using the left and right arrow keys on their keyboards and had to select those that correspond to the correct form using the "Z" key. Participants were given 15 s to complete a single page of the D2 task, after which they were given a break before progressing to the next round; there were 20 rounds of the D2 task in total. Our distribution of targets followed (Brickenkamp and Zillmer, 1998): on each page, there were correct targets and distractors that were either the correct notch and incorrect dots, incorrect notch and correct dots, or incorrect notch and dots.

The *Delayed Matching to Sample* (DMTS) test (Ferster, 1960; Sahakian et al., 1988; Robbins et al., 1997; Jäkälä et al., 1999) measures visual matching ability and short-term working memory. Participants are shown a visual object as a prompt and instructed to remember it as they would be required to identify it later. After a short delay, four choice patterns appeared, with one of them exactly matching the prompt and the other three being distractors. Similar to Sahakian et al. (1988), the visual object consisted of 4-quadrant abstract patterns that used one color and one form per quadrant (see **Figure 1**, middle). One of the four choice patterns was identical to the prompt. One of the three distractors was a novel distractor, differing in both color and form from the prompt. The remaining two distrators were 'partial distractors'; one had the colors of the prompt but the form of the novel distractor, while the other had the form of the prompt but the colors of the novel distractor. As with Robbins et al. (1997), each of the four choice patterns

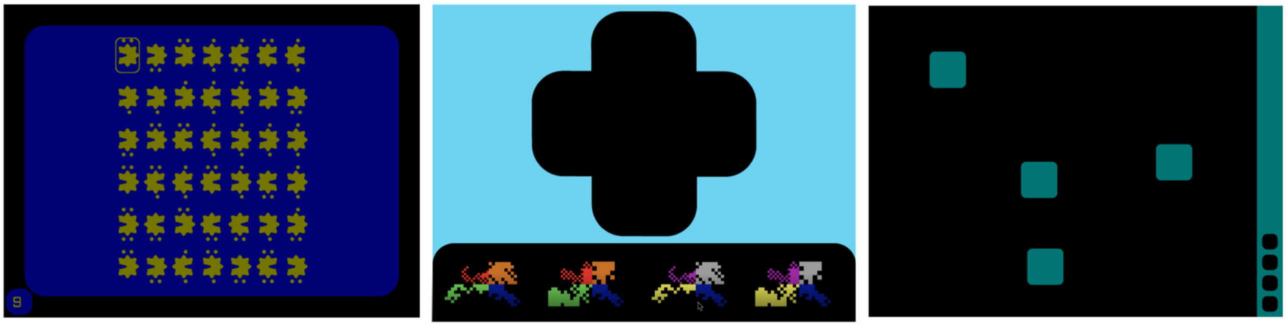

FIGURE 1 | Screenshots of the three attention tasks used in the studies: The D2 test of attention **(left)**, delayed matching to sample **(middle)**, and spatial working memory **(right)**.

had one random quadrant in common (both color and form) to discourage mnemonic strategies based on remembering the color and shape of a single quadrant. In our implementation, the prompt was shown for 4,500 ms and we used four different delays (0, 1, 4, and 12 s) between the prompt and the four choices. During the delay, a mask was presented, which was an animated rotation through distractor images. Participants selected the correct choice using mouse clicks and were given feedback in the form of red crosses and green checkmarks. If an incorrect choice was made, participants were required to continue selecting choices until the correct (prompt) stimulus had been chosen. For each delay, participants were given 10 prompts (40 in total).

The *Spatial Working Memory* (SWM) task (Owen et al., 1990; De Luca et al., 2003) assesses a participant's ability to retain and manipulate visuospatial information. The task begins with a set of boxes on display; participants have to search through the boxes to locate a hidden token. This repeats over several "sequences" (equal to the number of boxes); as tokens are discovered, they fill up a column on the right hand side of the screen (see **Figure 1**, right). Each box houses only one token per set of sequences, and participants are instructed that once a token has been found in a particular box, that box would not be used again to hide a token. After the set of sequences has been completed, the display is cleared and the position of the boxes are changed in the next trial to discourage the use of stereotyped search strategies. In our implementation, participants opened boxes using mouse clicks to search for the token until finding the correct box. After opening a box, an animation revealed whether the box was empty or contained the token. We used 6 different difficulty levels corresponding to different numbers of boxes to choose from in a trial (4, 6, 8, 10, 12, 14). Participants completed one trial at each difficulty level.

In our assessment tool, participants were randomly assigned a shape—a form and color combination that was used throughout the system. This shape was used in the D2 task with the notches on either side and dots above and below, in the DMTS as the background, and in the SWM as the token to be searched (see **Figure 1**). We chose this abstract shape approach intentionally as even a small change made to an established stimuli can affect performance in computerized assessments of attention (Price et al., 2015). Prior to each task, a step-by-step tutorial was provided to instruct participants on the goal of, and interaction within, the task. Following the tutorial, the task was completed.

2.2. Measures

We collected indicators derived from the participants' interaction with our digital assessment tool and self-report measures.

2.2.1. Digital Assessment Tool Measures

2.2.1.1. D2 Test of Attention

From the D2 test of attention, we calculated performance measures (summed across the 20 repeated trials) including: the *number of items* processed in the time limit, the *number of correctly marked stimuli*, *number of omission errors* (false negatives), *number of commission errors* (false positives), *total number of errors* (sum of omission and commission errors), and the *error rate* (number of errors per time).

2.2.1.2. Delayed Matching to Sample

We calculated the number of correct choices and latency (i.e., response time) for the four different levels of delay, across the 10 repeated trials. We then calculated our measures across the four delay levels (sum), including: *number of correct choices*, *average latency*, *number of color errors* (when participants selected an object with correct form but incorrect color), *number of shape errors* (when participants selected an object with incorrect form but correct color), *number of color+shape errors* (when participants selected an object with incorrect color and incorrect form).

2.2.1.3. Spatial Working Memory

The SWM task provides three types of outcome measures. Searching any box more than once within a sequence results in a within search error. Between search errors occur when returning to search an already emptied box in a trial. We calculated the sum of both within and between errors at each of the 6 difficulty levels individually. From this, we calculate the measures: *number of between errors* and *number of within errors*. In addition to errors, the SWM task allows calculation of a *strategy score*, (lower=better), which refers to the search strategy that is used to initiate searching. It is calculated as the sum of the different starting boxes. We calculated one total strategy score across all levels.

2.2.2. Self-Report Measures

We collected several self-report measures including the participants' demographics, whether they had vision impairments, corrected vision, color blindness, or motor impairments (potentially affecting the ability to control our digital toolbox), whether they had been diagnosed with depression, anxiety, or bipolar disorder, whether they took medications for these conditions, and optional descriptions for diagnosed conditions and medications.

PHQ-9: We assessed self-reported depression using the Patient Health Questionnaire (PHQ-9: Kroenke et al., 2001)—a standard self-report tool for assessing depression in clinical contexts. It is the 9-item depression module of the Patient Health Questionnaire and can be self-administered (Spitzer et al., 1999; Kroenke et al., 2001). Participants rated the frequency ("Over the last 2 weeks, how often have you been bothered by any of the following problems?") of 9 symptoms (e.g., "Feeling down, depressed or hopeless.") on 4-point scales (0 = "Not at all," 1 = "Several days," 2 = "More than half of the days," 3 = "Nearly every day"). The total score (sum of all scores) can range from 0 to 27, is a severity measure for depression (Kroenke et al., 2001), and represents the depression indicator that we predict with our assessment tool and refer to as *PHQ-9 score* for brevity. As the PHQ-9 was developed as a screening tool, the score is converted into a *level* that is used to determine the severity of the symptoms. As we also aim for biomarkers to be used as a screening tool, we predict the PHQ-9 score itself, which can be converted to the level later. The PHQ-9 includes an additional item about the difficulty resulting from the symptoms, which participants answered but was not used in the analysis.

2.3. Participants and Procedure

We deployed the experiment using an open-source software framework (Johanson, 2020), hosted on a University-owned data server. Participants were recruited from Amazon's Mechanical Turk (MTurk), which is an online marketplace that allows researchers to deploy studies through Human Intelligence Tasks (HITs) to diverse populations (Buhrmester et al., 2011). MTurk has been shown to be useful in behavioral research for its wide range of uses, diverse participant pool, speed, cost, and accessibility (Buhrmester et al., 2018), with valid data when precautions are taken (Mason and Suri, 2012). Upon accessing the HIT, participants provided informed consent, answered the demographic questionnaires and the trait inventories, completed a color blindness test, completed the digital assessment tool, and then completed scales evaluating the experience of using the tool. Finally, they were debriefed as to the purpose of the study, and given the option to withdraw their data (no participants chose to withdraw). Ethical approval for the studies was obtained from the Behavioural Ethics Research Board at the University of Saskatchewan.

In Study One, participants were randomly assigned to complete one of the three tasks. In Study Two, participants completed all three tasks. Because our goal was not to compare the tasks to each other, but to gather consistent performance from participants, they completed all three tasks in the same order, beginning with the D2 task, followed by the SWM task, and finishing with the DMTS task. As the attention of participants is likely to wane over time, it was important that all participants complete the tasks in the same order. In both studies, we recruited 100 participants per condition. Previous work on predicting PHQ-9 scores using smartphone sensors used n = 28 (Canzian and Musolesi, 2015), n = 79 (Farhan et al., 2016), n = 83 (Wang et al., 2018), n = 126 (Wahle et al., 2016), and n = 138 (Chikersal et al., 2021). We used the heuristic of 100 people per condition based on the sample sizes in this previous literature (Lakens, 2021). In Study One, we recruited n = 300, but there were missing data logs for 3 people, leaving n = 297 with complete data. In Study Two, we recruited n = 100, but there were missing data logs for 8 people, leaving n = 92 with complete data.

2.4. Data Filtering

Because data were gathered online in uncontrolled contexts, we needed to remove spurious responses from participants who did not engage with the experiment (e.g., were clicking randomly) and from potential bots. We followed best practices for collecting and cleaning online data (Meade and Craig, 2012; Buchanan and Scofield, 2018). In both studies, we filtered out participants who completed the study too quickly, defined as less than 1 s per item on more than two scales, which indicated a lack of attention in completing responses. Second, we removed participants who violated a zero variance filter, indicating there was zero diversity in their responses (they simply repeated the same response), on more than two scales. Third, we ran a variance filter to detect responses from participants that were more than three standard deviations above the mean variance, indicating that they were clicking randomly, on more than two scales.

In Study One, the filtering process removed 27 participants, leaving 269 valid responses (D2 = 90; DMTS = 92, SWM = 87) that were processed and used for further analyses. Participants were (female = 109, male = 160) aged 18 to 72 ($M = 36.665$; $Mdn = 34.000$; $SD = 11.377$). In Study Two, we removed 2 participants, leaving 90 valid participants used for further analysis. Participants (female = 33, male = 57) were aged 25 to 68 ($M = 37.944$; $Mdn = 35.500$; $SD = 11.155$).

2.5. Statistical Analyses

We conducted multiple regression analyses using the measures from the digital tool to predict PHQ-9 scores, with a significance threshold of $\alpha = 0.05$. Using hierarchical regressions, we controlled for age and gender by entering them in the first block and adding the measures of interest in the second block. We calculated separate regression models for each of the measures of the three tasks to assess suitability of the measures for prediction while accounting for their similarity resulting in substantial shared variance, and also a combined model in Study Two, in which the predictions are made by the non-shared rather than the shared variance within the set of predictors. We report unstandardized regression coefficients (B) with standard errors (*se* B), standardized regression coefficients (β), t-values, and p-values for individual predictors and R^2-values, F, p-values, R^2 change (ΔR^2), and F change (ΔF) for the regression models to demonstrate goodness of fit. We tested for multicollinearity using variance inflation factors (VIF), which were substantially lower

TABLE 1 | Descriptive statistics for Study One and Study Two.

	N_1	Mean$_1$	Std.Dev.$_1$	N_2	Mean$_2$	Std.Dev.$_2$
PHQ-9	269	6.836	6.913	90	7.022	6.892
Number of items	90	426.789	115.491	90	419.233	94.922
Number of correctly marked stimuli	90	172.344	48.566	90	168.133	43.076
Number of omission errors	90	21.222	27.834	90	22.211	22.142
Number of commission errors	90	20.811	49.508	90	20.600	37.195
Total number of errors	90	42.033	57.181	90	42.811	52.897
Error rate	90	9.654	11.448	90	10.244	11.217
Number of correct choices	92	32.533	6.046	90	31.700	6.523
Average latency	92	3241.195	1330.385	90	4128.393	6994.663
Number of color errors	92	1.902	2.589	90	1.933	2.508
Number of shape errors	92	4.261	2.897	90	4.767	3.006
Number of unrelated errors	92	1.304	1.880	90	1.600	2.350
Number of between errors	87	84.563	46.407	90	92.278	55.287
Number of within errors	87	16.414	39.549	90	19.822	38.204
Strategy score	87	40.046	8.158	90	40.511	8.260

TABLE 2 | Isolated D2 regression results.

Model		B	se B	β	t	p	R^2	F	p model	ΔR^2	ΔF
H_0	(Intercept)	14.505	2.585		5.612	<0.001					
	Age	−0.217	0.069	−0.329	−3.137	0.002					
	Gender	−0.051	0.696	−0.008	−0.073	0.942	0.107	5.212	0.007	0.107	5.212
H_1	Number of items	5.439e−4	0.006	0.009	0.089	0.929	0.107	3.438	0.020	0.000	0.008
H_1	Number of correctly marked stimuli	−8.436e−4	0.014	−0.006	−0.059	0.953	0.107	3.436	0.020	0.000	0.004
H_1	Number of omission errors	0.011	0.025	0.046	0.443	0.659	0.109	3.508	0.019	0.002	0.196
H_1	Number of commission errors	0.037	0.013	0.278	2.808	0.006	0.182	6.377	<0.001	0.075	7.883
H_1	Total number of errors	0.030	0.012	0.260	2.626	0.010	0.173	6.010	<0.001	0.066	6.898
H_1	Error rate	0.184	0.057	0.316	3.242	0.002	0.204	7.358	<0.001	0.097	10.512

H_0 is the results for age and gender; H_1 shows the results of adding the measures individually into the second block.

than values that have been suggested as thresholds for necessary corrections (Kock and Lynn, 2012) (Study One: all VIFs < 1.119, Study Two, Tasks in Isolation: all VIFs < 1.146, Study Two, Tasks in Combination: all VIFs < 1.504). JASP 0.14.1 was used for data analysis (JASP Team, 2020).

3. RESULTS

3.1. Study One: Tasks in Isolation

In Study One, we investigated the tasks in isolation (between-subjects design) and the suitability of their measures to predict PHQ-9 scores. **Table 1** shows the descriptive statistics.

3.1.1. D2 Test of Attention

Table 2 shows results for the D2 task. First, PHQ-9 scores had a significant negative association with age, while gender was not a significant predictor. Then, controlling for age and gender, PHQ-9 scores were not significantly predicted by the *number of items*, *number of correctly marked stimuli*, or the *number of omission errors*. In contrast, there were significant effects for the other measures. PHQ-9-scores were indicated by a higher *number of commission errors*, *total number of errors*, and *error rate*.

3.1.2. Delayed Matching to Sample

Table 3 shows results for the DMTS task. Age and gender were non-significant. Controlling for these variables, all measures were significant predictors for PHQ-9 scores. Higher PHQ-9 scores were negatively associated with the *number of correct choices* and accordingly positively associated with *number of color errors*, *number of shape errors*, and *number of color+shape errors*. Further, *average latency* predicted PHQ-9 scores.

3.1.3. Spatial Working Memory

Table 4 shows results for the SWM task. For these participants, age and gender were significant predictors. Age had a negative association with PHQ-9 scores and was higher for female

TABLE 3 | Isolated DMTS regression results.

Model		*B*	*se B*	β	*t*	*p*	R^2	*F*	*p* model	ΔR^2	ΔF
H_0	(Intercept)	4.876	2.607		1.870	0.065					
	Age	0.050	0.067	0.078	0.747	0.457					
	Gender	1.037	0.764	0.142	1.357	0.178	0.025	1.143	0.323	0.025	1.143
H_1	Number of correct choices	−0.483	0.113	−0.413	−4.253	<0.001	0.191	6.937	<0.001	0.166	18.084
H_1	Average latency	0.001	5.539e−4	0.280	2.683	0.009	0.099	3.215	0.027	0.074	7.199
H_1	Number of color errors	0.938	0.270	0.343	3.468	<0.001	0.142	4.865	0.004	0.117	12.024
H_1	Number of shape errors	0.694	0.254	0.284	2.735	0.008	0.101	3.311	0.024	0.076	7.480
H_1	Number of color+shape errors	1.573	0.362	0.418	4.341	<0.001	0.197	7.197	<0.001	0.172	18.845

H_0 is the results for age and gender; H_1 shows the results of adding the measures individually into the second block.

TABLE 4 | Isolated SWM regression results.

Model		*B*	*se B*	β	*t*	*p*	R^2	*F*	*p* model	ΔR^2	ΔF
H_0	(Intercept)	13.607	2.204		6.174	<0.001					
	Age	−0.172	0.056	−0.314	−3.089	0.003					
	Gender	−1.682	0.741	−0.231	−2.270	0.026	0.138	6.742	0.002	0.138	6.742
H_1	Number of between errors	0.027	0.015	0.174	1.727	0.088	0.168	5.594	0.002	0.030	2.982
H_1	Number of within errors	0.011	0.018	0.060	0.586	0.559	0.142	4.574	0.005	0.004	0.344
H_1	Strategy score	0.174	0.086	0.201	2.016	0.047	0.179	6.013	<0.001	0.040	4.064

H_0 is the results for age and gender; H_1 shows the results of adding the measures individually into the second block.

TABLE 5 | Combined D2 regression results.

Model		*B*	*se B*	β	*t*	*p*	R^2	*F*	*p* model	ΔR^2	ΔF
H_0	(Intercept)	13.966	2.571		5.433	<0.001					
	Age	−0.180	0.064	−0.291	−2.799	0.006					
	Gender	−0.487	0.739	−0.068	−0.659	0.512	0.083	3.944	0.023	0.083	3.944
H_1	Number of items	−0.002	0.008	−0.030	−0.292	0.771	0.084	2.630	0.055	0.001	0.085
H_1	Number of correctly marked stimuli	−0.031	0.016	−0.195	−1.931	0.057	0.121	3.955	0.011	0.038	3.728
H_1	Number of omission errors	0.103	0.030	0.329	3.380	0.001	0.191	6.752	<0.001	0.108	11.424
H_1	Number of commission errors	0.072	0.019	0.388	3.831	<0.001	0.217	7.934	<0.001	0.134	14.673
H_1	Total number of errors	0.053	0.013	0.409	4.183	<0.001	0.238	8.962	<0.001	0.155	17.501
H_1	Error rate	0.279	0.059	0.454	4.692	<0.001	0.270	10.604	<0.001	0.187	22.017

H_0 is the results for age and gender; H_1 shows the results of adding the measures individually into the second block.

participants ($M = 8.656$) than for male participants ($M = 5.727$). Controlling for age and gender, *strategy score* was a positive, significant predictor for PHQ-9 scores while effects for *number of between errors* and *number of within errors* did not reach significance.

3.2. Study Two: Tasks in Isolation

In Study Two, participants completed all three tasks. First, we investigated measures in isolation to confirm the suitability of individual metrics and tasks to predict PHQ-9 scores. As the same set of participants engaged in all tasks, the null model including age and gender was the same for all tasks. For this sample, PHQ-9 scores were not significantly predicted by gender, but showed a significant, negative association with age.

3.2.1. D2 Test of Attention

Controlling for age and gender, regression models for the D2 task measures showed mostly consistent results to Study One. Again, PHQ-9 scores were not significantly predicted by the *number of items* or *number of correctly marked stimuli* but significantly associated with higher *number of commission errors*, *total number of errors*, and *error rate*. Further, and in contrast to Study One, the relationship between PHQ-9 scores and the *number of omission errors* was also significant and positive in this study. **Table 5** shows these results.

TABLE 6 | Combined DMTS regression results.

Model		*B*	*se B*	*β*	*t*	*p*	*R*^{2}	*F*	*p* model	Δ*R*^{2}	ΔF
H$_0$	(Intercept)	13.966	2.571		5.433	<0.001					
	Age	−0.180	0.064	−0.291	−2.799	0.006					
	Gender	−0.487	0.739	−0.068	−0.659	0.512	0.083	3.944	0.023	0.083	3.944
H$_1$	Number of correct choices	−0.458	0.102	−0.433	−4.489	<0.001	0.257	9.926	<0.001	0.174	20.153
H$_1$	Average latency	1.589e−4	1.020e−4	0.161	1.557	0.123	0.108	3.481	0.019	0.025	2.424
H$_1$	Number of color errors	1.212	0.260	0.441	4.656	<0.001	0.268	10.481	<0.001	0.185	21.678
H$_1$	Number of shape errors	0.490	0.234	0.214	2.094	0.039	0.128	4.194	0.008	0.044	4.387
H$_1$	Number of color+shape errors	1.316	0.287	0.449	4.590	<0.001	0.264	10.260	<0.001	0.180	21.070

H$_0$ is the results for age and gender; H$_1$ shows the results of adding the measures individually into the second block.

TABLE 7 | Combined SWM regression results.

Model		*B*	*se B*	*β*	*t*	*p*	*R*^{2}	*F*	*p* model	Δ*R*^{2}	ΔF
H$_0$	(Intercept)	13.966	2.571		5.433	<0.001					
	Age	−0.180	0.064	−0.291	−2.799	0.006					
	Gender	−0.487	0.739	−0.068	−0.659	0.512	0.083	3.944	0.023	0.083	3.944
H$_1$	Number of between errors	0.040	0.012	0.319	3.246	0.002	0.183	6.429	<0.001	0.100	10.534
H$_1$	Number of within errors	0.050	0.018	0.276	2.733	0.008	0.156	5.315	0.002	0.073	7.471
H$_1$	Strategy score	0.223	0.083	0.267	2.692	0.009	0.154	5.233	0.002	0.071	7.245

H$_0$ is the results for age and gender; H$_1$ shows the results of adding the measures individually into the second block.

3.2.2. Delayed Matching to Sample

The results for the regression models for the DMTS task (see **Table 6**) were mostly consistent with those from Study One. Again, PHQ-9 scores were negatively and significantly associated with *number of correct choices* and accordingly predicted by *number of color errors*, *number of shape errors*, and *number of color+shape errors* with significant and positive relationships. In this study, the relationship of *average latency* with PHQ-9 scores did not reach significance.

3.2.3. Spatial Working Memory

Table 7 shows results for the SWM task. PHQ-9 scores had positive, significant relationships with all measures: *number of between errors*, *number of within errors*, and *strategy score*.

3.3. Study Two: Tasks in Combination

The previous analyses focused on validating the measures' suitability for predicting PHQ-9 scores individually. To complement this, we evaluated whether a digital assessment tool consisting of multiple tests might be even more powerful, i.e., better at predicting PHQ-9 scores.

For that purpose, we selected one metric from each task and combined them in a multiple regression. To identify the metrics that were most discriminating and individually useful, we conducted a principal component analysis (oblimin rotation) with three factors on the measures that were significant predictors in the linear regressions [$\chi^2_{(25)} = 3325.12, p < 0.001$]. As **Table 8** shows, the measures loaded on factors associated with their task (i.e., D2, DMTS, SWM); from these, we selected the metric for each task that loaded highest on the factor associated with a task metric for use in the multiple regression: *total number of errors* (D2), *number of correct choices* (DMTS), and *number of within errors* (SWM).

TABLE 8 | Component loadings.

	RC1	RC2	RC3	Uniqueness
Number of omission errors	0.862			0.313
Number of commission errors	0.916			0.145
Total number of errors	1.005			0.008
Error rate	0.949			0.058
Number of correct choices		−0.941		0.002
Number of color errors		0.672		0.284
Number of shape errors		0.928		0.287
Number of color+shape errors		0.709		0.171
Number of between errors			0.764	0.210
Number of within errors			0.811	0.393
Total strategy score			0.769	0.440

Factors related to D2 loaded on RC1, DMTS on RC2, and SWM on RC3.

Then, we conducted a hierarchical multiple regression analysis, again controlling for age and gender at the null model, and then entering the three predictors at the first level (forced entry). **Table 9** shows the results for this model. The results show that all three measures were significant predictors for PHQ-9 scores, indicating their individual value in a combined model.

TABLE 9 | Regression results for all tasks combined.

Model		*B*	*se B*	*β*	*t*	*p*	R^2	*F*	*p* model	ΔR^2	ΔF
H_0	(Intercept)	13.966	2.571		5.433	<0.001					
	Age	−0.180	0.064	−0.291	−2.799	0.006					
	Gender	−0.487	0.739	−0.068	−0.659	0.512	0.083	3.944	0.023	0.083	3.944
H_1	(Intercept)	16.176	4.516		3.582	<0.001					
	Age	−0.069	0.058	−0.112	−1.180	0.241					
	Gender	−0.649	0.637	−0.091	−1.019	0.311					
	Total number of errors (D2)	0.035	0.014	0.266	2.493	0.015					
	Number of correct choices (DMTS)	−0.272	0.115	−0.257	−2.371	0.020					
	Number of within errors (SWM)	0.038	0.017	0.213	2.316	0.023	0.344	8.799	<0.001	0.261	11.119

H_0 is the results for age and gender; H_1 shows the results of adding the measures simultaneously into the second block.

This model accounted for 34.4% of the variance in PHQ-9 scores, substantially outperforming all models with individual predictors and highlighting the value of the digital assessment toolbox with all three tasks.

4. DISCUSSION

4.1. Summary of Findings

Through two experiments, we consistently and significantly predicted PHQ-9 scores from error measures of attention tasks gathered online and *in situ*. In almost all models (except for isolated DMTS), age showed an overall negative association with PHQ-9 scores, consistent with prior knowledge on depression over the lifespan (Patten et al., 2006; Tomitaka et al., 2018). Our results conforming to expectations does lend support for the accurate self-report of depression using the PHQ-9 in our sample.

From the attention tests themselves, there were several good predictors of PHQ-9. For the D2 task, the *Number of commission errors*, *total number of errors*, and *error rate* were positive, significant predictors of self-reported depression in both studies. For the DMTS task, PHQ-9 scores were predicted by *number of correct choices* (negative relationship) and by *number of color errors*, *number of shape errors*, and *number of color+shape errors* (positive relationship) in both studies. For the SWM task, *strategy score* had a positive, significant relationship with PHQ-9 scores in both studies. Further, in the first study, we saw significant predictions from *average latency* in the DMTS, and in the second study, we additionally saw significant predictions from the *number of omission errors* in the D2 and the *number of between errors* and *number of within errors* in the SWM task.

While the between and within errors for SWM did not strongly predict PHQ-9 scores in Study One, they did so in Study Two. **Table 1** suggests that participants made more errors due to decreased attention in Study Two, when the SWM happened after the D2, which might suggest that these measures are good indicators only in some instances, e.g., when participants have decreased attention or are already fatigued. However, this idea requires further investigation. Similarly, the DMTS was performed last in Study Two, and the significant results for average latency seen in Study One did not replicate. However, **Table 1** shows that the average latency was slightly elevated in Study Two, in which the DMTS was done last, but also that the standard deviation was much higher, suggesting greater variance in latency responses.

Although there have been previously demonstrated relationships between both error metrics and timing metrics with depression, our findings point more to robustness in error-related measures in our experiment. We suspected in advance that this might be the case, and we posit that there are fewer repercussions of the uncontrolled environment in error measures than in response times, which can be affected by differences in hardware (e.g., known differences between mice and trackpads; Soukoreff and MacKenzie, 2004), software (e.g., cursor acceleration settings; Casiez et al., 2008), and networks (e.g., network latencies; Long and Gutwin, 2018). Although our results did not demonstrate strong relationships between timing variables and depression, we believe that our findings do not lie in contrast with earlier work on cognitive deficits in depression. We require more work to test the relationship between timing and depression to make claims on a theoretical level. It is possible that individuals interacting with digital assessment tools in their home context and on their variable computing systems just behave in a particular way, in which timing is less indicative of depression than error-based measures. Interestingly, speed-accuracy tradeoffs mean that participants often prioritize one of speed or accuracy, and recent work suggests that for attention tasks in particular, measures of accuracy (i.e., errors) are not consistently associated with measures of response time (Hedge et al., 2018a).

In Study Two, the combined model (with one metric from each task) outperformed all the individual models, and accounted for 34.4% of the variance in PHQ-9 scores, indicating that the combination of metrics has value over simply looking at metrics in isolation. Although these error metrics from the different tasks are related, the non-shared variance in the multiple regression model generated a better prediction than any of the isolated models. Further, the attention metrics explained a greater proportion of variance than age and gender alone, which in a single model explained only 8.3% of the variance in PHQ-9 scores (see **Table 9**). The addition of the scores from the digital tool were necessary to explain over a third of the variance in PHQ-9 scores.

4.2. Contextualization and Implications of Findings

The assessment of attention is a challenging undertaking, but is important as attention is a cognitive function that is indicative of human development and relates to mental health. Beyond depression, attention and attentional control are both related to a variety of other cognitive deficits, such as attention-deficit/hyperactivity disorder (Barkley, 1997) and dementia (Perry and Hodges, 1999), and also to human capabilities, such as reading ability (Franceschini et al., 2012). As accurately measuring attention could help assess and diagnose a number of common disorders, the success of our digital tool has implications beyond our intended goal of assessing depression remotely. Classification systems like the DSM-V (American Psychiatric Association, 2013) standardize diagnoses of mental health disorders; however, comorbidity of mental health symptoms is not the exception, but the norm (Kessler et al., 2005). Relevant to our work, there is high comorbidity between symptoms of depression and anxiety (Kircanski and Gotlib, 2015) and our results do not attempt to differentiate between these conditions. More work is needed to move toward transdiagnostic approaches to assessment that transcend categorical classification, but rather focus on underlying process mechanisms to inform diagnosis (Frank and Davidson, 2014). Future work can consider whether behavioral biomarkers can contribute to disentangling symptoms of multiple comorbid disorders.

It is challenging to compare our findings to prior work; there are no previous approaches that also used regression to predict PHQ-9 scores from performance data on a suite of tasks. Two meta-analyses on attentional deficits and depression report effect sizes (Cohen's d) that reflect the difference between performance on attention tasks between people with depression and healthy controls. These effect sizes range from 0.34 to 0.65 (Rock et al., 2014) and 0.59 (Wang et al., 2020), which indicate significant moderate effects. We cannot directly compare, as we do not examine group differences, but rather predict a range of PHQ-9 scores from a set of error scores. However, in calculating the effect size f^2 of the addition of the three error measures in our multiple regression from Study Two, we have an $f^2 = 35$, which indicates a large effect. It is not surprising that our effect size is large, as we used three measures in combination. The effect sizes for the individual predictors (which are a better comparator to the results from the meta-analyses) are slightly smaller, but still indicate moderate to large effects.

Of significance is that our approach was to use participants' own computers in the uncontrolled environment of their home. Measuring attention can be challenging in the lab; however, doing so in the uncontrolled context of people's own homes is even more difficult. As previously argued, the differences in hardware affect display latencies, screen resolutions, and visual angle, whereas the differences in software affect interactive input. By focusing on error-related measures, and not on response latencies or reaction times, we minimized the effects of variations in computing systems. However, there remain differences in the context of participants' homes that were uncontrolled; interruptions such as pets, children, auditory interruptions, and multi-tasking are all not controlled in our experiment and likely influenced the results.

Our approach uses continuous prediction, rather than binary classification. This regression approach means that we are not classifying people into PHQ-9 levels, but are predicting their score along a range. Classification is possible, but would necessitate machine learning techniques, such as those used in the passive sensing approaches of smartphone data (Chikersal et al., 2021) or social media data (De Choudhury et al., 2013). Although there is benefit in classification, a first step is to demonstrate a consistent statistical relationship between the metrics and PHQ-9 scores, which we provide in this paper.

Another difference between our approach and the passive sensing approaches described earlier is that our tool uses an explicit method of gathering data. The work on detecting depression from smartphones or social media assumes that people are using their phones and social media for other purposes, but then harnesses these signals for use as a depression detector. This passive sensing approach has the advantage of being applicable to any user of a smartphone or social media, which would reach the majority of the population. Our active sensing approach requires that people engage explicitly with our digital tool, and thus has a much smaller reach. However, by requiring explicit use, our tool also brings explicit consent of participation to the fore. Profiling technologies, such as those that detect personality disorders or mental health problems from stealthy methods such as eyetracking (e.g., Berkovsky et al., 2019) or social media use (e.g., Reece and Danforth, 2017) have been criticized for realizing a dystopian future in which marginalized populations that are already stigmatized experience further discrimination and harm from artificial intelligence and algorithmic decision making (Alkhatib, 2021). How data derived from digital sources is gathered, and for what purpose, is part of a larger discussion on the ethics of data use, dark patterns of interaction, and tech ethics (Kitchin, 2014; Mittelstadt et al., 2016). Although consent is not built into our digital tool, the explicit approach to gathering data does reduce the potential for large-scale unethical misuse.

4.3. Limitations and Future Work

Although our experiment suggests that remote assessment of depression has potential, there are several limitations to our study.

First, we assess depression using self-reported PHQ-9 scores. Although this is the gold standard self-report tool for clinical assessment (Kroenke et al., 2001), there are limitations with self-report. Answers can be affected by social desirability biases (Lavrakas, 2008b), can show unintended variance as has been demonstrated from test-retest reliability (Lavrakas, 2008c)) and respondents can be fatigued from answering many items on several questionnaires (Lavrakas, 2008a). Further, we predict the PHQ-9 score, and not the PHQ-9 level. To be effectively used as a screening tool, future work should determine if the biomarkers can be used to predict PHQ-9 level, using machine learning classification approaches, essentially indicating the severity of the symptoms. In future work, our digital assessment tool should be extended into clinical samples to predict diagnoses of depression as compared to a control group.

Second, our data was collected online, by intention. As our goal was to develop tools that can aid in remote assessment that will be undertaken *in situ*, testing our tool's validity in an uncontrolled environment was a necessary methodological approach. However, online studies can be subject to variations in response quality, and our tool should also be assessed in a controlled laboratory context.

Third, our tool was able to explain 34.4% of variance in a multiple regression model. Although this is, in practice, a large amount—over a third of the variance in PHQ-9 scores were explained by solely age, gender, and three attention metrics—additional measures may need to be incorporated for our tool to be used as a classification tool.

Fourth, some of the relationships between predictors and depression scores did not hold as expected (e.g., *number of items* in D2) or were inconsistent (e.g., *number of within errors* as non-significant in Study One but significant in Study Two). At this stage, we can only speculate about the reasons. For instance, it may be that longer exposure and more tasks are necessary for individuals to perform enough errors in SWM that they are indicative of depression scores. Thus, measures may be significant in Study Two, where participants completed the SWM after the D2 task. Alternatively, inconsistent or null effects may be due to specifics of our implementation and thus require further investigation. While our work does not aim to or allow for interpretation on a theoretical level, it is important to conduct further work to investigate inconsistent and null effects.

5. CONCLUSIONS

In this paper, we describe the design and evaluation of a non-clinical digital assessment tool that integrates digital biomarkers of depression. Based on three standard cognitive tasks (D2 Test of Attention, Delayed Matching to Sample Task, Spatial Working Memory Task) on which people with depression have been known to perform differently than a control group, we iteratively designed a digital assessment tool that could be deployed outside of laboratory contexts, in uncontrolled home environments on computer systems with widely varying system characteristics (e.g., displays resolution, input devices). We conducted two online studies, in which participants used the assessment tool in their own homes, and completed subjective questionnaires including the Patient Health Questionnaire (PHQ-9)—a standard self-report tool for assessing depression in clinical contexts. In a first study (n = 269), we demonstrate that each task can be used in isolation to significantly predict PHQ-9 scores. In a second study (n = 90), we replicate these results and further demonstrate that when used in combination, behavioral metrics significantly predicted PHQ-9 scores, even when taking into account demographic factors known to influence depression such as age and gender. A multiple regression model explained 34.4% of variance in PHQ-9 scores with several behavioral metrics from the tool providing unique and significant contributions to the prediction.

Our findings can help inform clinician assessment of depression with objective digital biomarkers of depression that are gathered easily on home computers outside of the clinical context. We contribute to the design of digital biomarkers of depression, which can be used in concert with existing assessments to promote accessible, equitable, early, ongoing, and large-scale assessment of depression.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Behavioural Research Ethics Committee at the University of Saskatchewan (BEH 17-418). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

RM led the research, designed the tool and experiment, conducted the analysis, and wrote the manuscript. MB contributed to the idea, the design of the tool, the experiment design, and the analysis plan. SV implemented the tool, designed the interfaces, and gathered the data for both studies. KW contributed to the assessment of attention online and wrote parts of the manuscript. ER implemented the prototype of the DMTS task and generated the visual stimuli. PB implemented the prototype of the SWM task. JF contributed to the experiment design, conducted the data analysis, and wrote the manuscript. All authors edited the manuscript.

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The Development of Explicit and Implicit Game-Based Digital Behavioral Markers for the Assessment of Social Anxiety

Martin Johannes Dechant, Julian Frommel and Regan Lee Mandryk*

Human-Computer-Interaction Laboratory, Department of Computer Science, University of Saskatchewan, Saskatoon, SK, Canada

Social relationships are essential for humans; neglecting our social needs can reduce wellbeing or even lead to the development of more severe issues such as depression or substance dependency. Although essential, some individuals face major challenges in forming and maintaining social relationships due to the experience of social anxiety. The burden of social anxiety can be reduced through accessible assessment that leads to treatment. However, socially anxious individuals who seek help face many barriers stemming from geography, fear, or disparities in access to systems of care. But recent research suggested digital behavioral markers as a way to deliver cheap and easily accessible digital assessment for social anxiety: As earlier work shows, players with social anxiety show similar behaviors in virtual worlds as in the physical world, including tending to walk farther around other avatars and standing farther away from other avatars. The characteristics of the movement behavior in-game can be harnessed for the development of digital behavioral markers for the assessment of social anxiety. In this paper, we investigate whether implicit as well as explicit digital behavioral markers, proposed by prior work, for social anxiety can be used for predicting the level of social anxiety. We show that both, explicit and implicit digital behavioral markers can be harnessed for the assessment. Our findings provide further insights about how game-based digital behavioral markers can be used for the assessment of social anxiety.

Keywords: social anxiety, assessment, digital biomarkers, digital games, interpersonal distance, in-game movement, behavioral markers

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Ioana Roxana Podina,
University of Bucharest, Romania

Reviewed by:
Lavinia Carmen Uscatescu,
University of Salzburg, Austria
Răzvan Jurchiş,
Babeş-Bolyai University, Romania

****Correspondence:***
Martin Johannes Dechant
martin.dechant@usask.ca

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INTRODUCTION

Social anxiety, one of the most common mental problems worldwide (Kessler et al., 2005), is characterized by the intense fear of being exposed to the judgment of others. This intense fear may push affected individuals to withdraw from social interaction or can lead to elevated stress when facing an unavoidable social encounter (National Collaborating Centre for Mental Health, 2013; Karasewich and Kuhlmeier, 2020). But this intense fear of evaluation in social contexts stands in strong contrast to the universal human need to be part of a social group and form and maintain social bonds with others (Deci and Ryan, 2000; Taormina and Gao, 2013). As prior research shows, social anxiety is a highly prevalent mental illness worldwide and especially affects children and adolescents (Rao et al., 2007; Knappe et al., 2015). Unfortunately, the characteristic social inhibition and withdrawal of affected individuals are often mistaken for shyness by others or perceived as a character flaw by the individual (Heiser et al., 2009; Poole et al., 2017). Additionally, social anxiety and the underlying fear of any evaluation may cause individuals to avoid consultation with mental health professionals about their concerns (Lecrubier et al., 2000). As a result, only a minority of socially anxious individuals receive treatment (Ruscio et al., 2008). Individuals seeking help have to face not only the challenges of the mental disorder and the inherent social fears themselves, but also have to overcome sociocultural barriers, such as stigmatization and discrimination of mental health problems, economic barriers (Vigo et al., 2016), such as lack of financial coverage for mental health treatments, and geographical barriers (e.g., limited access to mental health care in remote communities) (Olfson et al., 2000; Kumar and Phookun, 2016).

The heavy burden of social anxiety may be decreased through early and easily accessible assessment; prior work showed that early assessment of social anxiety in adolescenthood—which is a critical time for the development of social anxiety (Velting and Albano, 2001; Rao et al., 2007)—increases the efficacy of treatment and could prevent the development of the most harmful effects (Dams et al., 2017). Prior research suggests evidence-based assessment of social anxiety as a reliable way to identify affected individuals (Silverman and Ollendick, 2005). This approach combines information gathered from multiple perspectives to characterize the patient's concerns, develop suitable treatment strategies, and monitor the patient's response to the selected treatment approaches (Tulbure et al., 2012). Assessment combines the personal perspective of the patient and the analysis of the patient's behavior when confronted with social situations (Gordon et al., 2014). Mental health professionals utilize standardized questionnaires and interviews, in which the expert identifies concerns and the potential severity of social anxiety. While this approach is very effective in most cases, the subjective answers may be biased by several problems related to self-report measurements such as social desirability bias (Van de Mortel, 2008) and practice effect (Calamia et al., 2012). Within the context of social anxiety, these biases can often occur due to the desire of the patients to "please" the expert or to fit into the surrounding cultural and social context (Furnham and Henderson, 1982). To compensate for these effects, experts analyze behavioral data either by recording the reaction of the patient while being exposed to social situations within clinical assessment or by interviewing people close to the patient (Antony and Rowa, 2005). However, these approaches of behavioral information gathering are time consuming, can become expensive, and further involve additional people beyond the patient and the expert, which can introduce biases and false assumptions leading to biased conclusions (Davis, 2009; Ollendick and Davis, 2012). However, any accurate assessment is prevented when socially anxious individuals avoid reaching out for support because they are ashamed of their illness or in fear of negative evaluation (Lecrubier et al., 2000).

But prior research suggests a promising tool to assist existing techniques in assessing social anxiety: digital biomarkers. Digital biomarkers are measurable responses gathered from digital devices and used to reliably predict the incidence of a dysfunction or disorder (Gielis et al., 2019; Mandryk and Birk, 2019). Digital biomarkers can be harnessed to predict the severity of a disease and increase the temporal and spatial resolution of recorded behavior during an assessment (Dorsey et al., 2017). Furthermore, digital biomarkers are more resistant against human bias and may be less stress-inducing for patients (Shehab and Abdulle, 2011). Through various sensors [e.g., gaze tracking (Dechant et al., 2017)], platforms [e.g., social media platforms (Pourmand et al., 2019)], and devices [e.g., smartphones and wearables (Huang et al., 2016; Jacobson et al., 2020)], researchers can access a rich source of previously unobtainable insights, recorded with minimal effort from the patient and the expert alike (Torous et al., 2017). One subcategory of these digital biomarkers are digital behavioral markers which focus on the overall behavior, such as movement patterns using GPS coordinates (Mohr et al., 2017). More recently, motivated to harness the popularity of digital games, researcher have started to develop ways to incorporate game-based digital behavioral markers into the context of mental-health assessment (Dechant M. et al., 2021).

In 2019, two-thirds of the online population enjoy digital games (Wijman, 2020), including players of all ages, genders, and ethnicities from around the world. While enjoying digital games, players produce a large volume of data that can be used to create digital behavioral markers for the assessment of mental health concerns. Mandryk and Birk (2019) describe two complementary ways for developing game-based biomarkers: by harnessing in-game behavior data, which was produced naturally through interactions with the digital game or by developing custom games that place a player in a relevant context and record their response or performance using known behavioral correlates of mental health. Within the context of social anxiety, prior research outlined several reasons why behaviors related to social anxiety may translate into the context of a game: First, interpersonal interaction biases of the physical world have also been observed in similar player-avatar interactions (Bian et al., 2015); second, cognition biases and the characteristic avoidance behavior of social anxiety have been shown to manifest in-game as players of massively multiplayer online role player games (MMORPG) affected by social anxiety tend to avoid social interactions and highly challenging activities (Dechant et al., 2020). Third, prior research shows typical avoidance behavior of social anxiety in virtual reality simulations (Lange and Pauli, 2019). Finally, the media equation theory suggests that people react to computers with social responses (Nass and Moon, 2000; Rehm et al., 2016), which likely includes how socially anxious individuals react to virtual characters.

In developing digital behavioral markers, a first step is to identify behaviors that are characteristic of the mental health concern; the next step is to determine if these behaviors can be measured reliably by a system.

Characteristic Behaviors of Social Anxiety

At the core of social anxiety is an intense fear of potential exposure to negative or positive evaluation from others (National Collaborating Centre for Mental Health, 2013; Spence and Rapee, 2016). This fear leads to changes in an individual's behavior, for example social withdrawal, but also in physical symptoms such as blushing, trembling, or sweating. Prior work suggests that social anxiety is one of the most common anxiety disorders with a population prevalence of 2.0% (Fehm et al., 2005, 2008). This mental burden is most accurately expressed along a severity continuum where someone can experience a high level of social anxiety but not reach the threshold for a clinical diagnosis (Spence and Rapee, 2016). Several personal as well as environmental risk factors, such as social environment, can cause the development of social anxiety and affect how individuals could be affected by this mental burden. For example, people may experience high social anxiety only in a certain context, such as presenting in front of an unfamiliar audience, whereas the same task is less distressing with a familiar audience. Prior research emphasizes that adolescence is a critical phase for the development of social anxiety, which can grow into a chronic and generally unremitting course through a lifespan if left untreated (Perugi et al., 1999; Kessler, 2003; Villarosa-Hurlocker et al., 2019).

Socially anxious individuals face greater difficulties forming and maintaining social relationships with others (Miers et al., 2013). As a result of this fear, individuals tend to have fewer close friends, but are also at greater risk of being rejected or ignored by their peers. Additionally, affected individuals are also at higher risk of being victimized by others due to their lack of social competence (Navarro et al., 2012). As a way to escape this vicious circle for a moment, some socially anxious individuals develop dangerous coping strategies, such as substance abuse (Buckner et al., 2008). Untreated social anxiety can also lead to other severe mental illnesses, such as depression (Van Ameringen et al., 1991; Perugi et al., 1999).

As prior research shows, social inhibition and private anguish are inherent to social anxiety. However, these symptoms are often misinterpreted as shyness or as a character flaw of the individual rather than a mental illness (Poole et al., 2017; Jacobson et al., 2020). Also patients affected by social anxiety may avoid the consultation about their psychological problems with their physicians due to elevated experience of shame (Lecrubier et al., 2000). As a result, the nuanced effects of social anxiety are frequently underreported and under recognized. According to previous estimations, only 35% of individuals with symptoms of social anxiety disorder receive proper treatment for their anxiety (Ruscio et al., 2008). Therefore, to increase the efficacy and success rate of treatment, reliable assessment of social anxiety plays an important role in preventing serious harm (Herbert et al., 2009).

Leveraging (Digital) Behavioral Markers for the Assessment of Social Anxiety

Mental health experts use standardized procedures that combine interviews, questionnaires, and behavioral information to achieve reliable assessment of mental health concerns. Most of the used scales, such as the Liebowitz Social Anxiety Scale (Liebowitz, 1987; Baker et al., 2002), depict different social scenarios and ask respondents to rate their fear and/or avoidance within the described situations. Other tools focus on the special needs of specific groups, such as children (Delgado et al., 2019). But there is an ongoing discussion about the advantages of evidence-based assessment, which harnesses not only self-reported perspectives but also relies on objective evidence for the mental illness. This search for evidence-based assessment approaches has fueled an interest in finding behavioral correlates that are also predictive of mental health. These behavioral correlates are often referred to as biomarkers, which are defined by the World Health Organization (WHO) as *"any substance, structure, or process that can be measured in the body or its products, and that influences or predicts the incidence of outcome or disease"* (Strimbu and Tavel, 2010). One example within the context of social anxiety would be the measurement of the individual's blood pressure while being exposed to a social interaction. However, prior research provides only mixed results about the benefits of biomarkers for the assessment of social anxiety. *Digital Biomarkers* focus on objective, quantifiable physiological and behavioral data, which are collected and measured by means of various digital devices (e.g., wearable devices) (Jacobson et al., 2020).

To enhance the research agenda of finding reliable biomarkers for social anxiety, researchers have identified potential cognitive and behavioral characteristics of social anxiety which could be used for the assessment of social anxiety in a gaming task. Cognitive characteristics of social anxiety include aspects such as attentional biases (Pineles and Mineka, 2005) and interpretation (Miers et al., 2011) or memory biases (Glazier and Alden, 2019) that are affected by social anxiety. Prior work shows that socially anxious individuals prefer to maintain a greater distance from strangers (Givon-Benjio and Okon-Singer, 2020). Depending on the personality of an individual, these biases may cause the development of behavioral characteristics, such as the reliance and usage of avoidance and safety behaviors in the physical world (Voncken et al., 2006; McManus et al., 2008). These behaviors include individual approaches that aim to reduce the risk of drawing attention to oneself and therefore the risk of subsequent evaluation by others. For example, individuals with social anxiety over-rehearse a speech to prevent stuttering or other feared situations in front of an audience. But excessive reliance on safety behaviors results in consequences, such as the increased experience of anxiety, as well as self-focus attention, maintenance of negative beliefs, and even contamination of social situations, as the affected individual may come across as uninterested and insecure to others (Kley et al., 2012). Through various sensors, such as global positioning system (GPS) devices (Huang et al., 2016), gaze tracking devices (Chen et al., 2015), and skin conductance sensors (Voncken and Bögels, 2009), researchers successfully identified several promising digital biomarkers for social anxiety. Especially within virtual reality simulations, researchers have demonstrated the robustness of describing cognitive and behavioral markers for social anxiety, mostly by simulating physical situations in the safe space of virtual reality applications (Safir et al., 2012; Chesham et al., 2018). However, instrumenting people with contact sensors (e.g., gaze or skin conductance) limits the accessibility of the developed biomarkers. To gain the widest reach, digital biomarkers and behavioral markers should be extracted from standard interactions with computers or smartphones. One common source of engagement on computers or smartphones is through digital gaming.

Prior research has shown preliminary evidence that in-game behavior might be harnessed for the assessment of social anxiety (Dechant M. et al., 2021). In this earlier study, participants were asked to bypass a non-playable character (NPC) and move toward a targeted position in the room. Speed, accuracy, and path characteristics were measured per trial. Furthermore, two common game design aspects were altered to investigate design choices that may affect the visibility of typical social anxiety behaviors in the game. The results suggested that a third-person camera perspective combined with a customized self-representation resulted in the strongest effects of social anxiety on in-game behavior. People with higher levels of social anxiety tended to walk farther around the NPC and were less accurate in finding the final destination. This first investigation lays the essential foundation for further research about how digital behavioral markers in-game can be harnessed within digital games for the assessment of social anxiety. However, this initial work did not fully demonstrate the validity of in-game behaviors as a digital behavioral markers, as effects were shown on a trial level. To substantiate the initial evidence, we require further insights showing relationships per participant—a necessary approach for classifying individuals and suggesting the incidence of the mental health concern.

The Present Research

Given the need for digital behavioral markers to assist with the assessment of social anxiety, the accessibility and prevalence of digital gaming, and preliminary evidence that behaviors characteristic of social anxiety also manifest in digital contexts, we conducted a study with the aim of identifying promising digital behavioral markers of social anxiety, drawn from interactions with a digital game.

Our game environment involves a player using a customized self-representation to interact with a NPC through a dialog, and to move around the NPC in the digital world. Based on previous work (Dechant M. et al., 2021), we look for the manifestation of movement behaviors, such as moving farther around an NPC. We also introduce new measures that rely on explicit behaviors (e.g., ask participants to indicate a comfortable distance to a stranger), and not just implicit ones (e.g., the movement behavior around a stranger), similar to prior work (Lange et al., 2008; Ritter et al., 2013). Explicit measurements are valuable for the prediction of deliberate and controlled behavior, whereas implicit measurements are assumed to be more indicative of less controlled and more impulsive behavior. Within the context of in-game digital biomarkers and behavioral markers for assessing social anxiety, prior work leveraged implicit measurements, which means that these behaviors are characteristic of less controlled, more impulsive, and rather autonomic in nature. However, an explicit measurement of behavior could also hold valuable insights for the development of further digital behavioral markers for the assessment of social anxiety. For example, *interpersonal distance (IPD)* describes the distance between an individual and a stranger at which individuals are comfortable to interact (Perry et al., 2015). Prior research shows that socially anxious individuals prefer to stand farther away in social interactions (Kroczek et al., 2020), resulting in a higher IPD. Therefore, the goal of this work is to answer the question of whether both explicit and implicit measurements of in-game behaviors can be harnessed as digital behavioral markers for the assessment of social anxiety. To be a reliable digital behavioral markers, measurements also must be able to identify affected individuals, a more challenging task than identifying characteristic behavior in a single trial. As such, we model the relationship between behavior and social anxiety at the level of participant.

MATERIALS AND METHODS

We conducted an experiment to investigate whether aspects of an in-game movement path as well as the interpersonal distance between player and an in-game character can be harnessed for the assessment of social anxiety of players. In the task, participants were asked to deliver documents to different teams in a building.

Task Description

The task itself consists of two elements: The character editor and the assessment task; these elements will be described in the following sections.

Character Editor

Prior to the in-game task, participants were asked to create an avatar for the game, as prior work shows that customized avatars not only increase the engagement with a game but also affect the expression of social anxiety in-game (Dechant M. et al., 2021). First, participants selected the gender of their avatar (woman, man), then adjusted major aspects of the avatar's body (i.e., height, weight, muscles, head offset, and breast size) and selected the hairstyle and skin and eye color of their avatar. Due to technical limitations of the underlying framework for the character creation, we were not able to offer a non-binary gender option in this experiment. Next, participants shaped the head of their avatar *via* 34 sliders to define different aspects of the head, such as face, eye, brows, nose, mouth, chin, jaw, ear, neck. After that, participants could choose the outfit of their avatar by selecting the style and color of clothing on the upper body, lower body, and shoes, as well as through head accessories, such as glasses, headphones, face masks, or hats (13 different options per element). To further enhance the participant's identification with their avatar, we asked participants to describe the personality of their avatar by adjusting five sliders, which each represented one personality trait based on the Big Five Inventory. The 10 items of the BFI-10 (Rammstedt and John, 2007) were grouped into bipolar semantically anchored categories for the five traits and participants were asked to choose the slider position between the elements (e.g., calm to anxious). Participants had to spend at least 4 min with the design of their avatar. After 4 min, a button appeared on the screen that allowed participants to move to the next step of the experiment.

After customizing their in-game representation, participants filled out the Player Identification Scale (PIS) (Van Looy et al., 2012). Through the PIS, we were able to determine how much participants associated their avatar with themselves on the following three dimensions: similarity, embodied, and wishful identification. These insights were used to explain potential variance when participants may have felt they were limited in their self-expression due to the limitations of the character editor, such as the missing non-binary options as well as the lack of certain hair styles, such as curly hair styles. **Figure 1** shows the character editor.

Assessment Task

In the beginning, participants were introduced to the background story and the control scheme of the task: As new interns at a large company, participants were instructed to deliver documents to 20 teams in a large building, named after Greek letters (e.g., Team alpha). Each team was randomly assigned to one floor number. These floors were then assigned to two elevators (1–10: right elevator; 11–20: left elevator). To find out the floor number, participants were instructed to walk toward a NPC, which stood ten meters in front of both elevators and centered in the room (see **Figure 2**), and to ask them on which floor they could find the team they were looking for. This interaction was intended to replicate a social situation with another stranger similar to prior work in the context of social anxiety assessments (Dechant et al., 2017).

Once participants stood at a comfortable distance to the NPC, they had to press spacebar to start a conversation with the NPC. The NPC reacted either in a friendly manner, greeting participants and offering to help, or angry manner, insulting participants at the beginning of the conversation. In the conversation, the camera focused the face of the NPC and a chat interface appeared (see **Figure 3**). After either a friendly (e.g., "Hi! Nice to meet you. Let me know if I can help you.") or angry (e.g., "What do you want, idiot?") introduction, participants were asked to enter their question for the NPC, including the team name. Next, the NPC stated the floor number of the desired team in a friendly (e.g., "Team alpha is on floor 12") or insulting manner (e.g., "Team alpha is on floor 12, idiot"). The two emotional reactions were balanced across the elevator sides over the experiment (five time for each side for each emotion). After the conversation, participants were asked to go to the elevator that led to the floor of the team. Once in front of the elevator, participants had to hit the space bar to confirm their selection. After that, we asked participants to rate the friendliness of the NPC on a scale from 0 (= "very angry") to 100 (= "very friendly"). In total, participants had to deliver 20 files (2 elevator sides × 2 emotions × 5 repetitions). For each trial (one delivery of a file), we used a distinct team name. Prior work suggested the usage of a third-person camera setup, so that the participant can see over the shoulder of their own avatar over the whole trial to maximize in-game expression of social anxiety (because the self-representation is always visible on screen) (Bögels et al., 2002; George and Stopa, 2008). Whenever the player interacted with the NPC, the camera focused the NPC. **Figure 3** summarizes the task implementation.

The task was implemented using the Unity Engine (Unity Technologies, 2020) combined with the Asset-Bundle "Advanced People Pack 2" (Lenk, 2020) and deployed in a web browser using the Bride of Frankenstein framework (Johanson, 2020). The asset package offers prepared 3D objects with blend shapes, which allowed us to adjust the body shape (e.g., weight and muscularity) as well as the face characteristics (e.g., the shape of the eyes). Furthermore, the package includes a suitable variation of clothing and hair styles for both genders that we could use for customization.

Participants and Procedure

The experiment was deployed online, and participants were recruited using Amazon's Mechanical Turk (MTurk). MTurk is an online platform, on which human intelligence tasks (HIT) can be offered by requesters. Workers can opt-in to these HITs. Prior researchers in different areas (Depping et al., 2018; Johanson et al., 2019; Passmore et al., 2020; Miller et al., 2021) successfully used this platform to collect data online. However, researchers need to carefully examine the data and ensure that bots or negligent workers are removed from the final analysis (Mason and Suri, 2012). Participants who were not able to play a 3D interaction game on their computers and those who left the experiment prior to completion were excluded from our data file. To avoid any behavioral bias induced by knowing the original goal of the story [e.g., white coat hypertension (Shehab and Abdulle, 2011)], we used a cover story to explain why participants were engaging in this task. For this experiment, we used the cover story that the goal of the experiment is to analyze effects of lag (input lag or network lag) on performance in a 3D game. The experiment itself as well as the usage of the cover story was approved by the Ethics board of the University of Saskatchewan. The actual goal of the experiment was revealed in the debrief of the study, at which point participants could ask to have their data excluded from further analysis.

MTurk allows requesters to use predefined or custom filters, such as demographics, prior work experience or how many HITs the worker successfully finished. For this study, we recruited participants who indicated that they live either in Canada or the United States of America, had at least 500 successfully completed HITs, and had a high approval rate of previous HITs (>95%).

We recorded the data of 117 participants following the suggestions of prior work (Dechant M. et al., 2021). First, we identified negligent participants based on their time spent answering the trait social anxiety questionnaire (LSAS; described later) and a short summary of the experiment, which they were required to provide in an open text field after the experiment. Participants who spent less than 1.5 s per item in the LSAS questionnaires were removed from the sample as well as participants who provided a non-descriptive or inaccurate summary of the experiment (e.g., "This is a nice experiment"). Furthermore, we removed participants who did not complete all 20 trials. After removing suspected bots and negligent participants (n = 11), we conducted our analysis with the remaining 102 participants (39 women, 62 men, one non-binary), aged 20–65 (M = 37.5, SD = 9.893). All participants received $8 USD compensation for participating in this study, which took approximately 40 min to be completed.

After providing consent, participants were provided with the cover story and had to answer one questionnaire to assess trait social anxiety and multiple about aspects of their gaming behavior, as well as their personal experience with lag

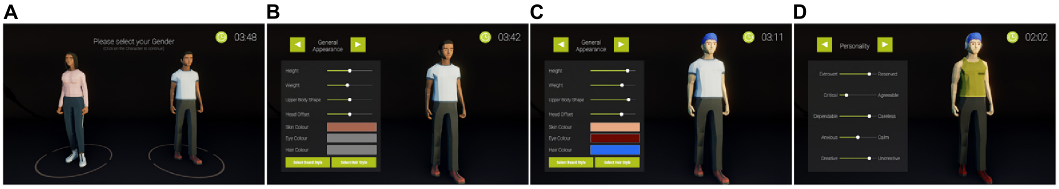

FIGURE 1 | The character editor interface: First, participants selected the gender **(A)**, then customized their avatar's body **(B)** and outfit **(C)**, and then selected their personality traits **(D)**. Images of the character assets reproduced with permission from Alex Lenk.

in digital games (see section "Measurements"). These gaming questionnaires were used to emphasize the cover story. Following this, the task started with the previously introduced character creation interface, in which participants were instructed to design an avatar that represented them as best as possible. After that, the assessment task started, and participants completed their 20 trials. After the assessment task, demographic information was recorded, and participants were debriefed about the goal of the study. Additionally, we offered support resources such as contact information to a crisis hotline, and a link to picture of baby animals to reduce the potential negative effect on participants in considering their individual level of social anxiety.

Measurements

Trait Social Anxiety

Participants answered the self-report version of the Liebowitz Social Anxiety Scale (LSAS) (Liebowitz, 1987; Baker et al., 2002). The LSAS consists of 24 items, split into two categories, which describe different social situations and interactions: social interaction (11 items; e.g., "Giving a party") and public performance (13 items e.g., "Eating in a public place"). These items are rated on two 4-point Likert scales, one to measure the fear (0 = "none," 3 = "severe") and a second on how often these items were avoided in the last 2 weeks (0 = "0%/never," 3 = "usually/68–100%"). The answers are summed together to estimate the level of trait social anxiety, between 0 and 144, where higher values indicate a higher level of social anxiety. Prior work suggests a score of 30 as a threshold to distinguish between non-anxious and anxious individuals, while a threshold of 60 provides the threshold that identifies a high risk of generalized social anxiety. In this sample, LSAS scores ranged from 1 to 126 (M = 58.7; SD = 28.65) with a high internal consistency (Cronbach's α = 0.97). On average, our sample scored higher in comparison to a study with 31,243 cross-cultural participants (M = 44.07) (Caballo et al., 2019) as well as a study of 1,007 college students in the United Kingdom (M = 34.7) (Russell and Shaw, 2009); However, this study is in line with prior work examining United States MTurk samples [M = 51.24 (Dechant et al., 2020) and M = 58.85 (Dechant M. et al., 2021)], which contain workers with elevated levels of social anxiety.

Avatar Identification

In this experiment, we leveraged the avatar-related subscales of similarity, embodied identification, and wishful identification from the Player Identification Scale (PIS) (Van Looy et al., 2012). Participants rated their agreement to different statements such as "My avatar is like me in many ways" on 5-point Likert scales from 0 (= "strongly disagree") to 4 (= "strongly agree"). Internal consistency was high for all subscales: similarity (Cronbach's α = 0.93), embodied (Cronbach's α = 0.94), and wishful identification (Cronbach's α = 0.90).

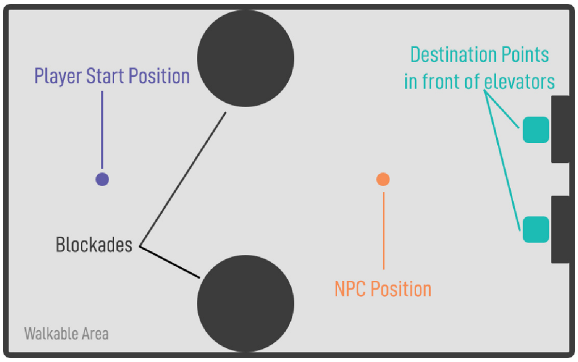

FIGURE 2 | The setup of the of the assessment room: The avatar of the player stands at every trial on the purple point, the NPC on the orange point. Blockades (black) were used to guide the users' movement toward the NPC.

Perceived Emotion of the NPC

After each trial, participants were asked to rate the perceived emotional state of the NPC on a scale ranging from 0 (= "very angry") to 100 (= "very friendly"). This measurement was used to emphasize the reflection of the social interaction with the NPC.

In-Game Digital Behavioral Markers for Social Anxiety

To assess the level of social anxiety within the digital game, we recorded the following aspects of the participant's in-game behavior: comfortable interpersonal distance, movement features, and temporal features.

Comfortable Interpersonal Distance

As previously described, participants were asked to approach the NPC and had to press the spacebar once they reached a comfortable distance to start a conversation. We calculated the Euclidian distance between the position of the participant's avatar and the NPC when they hit spacebar to start the conversation with the NPC. This measurement is referred to as interpersonal distance (IPD). Prior research shows that individuals with social anxiety show a distance estimation bias. As a result of this bias,

Approach the person and hit space bar once you stand at a comfortable distance to the other person.

Ask the person which floor level the team is you have to deliver .

Hi there, how are you doing? How can I help you?

Ask the person which floor level the team is you have to deliver .

No problem! That team is on the 18th floor. Have a nice day!

Go to the indicated door and hit space if your avatar stands in the indicated area in front of the door

FIGURE 3 | The task: First, participants have to approach the NPC and then ask for directions. Afterward they have to select the correct elevator. Images of the character assets reproduced with permission from Alex Lenk.

socially anxious individuals tend to prefer a larger IPD to other individuals, not only in the physical world, but also in virtual reality simulations (Lange and Pauli, 2019; Givon-Benjio and Okon-Singer, 2020; Kroczek et al., 2020). Therefore, we expected that elevated levels of social anxiety would result in a higher IPD.

Speed and Movement Features

We measured the time in seconds from starting the trial until participants completed the whole trial (*time spent in room*). This time measurement includes the time in the conversation and the rating screen in the end of the trial.

According to prior research, socially anxious individuals tend to walk farther around other individuals in the physical world as well as in simulated realities, such as virtual-reality experiences (Lange and Pauli, 2019). Furthermore, prior work suggests several aspects of the movement behavior in-game which can be used to identify social anxiety (Lange and Pauli, 2019; Dechant M. et al., 2021). Similar to prior work, we recorded the location of the participant's avatar in the digital world with a timestamp, sampled every 50 ms after the conversation with the NPC was completed, as they approached the elevator.

Based on these samples, we calculated the following movement features, as suggested by prior work: The *path length* describes the absolute travelled distance per trial from the point where the conversation with the NPC started to one of the selected elevator doors.

Prior work shows that socially anxious individuals prefer to stay farther away from strangers in the physical realm (Givon-Benjio and Okon-Singer, 2020) and also in the digital realm (Kroczek et al., 2020). To confirm these findings, we measured the minimum distance between the participant's avatar and the NPC after the conversation, measured as the smallest Euclidean distance to the NPC over the whole trial. We expected that participants with elevated social anxiety will show higher minimum distances as they prefer to stay farther away and walk farther around strangers (Lange and Pauli, 2019). The *mean distance to the NPC* represents the average distance to the NPC of all recorded samples per trial. Like prior work recommends, we additionally took all samples per trial and calculated two statistics related to the distribution of the samples: skew and kurtosis. Participants walking farther around the NPC should result in an elevated (right-leaning) skew. An elevated kurtosis is reflective of a narrower distribution, which results from a more consistent path with fewer points either very close to or very far from the NPC, indicative of less exploration and more controlled movements characteristic of people with elevated social anxiety (see **Figure 4**).

In summary, we had one explicit measurement, the (1) IPD, and six implicit measurements: (2) minimal and (3) mean distance to NPC, (4) time spent in room, (5) kurtosis and (6) skew of the distribution of the distances and the (7) path length.

Demographics

We recorded a variety of demographic factors, such as: age, gender, income, marital status, and ethnicity. See **Table 1** for details about the characteristics of the sample.

Hypotheses Based on Prior Work

Prior work suggests that highly socially anxious participants will aim to complete the task—which includes potential social threats and performance aspects—as quickly as possible, resulting in reduced time spent in the task (*time spent in room*). Further, elevated levels of social anxiety will result in elevated levels of *skew* and *kurtosis*, as participants with elevated social anxiety will try to walk farther around the NPC and have a higher *minimum* and *mean distance* to the NPC. As a result of this behavior, also the *path length* will increase as participants need to travel greater distances. Furthermore, we expect that the distance estimation bias caused by social anxiety (Givon-Benjio and Okon-Singer, 2020) will lead to an increased *IPD* for people with elevated levels of social anxiety.

Analysis

Data were gathered and stored using an on-premises server and then exported once data collection was complete. All data were analyzed using SPSS 26; moderated regressions used the Process 3.4 integration. Statistical tests are described prior to reporting the results.

RESULTS

Characteristics of the Sample

We first looked at the characteristics of the recorded sample and whether players feel represented and connected to their self-created in-game representation. **Table 1** summarizes the characteristics of our sample of 102 participants. The PIS subscales revealed that players felt that the self-representation is similar to their own visual appearance, resulting in a high score of similar identification score compared to prior work (Dechant M. et al., 2021).

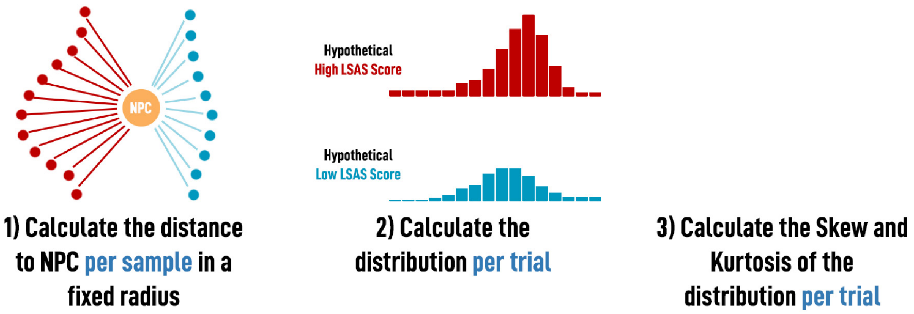

FIGURE 4 | The calculation of skew and kurtosis of the distribution per trial.

RQ2: Is There an Influence of the NPC's Emotion as Well as the Elevator Side?

First, we investigated whether the emotion of the NPC as well as the side of the destination elevator affected the explicit and implicit measurements. We used a repeated measures MANCOVA with side and emotion of NPC as repeated within-subject factors on the seven previously introduced dependent measures, controlling for age and gender. We found no significant results indicating that either the side of the elevator (all $p > 0.129$) nor the emotion of the NPC (all $p > 0.148$) significantly affected any movement behaviors. Therefore, we merged all trials together to calculate the central tendency, using the means of each measurement, and modeled the results on the participant level. **Table 2** summarizes these results.

RQ3: Can We Predict the Participant's Trait Social Anxiety Through in-Game Behavior?

To find out whether the proposed measures can be used for assessing the social anxiety of a player, we conducted hierarchical linear regressions for each measure to analyze whether it predicts trait social anxiety, expressed by the LSAS score (Liebowitz, 1987; Fresco et al., 2001). We included age and dummy-coded gender (−1 = man; 1 = woman, removed 1 non-binary participant) in the first block, and the movement feature in the second block, with LSAS as the dependent measure. We report unstandardized regression coefficients (denoted as B) and standardized regression coefficients (denoted as β). In all models for which the feature was significantly predicting social anxiety, the model fit was significant. **Table 3** summarizes these results.

The results show that most of the proposed in-game behavioral markers were useful for the prediction of trait social anxiety. As expected and suggested by the literature (Perry et al., 2015; Givon-Benjio and Okon-Singer, 2020), the interpersonal distance shows that players with elevated social anxiety explicitly prefer to stop at a larger distance when approaching an NPC. Furthermore, kurtosis and skew indicate that individuals with elevated social anxiety tend to maintain a consistently farther route around the NPC and avoid any close distance to the NPC, as the minimum distance to the NPC shows. Contrary to prior work (Dechant M. et al., 2021), the complete length of the path starting from the recording of the IPD to the selected elevator door, shows no significant relationship with LSAS. Also the mean distance between the player's avatar and the NPC indicated no significant relationship with LSAS once modeled on the participant level. **Figure 5** visualizes these results.

TABLE 1 | Overview of demographic information, LSAS and PIS measurements.

Variable	Categories	*N*	%	M	SD	Min	Max
Age		101		37.5	9.89	20	65
Gender	Woman	38	38.2				
	Man	62	60.8				
	Non-binary	1	1.0				
LSAS Score		102		58.7	28.65	1	126
Similarity Identification		102		3.015	0.7	0	4
Embodied Identification		102		2.65	0.87	0	4
Wishful Identification		102		2.27	0.95	0	4

DISCUSSION

Summary of Results

In summary, the results of this study confirm that characteristic behaviors of social anxiety appear within the realm of digital games. We show that higher levels of social anxiety result in a biased movement pattern expressed by an increased kurtosis and skew as well as increase in the minimum distance to the NPC. Additionally, we show that the characteristic preferences of social anxiety are also expressed by players prior to interacting with the NPC, as displayed in the increasing interpersonal distance. Contrary to prior work, the mean distance to the NPC as well as the path length around the NPC were not significant predictors for social anxiety.

Explanation of Findings

In line with prior work, the results of this study show that explicit and implicit behaviors characteristic to social anxiety that have been observed in the physical world may also manifest in-game.

According to prior work in the physical world, as well as in virtual reality simulations, individuals with elevated social anxiety show that they prefer a larger physical distance between themselves and other individuals. Socially anxious individuals

TABLE 2 | Results of the MANCOVA.

Effect			**Value**	***F***	**Hypothesis df**	**Error df**	***p***	**Partial Eta Squared**
Between Subjects	Intercept	Pillai's Trace	0.992	1,232.904	9	91	0.0	0.992
		Wilks' Lambda	0.008	1,232.904	9	91	0.0	0.992
		Hoteling's Trace	121.936	1,232.904	9	91	0.0	0.992
		Roy's Largest Root	121.936	1,232.904	9	91	0.0	0.992
	Age	Pillai's Trace	0.286	4.1	9	91	0.0	0.289
		Wilks' Lambda	0.711	4.1	9	91	0.0	0.289
		Hoteling's Trace	0.406	4.1	9	91	0.0	0.289
		Roy's Largest Root	0.406	4.1	9	91	0.0	0.289
	Sex	Pillai's Trace	0.182	2.252	9	91	0.025	0.182
		Wilks' Lambda	0.818	2.252	9	91	0.025	0.182
		Hoteling's Trace	0.223	2.252	9	91	0.025	0.182
		Roy's Largest Root	0.223	2.252	9	91	0.025	0.182
Within Subjects	Emotion	Pillai's Trace	0.067	0.726	9	91	0.684	0.067
		Wilks' Lambda	0.933	0.726	9	91	0.684	0.067
		Hoteling's Trace	0.072	0.726	9	91	0.684	0.067
		Roy's Largest Root	0.072	0.726	9	91	0.684	0.067
	Side	Pillai's Trace	0.3	0.316	9	91	0.968	0.030
		Wilks' Lambda	0.970	0.361	9	91	0.968	0.030
		Hoteling's Trace	0.31	0.361	9	91	0.968	0.030
		Roy's Largest Root	0.31	0.361	9	91	0.968	0.030

TABLE 3 | The regression results.

	B	**β**	***p* (predictor)**	***R***	**R^2**	***p* (model)**
Interpersonal Distance (IPD)	**7.637**	**0.199**	**0.044**	**0.307**	**0.094**	**0.022**
Time Spent in Room	**0.386**	**0.229**	**0.023**	**0.308**	**0.095**	**0.01**
Kurtosis	**10.895**	**0.217**	**0.027**	**0.319**	**0.101**	**0.015**
Skew	**27.482**	**0.236**	**0.019**	**0.328**	**0.107**	**0.011**
Minimum Distance to NPC	**15.859**	**0.267**	**0.008**	**0.348**	**0.121**	**0.006**
Mean Distance to NPC	4.571	0.068	0.507	0.244	0.59	0.113
Path Length	1.299	0.093	0.379	0.249	0.062	0.1

B denotes unstandardized regression coefficients.
β denotes standardized coefficients.
Significant results are bold.

have also been shown to prefer less intimidating communication platforms, such as online chats (Miller et al., 2021) over voice or in person meetings. Within the context of digital games, players affected by social anxiety have been shown to be drawn toward games with a focus on playing together with others, such as MMORPGs; however, even in this context, the characteristic preference for distance toward others appears and biases the players' preferences. Players with an elevated level of social anxiety withdraw from social activities in-game and avoid highly challenging tasks to avoid any potential exposure to the judgment of other players (Dechant et al., 2020). The results of our study contribute a similar result: socially anxious participants showed that they prefer greater distance between themselves and NPCs in-game, similar to within the physical world. However, this preference bias induced by social anxiety also appears in our study as what may be characterized as some visible strategies, similar to safety behavior techniques in the physical world. Prior work provides evidence for a distance estimation bias of socially anxious individuals. This bias may cause individuals to walk farther around another individual to not harm the personal space of another person as previously discussed. This study demonstrates similar behavior in the digital realm, which may stem from a similar strategy, or may be a habitual transfer of behaviors from the physical realm into the digital one.

A potential explanation for why social anxiety may trigger avoidance and preference biases that we observe in movement patterns may come from the elevated experience of self-awareness intensified by social presence; experiments in which socially anxious patients had to interact in front of a mirror show an association between experiencing social anxiety and elevated self-awareness (George and Stopa, 2008). This increased self-awareness plays an essential role in the maintenance of social anxiety, because socially anxious individuals are highly aware of their self-presentation to avoid any negative consequences (Bögels et al., 2002). In our study, the third-person camera perspective can be seen as a mirror which shows the player's action within the digital realm of the game. Additionally, this effect is intensified through the use of a customized self-representation in the game. The combination of both resulted in prior work in the strongest expression of social anxiety within the game. Therefore, this study may provide more evidence for the hypothesis that customizing the own avatar and seeing it throughout the whole task enhances identification with the avatar, which triggers self-awareness and prompts the expression of safety behaviors.

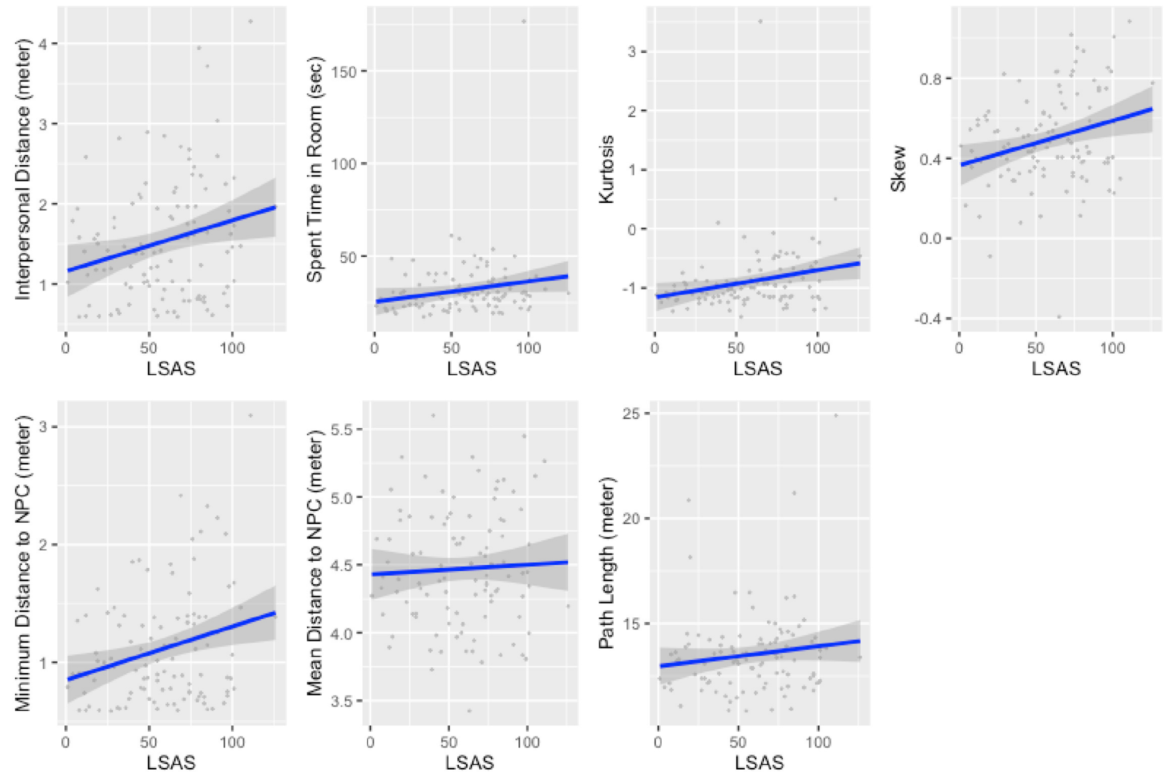

FIGURE 5 | Scatter plots of the regression results for all proposed features.

Furthermore, the usage of customized avatars may enhance the experience of social presence (Bente et al., 2008). Social presence describes the experience that others are sharing the digital space with the player (Felnhofer et al., 2019). For the therapeutic effectiveness of digital interventions for social anxiety, the experience of social presence plays an essential role, because the experience of social presence may be more predictive of social anxiety responses than the self-reported experience of physical presence in a virtual world (Clutton-Brock et al., 2009). For example, prior work shows that participants experienced elevated social anxiety when their self-representation looked more similar to themselves (Vasalou et al., 2007; Aymerich-Franch et al., 2014). Also, social presence may also intensify the self-awareness of participants which may cause even stronger expression of social anxiety within the digital realm. Customizing avatars has also been recently shown to enhance fear within an exposure task for social anxiety (Dechant M.J. et al., 2021); the authors show that the customization enhances identification with the avatar, and speculate that customization enhances the invested effort and engagement in the task. In our study, all players customized their avatar, which may have helped reinforce the perception that they themselves were interacting with the NPC, aiding in the transference of behaviors and coping strategies common in physical spaces into our game.

Digital behavioral markers embedded in a gaming task may help to develop new approaches for the assessment of social anxiety, which may offer many benefits for health professionals as well as the affected individuals. Early assessment, such as when individuals are still young and developing their identities (Grant et al., 2005), habits, and behaviors, may prevent the harshest outcomes of social anxiety (Miers et al., 2013). However, a common challenge for the assessment is the risk of attrition due to waning of the patient's motivation to continue with the process. Game based assessment may help to increase the engagement of patients who enjoy playing video games (Birk et al., 2016; Mandryk and Birk, 2019), which is not only limited to younger generations, as the still growing popularity of digital games in older generations suggests (ESA, 2019). These customized games may offer an easily accessible screening tool in combination with other existing tools as well as a way for continuous monitoring of the current progress in a treatment. However, researchers as well as developers need to be aware of several ethical implications when harnessing digital biomarkers in a gaming task.

Ethical Implications

Despite the suggested benefits of digital biomarkers in general within a digital game, the growing discussion about the appropriate usage of data derived from digital sources raises several ethical concerns that are part of an ongoing discussion (Floridi and Taddeo, 2016; Metcalf and Crawford, 2016; Mittelstadt et al., 2016; Kenwright, 2018). When harnessing digital biomarkers, we need to ensure the protection of the user's privacy as well as the creation of a safe space for the patient grounded on a legal basis. The communication about measured (mental) health issues might have negative effects for the patient, and experts need to be aware of the potential harm the communication can cause for the player. When deployed by mental health experts, assessment data is interpreted within a safe context that can lower the risk for a biased interpretation of the results of the assessment. Additionally, to leverage these approaches in an appropriate and healthy manner, developers must ensure the safety of the patient as well as the therapist while using such tools.

However, designers of these applications need to balance the enjoyment of the digital game and the requirements of an effective assessment. Depending on the complexity of the game mechanics as well as the context of the game, players may behave differently in the digital realm as compared to the physical. As prior work outlines, games allow players to explore and enact different roles or fantasies, which guides them to behave differently. Furthermore, excessive play of video games should be avoided especially within the context of social anxiety. Prior work emphasizes a relationship between problematic gaming behavior and social anxiety (Cole and Hooley, 2013; Lee and Leeson, 2015). However, this relationship highlights the potential of using game-based behavioral markers applied by medical experts for assessing social anxiety. Overall, these techniques should only be applied within a health and safe patient-therapist relationship.

Limitations and Future Research

There are several questions future research may address in further follow-up investigations. First the lack of non-binary representation; although only one participant identified themself as non-binary, future research should overcome the technical limitations of the used framework to offer participants a non-binary character option, which will allow them to identify themselves with their character. Second, we must consider the influence of culture on the expression of social anxiety. This work focused on the development of digital b behavioral markers for characteristics linked to social anxiety in a western context. However, the literature suggests the differentiation of social anxiety and *Taijin kyofusho* (Kleinknecht et al., 1997) which, in comparison to social anxiety (disorder), focuses on the fear of embarrassing or *offending another person* rather than *embarrassing oneself* in front of others. Furthermore, the preference of the interpersonal distance may also be biased by the cultural background, where the shape of what constitutes personal space varies over different cultures. Therefore, future research may investigate the effect of the cultural background on the expression of social anxiety behavior within the digital realm. Third, we acknowledge the lack of comparison to other mental illnesses. Prior research suggests a comorbidity between different mental illnesses, such as Autism and Social anxiety. Therefore, future work may investigate if related mental illnesses will be expressed differently through the proposed in-game digital behavioral markers. However, this paper further confirms that prior suggested in-game movement behaviors and preference features embedded into a game can be used for assessing the personal level of social anxiety.

CONCLUSION

Social anxiety, one of the most common mental disorders worldwide, is underdiagnosed due to several barriers induced by the disorder as well as by existing assessment approaches. However, prior work suggests digital behavioral markers embedded in a gaming task to complement existing assessment techniques. These behavioral markers allow for a timely identification for early intervention, ongoing assessment during an intervention and lowering barriers to access systems of care, due to their broad accessibility and low cost. This study replicated previous findings that movement behaviors characteristic of people with social anxiety also manifest in digital spaces, and also provides new evidence that digital behavioral markers within a game can be harnessed to assess the personal level of social anxiety. Specifically, the player's preferred distance from an NPC prior to interaction as well as altered movement path around the NPC after interaction were able to predict social anxiety. However, certain aspects of the movement path, such as the length of the path, were less useful as they were strongly affected by the surrounding game environment. The presented findings confirm prior research showing how game-based digital behavioral markers can be effectively used to assess social anxiety and offering the benefits of early and ongoing digital assessment for the mental health expert and the patient.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Ethics Board of the University of Saskatchewan. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

MD led the research, co-designed the task and experiment, implemented the task, gathered and analyzed the data, and wrote the manuscript. JF provided feedback on the task and experiment design, contributed to the analyses, and edited the manuscript. RM co-designed the task and experiment, guided the analyses, and edited the manuscript. All authors contributed to the article and approved the submitted version.

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Making a Virtue Out of Necessity: COVID-19 as a Catalyst for Applying Internet-Based Psychological Interventions for Informal Caregivers

Michelle Semonella[1]*, *Gerhard Andersson*[2,3,4], *Rachel Dekel*[5], *Giada Pietrabissa*[6,7] *and Noa Vilchinsky*[1]

[1] *Department of Psychology, Bar-Ilan University, Ramat Gan, Israel,* [2] *Department of Behavioral Sciences and Learning, Linköping University, Linköping, Sweden,* [3] *Department of Biomedical and Clinical Sciences, Linköping University, Linköping, Sweden,* [4] *Division of Psychiatry, Department of Clinical Neuroscience, Karolinska Institute, Stockholm, Sweden,* [5] *School of Social Work, Bar-Ilan University, Ramat Gan, Israel,* [6] *Department of Psychology, Catholic University of Milan, Milan, Italy,* [7] *Psychology Research Laboratory, Istituto Auxologico Italiano - Istituto di Ricovero e Cura a Carattere Scientifico, Milan, Italy*

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****Correspondence:***
Michelle Semonella
michelle.semonella@biu.ac.il

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Coronavirus disease 2019 (COVID-19), which dates from December 2019, has been recognized by the World Health Organization (WHO) as a global pandemic on March 11, 2020. In order to face the ongoing pandemic and prevent the spread of the virus, national governments worldwide imposed various restrictions (Sandford, 2020). Yet, lockdown, mobility restrictions, and fear of uncertainness put the mental wellbeing of many individuals at risk (Serafini et al., 2020). Many studies have reported on negative health outcomes during the COVID-19 outbreak, such as maladaptive and unhealthy behaviors (e.g., sedentary lifestyle, consumption of alcohol, or unhealthy diet) (Brooks et al., 2020), higher levels of anxiety, depressive symptoms, irritability (Pearman et al., 2020; Rossi et al., 2020), posttraumatic stress and psychological stress (Cooke et al., 2020), disinterest, poor health perception (Le and Nguyen, 2021), and concern for one's self and worry for the others (Khan et al., 2020), along with feeling lack of personal freedom and to be under constant emergency during the quarantine (Brooks et al., 2020; Durosini et al., 2021).

Particularly, some populations, due to their unique characteristics or societal role, have endured a worse impact than others. One such population which has gained relatively little attention in the literature, is informal caregivers (Budnick et al., 2021; Sheth et al., 2021). Informal caregivers are family members, neighbors, friends, or other non-kin who provide unpaid care to an older, frail, or ill person (Triantafillou et al., 2010). Above and beyond the fear of infection and economic difficulty, informal caregivers have experienced an extended burden due to their unique social role (Lorenz-Dant, 2020). Different studies conducted during the pandemic have identified three main challenges for those who provide informal care: 1. decreased routinely provided healthcare options, 2. emotional distress, and 3. economic stress (Glaser et al., 1967; Phillips et al., 2020; Sheth et al., 2021). The restrictive and preventive measures that have been put in place to stop the spread of the virus have given way to an increase in informal care duties due to the drastic reduction in the availability of family members and/or respite care (Schmidt et al., 2020), and diminished availability of volunteers and social services (Arnold et al., 2021).

Especially among non-cohabiting informal caregivers, there has been an increase in "competing" care needs. For example, the closing of schools has required informal caregivers who are also parents to manage the needs of both their children and their care recipients, making the role of informal caregivers even more stressful than in ordinary times (Rodrigues et al., 2021). The virus's high infectiousness has led to the fear of being infected and, consequently, to the infection of care receivers, and/or to caregivers being quarantined and unable to visit the person they are caring for (Cipolletta et al., 2021). Economic stressors, linked to job loss or a decrease in working hours, and consequently salaries, are also factors in this increased burden (Arnold et al., 2021). Clearly, the caregiving situation, which was challenging to begin with, has become even more complex. In addition, the restrictions posed on society have made it harder to be helped by means of traditional psychotherapy sessions which are usually delivered face-to face. Not only have caregivers experienced more distress and burnout, but the ways of helping them have also been made more challenging.

Indeed, many of these challenges cannot be overcome; nevertheless, we can help caregivers cope better *emotionally* with their situation. Any possible solution should take into account not only the challenges that informal caregivers have been facing due to the pandemic restrictions, but also the limitations which characterize their role in general, such as time limitations. Thus, caregivers will gain from interventions that help them cope with their challenges but also pay heed to the new imposed constraints. One such possible solution are digital-based interventions.

The pandemic has led to an increased interest in diverse digital-based solutions, comprising videocall meetings, telephone calls, and mobile applications that were shown to be effective even before the pandemic (Bertuzzi et al., 2021). In the specific context of relieving caregiver burden, the use of digital solutions has increased, along with caregivers' acceptance of and willingness to use them, and have been adopted by different healthcare entities to deliver services (e.g., videoconferencing, and mobile applications) (Blumenstyk, 2020; Bertuzzi et al., 2021).

Although there is great potential in the use of digital solutions for supporting caregivers (Hassan, 2020), these solutions are not necessarily optimally tailored to the specific needs (e.g., time constraints, anonymity) of informal caregivers (Semonella et al., 2020). For example, the need to schedule meetings in advance, and to be present synchronously in sessions, might be highly problematic for busy caregivers. Also, psychological support interventions which are delivered *via* telephone or videocall with an actual therapist might not provide the level of anonymity that caregivers prefer, due to issues of guilt or shame (Springate and Tremont, 2014; Woodford et al., 2018; Moudatsou et al., 2021). Thus, there is a need for interventions that can be delivered *via* ordinary technological devices (i.e., mobile phone or personal computer) that informal caregivers can use easily. In addition, such interventions should be monitored by a therapist in an asynchronous and anonymous manner. Hence, we need solutions that are feasible, suitable, and sustainable over time, above and beyond the demands of the current pandemic.

As such, we suggest using specific digital solutions, which have been termed internet-based interventions. Internet-based interventions consist of psychological support *via* a comprehensive internet-based platform including therapeutic modules, usually based on cognitive and behavioral therapy, and weekly therapeutic tasks that need to be completed *via* use of the computer (Andersson and Titov, 2014). Using internet-based interventions might address the three main challenges confronted by informal caregivers, in ordinary times as well as during the pandemic. First and foremost, different studies have shown the beneficial effects of internet-based interventions on informal caregivers' mental health, including reduction of depression, stress, anxiety, and burden (Egan et al., 2018; Sherifali et al., 2018). In addition internet-based interventions have been found to increase caregivers' self-efficacy and self-esteem (Ploeg et al., 2018) as well as their sense of competence, coping skills, and quality of life (Guay et al., 2017). In fact, internet-based interventions have been found to be as effective as other treatment formats (Andersson et al., 2013).

Moreover, although other digital solutions have been found to be beneficial for reducing caregivers' distress, particularly during COVID-19 (Bertuzzi et al., 2021), what makes internet-based interventions feasible is the fact that one has maximum time flexibility when using the platform. Such flexibility is most likely an advantage for caregivers, as finding additional time slots for face-to-face therapy might be impossible for them (Caregiving NAf, 2015). Also, unlike other digital solutions (i.e., calls *via* telephone or video conferencing platforms such as Skype, Zoom, Google Meet, etc.), which require synchronized participation of both patient and therapist, internet-based interventions allow clients to access the therapeutic platform whenever and wherever it suits them; they only need a computer/tablet/mobile phone and internet access (Johansson et al., 2021). It can be difficult and time-consuming for informal caregivers to reach clinics or therapists, especially for those who live far away from their therapist and/or clinic (Bei et al., 2020). By using internet-based interventions it is possible to reach therapists from a distance. Moreover, this specific way of delivering interventions offers a secure platform, allowing the maintenance of one's anonymity (Andersson, 2016). Pre-set reminders are being sent to informal caregivers to complete the modules and to check homework. Moreover, informal caregivers can communicate with the therapist using the platform when needed, with maximum time flexibility and anonymity. Finally, financial strain notwithstanding, it has been shown that internet-based interventions are more cost-effective than face-to-face treatment (Andersson and Titov, 2014; Kolovos et al., 2018).

Despite the benefits of using internet-based interventions within the informal caregiving context, healthcare professionals' acceptance hesitancy and other expected barriers did not, prior to the pandemic outbreak, allow for a full integration of internet-based interventions in clinical practice (Topooco et al., 2017). Further studies on informal caregivers should exploit the advantages of what has emerged from the current situation to shift the perspective in thinking and deliver therapeutic solutions to support informal caregivers around the world. For example, as part of a joint European consortium, an internet-delivered cognitive behavioral therapy (iCBT) intervention for informal caregivers has already been tested in Lithuania. The results of this study suggest that this internet-based intervention can be effective in reducing caregivers' burden, anxiety, depression, and stress, and in improving quality of life (Biliunaite et al., 2021). In light of this successful endeavor, we are currently evaluating the efficacy of a similar internet-based intervention for informal caregivers in Italy, a huge country with a substantial percentage of caregivers (ISTAT, 2018) and in which, surprisingly, no such solution has been provided before (Semonella et al., 2020).

In conclusion, beyond all the well-known negative outcomes of this pandemic, COVID-19 also appears to have been a catalyst for many positive advances, including the reduced antagonism toward digital tools, such as internet-based interventions (Wind et al., 2020). The current momentum should be harnessed for the development and implementation of internet-based interventions around the globe, especially for populations in great need of these state-of-the-art solutions, such as informal caregivers.

AUTHOR CONTRIBUTIONS

MS and NV wrote the first draft of the manuscript. GA, RD, and GP revised the manuscript and giving precious feedback and suggestions. All the authors contributed to the conceptualization of the manuscript. All authors contributed to the article and approved the submitted version.

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Research on the Method of Depression Detection by Single-Channel Electroencephalography Sensor

Xue Lei[1], Weidong Ji[2,3], Jingzhou Guo[1], Xiaoyue Wu[1], Huilin Wang[4], Lina Zhu[1] and Liang Chen[1]**

[1] School of Business, East China University of Science and Technology, Shanghai, China, [2] Mental Health Center, East China Normal University, Shanghai, China, [3] Shanghai Changning Mental Health Center, Shanghai, China, [4] Shanghai Fujia Cultural Development Co., Ltd., Shanghai, China

Edited by:
Cristina Costescu,
Babeş-Bolyai University, Romania

Reviewed by:
Serap Aydin,
Hacettepe University, Turkey
Malin Stenman,
Department of Molecular Medicine and Surgery (MMK), Sweden

***Correspondence:**
Weidong Ji
wdji@psy.ecnu.edu.cn
Liang Chen
sanlychen@126.com

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Depression is a common mental health illness worldwide that affects our quality of life and ability to work. Although prior research has used EEG signals to increase the accuracy to identify depression, the rates of underdiagnosis remain high, and novel methods are required to identify depression. In this study, we built a model based on single-channel, dry-electrode EEG sensor technology to detect state depression, which measures the intensity of depressive feelings and cognitions at a particular time. To test the accuracy of our model, we compared the results of our model with other commonly used methods for depression diagnosis, including the PHQ-9, Hamilton Depression Rating Scale (HAM-D), and House-Tree-Person (HTP) drawing test, in three different studies. In study 1, we compared the results of our model with PHQ-9 in a sample of 158 senior high students. The results showed that the consistency rate of the two methods was 61.4%. In study 2, the results of our model were compared with HAM-D among 71 adults. We found that the consistency rate of state-depression identification by the two methods was 63.38% when a HAM-D score above 7 was considered depression, while the consistency rate increased to 83.10% when subjects showed at least one depressive symptom (including depressed mood, guilt, suicide, lack of interest, retardation). In study 3, 68 adults participated in the study, and the results revealed that the consistency rate of our model and HTP drawing test was 91.2%. The results showed that our model is an effective means to identify state depression. Our study demonstrates that using our model, people with state depression could be identified in a timely manner and receive interventions or treatments, which may be helpful for the early detection of depression.

Keywords: depression detection, state depression, EEG sensor, PHQ-9, HAM-D, house-tree-person (HTP) drawing test

INTRODUCTION

Depression is the most prevalent mental health disorder and a leading cause of disability worldwide. Globally, more than 300 million people in the world are living with depression, and it has increased 50% in incident cases from 1990 to 2017 (Liu et al., 2020; Hobden et al., 2021). People with depression may greatly suffer and function poorly at work, at school and in the family. Because depression can be long-lasting or recurrent and lead to suicide (Stringaris, 2017; Liu et al., 2020), the World Health Organization (WHO) ranks it as a major contributor to the global burden of disease (Bhatti et al., 2016). In addition, patients with major depressive disorder have increased risks of developing cardiovascular disease and increased morbidity and mortality (Seligman and Nemeroff, 2015; Luo et al., 2018). Although depression incurs huge psychological and physical harm to human beings, people who are depressed are often not accurately identified and treated. As a result, identifying and diagnosing patients with depression early and giving timely treatment are important issues to solve. Early detection of depressive tendencies and mild depression is conducive to timely and active intervention, which can avoid further aggravation of depression (Dong et al., 2020). Therefore, new methods are required to accurately assess depression.

Depression is considered a mood disorder that lasts for at least 2 weeks, with the presence of depressed mood and loss of pleasure being the core features (Su et al., 2021). The severity of symptoms of depression varies from feeling sad or gloomy in a relatively short period of time to extreme hopelessness, despair, extreme guilt, and thoughts of death that can lead to suicide (Spielberger and Reheiser, 2009). Obviously, depression is a complex and multifaceted syndrome with many potential dimensions. In this study, we focus on state depression, which is defined as the intensity of depressive feelings and cognitions at a particular time (Spielberger and Reheiser, 2009).

In the past, depression is hard to precisely diagnose mainly because of the subjectivity of patients to answer the psychological evaluation. With the development of electroencephalography (EEG), scientists began to use it as a tool to diagnose many neurological and psychological diseases, such as depression. EEG activity reflects the temporal aggregation of synchronous activity of millions of spatially aligned cortical neurons. The most deliberated waveforms include delta (0.5–4 Hz), theta (4–7 Hz), alpha (8–12 Hz), sigma (12–16 Hz), and beta (13–30 Hz). Compared to the traditional diagnose evaluation using questionnaires, EEG biomarkers could help diagnose the depression in a more objective way. Extensive studies have explored the use of EEG to find depression biomarkers for diagnostic purposes (de Aguiar Neto and Rosa, 2019; Mahato and Paul, 2020). According to the research, the spectral coupling between the delta and beta oscillations has been proven to be related to social anxiety (Miskovic et al., 2011). And over recent decades, many researchers have attempted to detect Schizophrenia from EEG signals (Kim et al., 2015; Johannesen et al., 2016). Recently, researchers have been developing an automatic Schizophrenia identification scheme using EEG signals that can eradicate the aforementioned problems and support clinicians and researchers (Siuly et al., 2020).

Linear features including Band Power and Alpha Asymmetry have been studied for diagnosing depression. For instance, gamma and theta band have good depression diagnostic capabilities (Mohammadi et al., 2015; Fitzgerald and Watson, 2018), whereas alpha asymmetry may predict specific symptoms and treatment outcome (Nelson et al., 2018), although for diagnostic purposes it may not be suitable (van der Vinne et al., 2017). Compared with linear feature measures, non-linear methods such as Detrended Fluctuation Analysis (DFA), Higuchi's Fractal Dimension (HFD), Lempel-Ziv Complexity (LZC) could obtain additional information for analyzing EEG signal features (Hosseinifard et al., 2013; Mumtaz et al., 2015; Bachmann et al., 2018). Considering signal complexity, HFD appears to be higher in depressed brains (Mahato and Paul, 2019). Besides, network-based features (e.g., Cluster Coefficient, Zhang et al., 2018) and evoked potentials (e.g., Late Positive Potential, Grunewald et al., 2019) have been studied to be the potential depression biomarkers. Among these research, recent studies utilizing machine learning techniques is showing a great success in the automatic detection of depression (Hosseinifard et al., 2013; Lin et al., 2018). For instance, machine learning algorithms combining support vector machine (SVM) and convolutional showed a high accuracy for depression recognition (Li et al., 2019).

However, most of the previous studies detected depression based on analyzing multichannel EEG signals. Although EEG sensors in most previous studies can precisely record brain activities with proper preparation, their usage is only limited to the clinical and laboratory setups because the sensors are multichannel (such as 256 channels), use wet electrodes and transmit data via a set of wires, which demand longer time for preparation and offer lower usability (Patel et al., 2017). R To increase common use, recent developments in techniques simplified these multichannel EEG devices (Ni et al., 2020). Therefore, in this study a wearable Bluetooth headset EEG acquisition device (NeuroSky headset) is used, which is easy to wear and computationally efficient (Bhatti et al., 2016). Studies considering depression recognition based on single channel EEG signal analysis are relatively limited. Spectral asymmetry index (SASI) was successfully applied for detection of depression employing single channel EEG (Bachmann et al., 2017). Depression recognition based on single channel EEG signal is a promising trend.

By relying on attention and meditation signals recorded from the MindWave mobile headset, a single-channel and dry-electrode EEG product produced by the NeuroSky company, we built a model to detect state depression. Many researchers are interested in NeuroSky's MindWave mobile headset because of its higher usability at a significantly lower cost and the ability to conduct research in informal environments such as schools and homes (Sezer et al., 2015; Ni et al., 2020).

NeuroSky's MindWave mobile headset was developed as a biosensor to record EEG data signals and can be used to detect the electric activities of the brain in a state of attention and relaxation (Sezer et al., 2015; Ni et al., 2020). The MindWave mobile headset comprises an TGAM EEG acquisition module (EEG acquisition point), a forehead electrode (reference point), an ear clip electrode (grounding circuit), a Bluetooth transmitting module, a Bluetooth receiving module, as well as a computer connected to the device (Zhang et al., 2019). Since the device uses a dry-sensor, it requires no saline or gel in order to ensure proper connectivity with the surface of the forehead and noise-free EEG signals. Contact with the dry sensor electrode is achieved by the pressure of the electrode against the subject's forehead and held in place by the headset. The sampling rate is 512 Hz. The headset is easy to wear on head while the sensor is placed on forehead at FP1 location (according to 10/20 EEG placement system) and a reference electrode is connected to the ear lobe to complete the circuit. The main benefit of this headset was the ease in data acquisition setup and wearability. The headset used Bluetooth to transmit recorded data to the hardware host for analysis and hence provided mobility to the end user (Bhatti et al., 2016). The NeuroSky company has conducted benchmark tests by comparing EEG signals measured by the NeuroSky headset with signals from the Biopac system, a well-known wet electrode EEG system widely used in medical and research applications (NeuroSky, 2009).

The TGAM module is used by the MindWave mobile headset to process and output the brain wave spectrum, original brain wave, EEG signal quality, and two NeuroSky eSense parameters: attention and meditation detection (see **Supplementary Appendix A** for more details about the TGAM module). The device quantifies the psychological state of the subjects as attention and meditation values (Sezer et al., 2015; Ni et al., 2020). The reliability of the attention and meditation meters have been supported by previous studies (Rebolledo-Mendez, 2009; Crowley et al., 2010). The MindWave mobile headset also has noise-filtering technology to eliminate interference from daily living environments or other electronic equipment.

In this study, using "attention" and "meditation[1]" indices from NeuroSky's MindWave mobile headset, we discovered an M-shaped brainwave that accompanies the occurrence of depressive emotions and thus built a model to detect state depression. We hypothesized that our brainwave model is an effective means to identify state depression, i.e., transient states of depressive thoughts/emotions. This method can assist in detecting and correctly diagnosing depression early in a large population, therefore individuals with depression can receive timely interventions or treatments.

Specifically, to examine whether our model can correctly identify state depression, we compared the results with other commonly used methods for depression detection, such as the PHQ-9, Hamilton Depression Rating Scale (HAM-D), and House-Tree-Person (HTP) drawing test, a type of psychological projective technique (Buck, 1948; Chen and Xu, 2008).

MATERIALS AND METHODS

Below we provide detailed information for the pilot study and the following three studies. First, in the pilot study, we discovered an M-shaped pattern in EEG brain waves during a psychological counseling intervention for depression and developed a model for state depression detection. To confirm this model was a reliable measure for state depression, we further conducted study 1–3 in samples of senior high students, adults who were seeking psychological assistance, and healthy adults. In study 1, we compared the results of our model with PHQ-9. The results showed that the consistency rate of the two methods was 61.4% among 158 subjects. In study 2, the results of our model were compared with HAM-D among 71 subjects. We found that the consistency rate of state-depression identification by the two methods was 63.38% when a HAM-D score above 7 was considered depression, while the consistency rate increased to 83.10% when subjects showed at least one depressive symptom (including depressed mood, guilt, suicide, lack of interest, retardation). In study 3, 68 subjects participated in the study, and the results revealed that the consistency rate of our model and HTP drawing test was 91.2%.

Pilot Study Discovering the M-Shaped Brainwaves

Measurement Devices

NeuroSky's MindWave mobile headsets were adopted in all the studies. This is a commercial EEG device to measure brain waves. Prior research has shown that brain waves have a frequency value of 0–100 Hz (Mostow et al., 2011) and are grouped into five basic bands: delta (0–3.5 Hz), theta (4–7 Hz), alpha (8–12 Hz), beta (13–30 Hz), and gamma (>30 Hz) (Neurosky, 2011; Sałabun, 2014; Sezer et al., 2015). There is also a direct correlation between frequency and brain activity (Sezer et al., 2015). In our study, the device captures brain waves and produces an original value. The results of the data analysis were evaluated with the manufacturer's eSense Metric, and the value of attention and meditation was 0–100 (Neurosky, 2011; Sezer et al., 2015). Previous studies have tested the reliability of NeuroSky's MindWave headsets in measuring attention and meditation (Sezer et al., 2015) and confirmed that the device had good measurement accuracy (Ni et al., 2020).

Procedures and Findings

In the initial exploration stage, we recorded the brainwaves of subjects during the entire process of psychological consultation using the headsets. We found that when the subjects were depressed, an M-shaped pattern appeared in their brainwaves of "attention" and/or "meditation" signals. Specifically, we first found an M-shaped pattern when subject A1 was receiving a psychological counseling intervention for depression, and such patterns as circled in red in **Figure 1** repeatedly appeared at

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[1] The eSense Attention meter indicates the intensity of a user's level of mental "focus" or "attention," and the eSense Meditation meter indicates the level of a user's mental "calmness" or "relaxation." Their values range from 0 to 100. As shown in **Figure 1**, the orange and blue lines represent the eSense Attention and Meditation meter, respectively, based on algorithms that convert original EEG signals of different frequencies (alpha, beta, etc.) to the current two waves. More details on the eSense Attention and Meditation algorithms can be found on Neurosky website http://neurosky.com/biosensors/eeg-sensor/algorithms/.

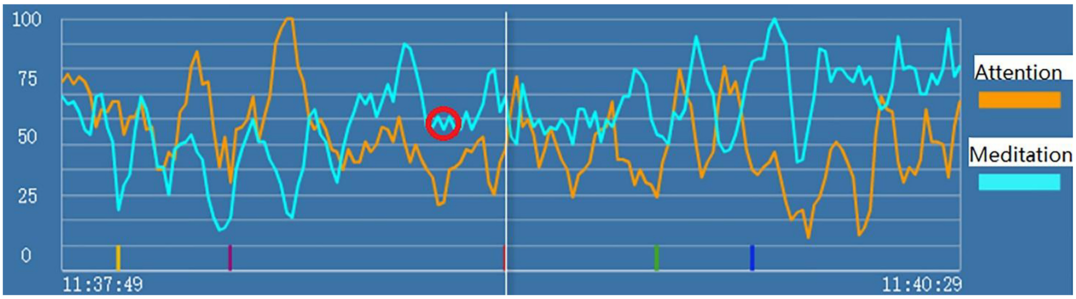

FIGURE 1 | "Attention" (the orange line) and "meditation" (the blue line) signals during psychological counseling intervention for depression of Subject A1. The red circle indicates the markers of state depression.

multiple time points in the attention and meditation signals when subject 1 showed symptoms of depression like mentioning helpless feelings or thoughts of committing suicide. Then, we verified this phenomenon in various subjects. For example, subject A2 communicated with one of our researchers for the first time, and she cried and talked about all types of unpleasant experiences and problems in her family. During this process, the M-shaped pattern also appeared in her attention and meditation signals.

Therefore, we hypothesized that when subjects have state depression, M-shaped patterns appear in their attention and/or meditation signals. Building on this phenomenon, we developed a specific model to identify state depression based on the brainwave, with detailed criteria to classify the M-shaped patterns. More details about the model are described in our patent (patent number 202110609863.9).

Discussion

In the initial exploration stage, we developed a model to detect state depression based on the attention and mediation signal produced by a single-channel EEG headset. In order to verify the accuracy of our model, in Study 1–3, we compared the results of our model with other methods to diagnose depression, including the PHQ-9, Hamilton Depression Rating Scale (HAM-D), and House-Tree-Person (HTP) drawing test (Buck, 1948; Chen and Xu, 2008; Gu et al., 2020).

Study 1 Electroencephalography Model of State Depression and Patient Health Questionnaire-9

Materials and Methods

Subjects

We recruited 161 senior high school students from a boarding high school in Shanghai. Among these, three students did not have valid brainwave data, which led to a final sample of 158 subjects. This study was conducted with approval from the Institutional Review Board (IRB) at the second author's institute under strict supervisions to protect subjects' privacy and participants have the right to end the experiment at any time. Following IRB instructions, consent forms were obtained from the students' parents before the experiment.

Measures

PHQ-9 is a self-report questionnaire that has been used widely to screen depression in primary care (Zuithoff et al., 2010; Thekkumpurath et al., 2011; Zhang et al., 2013; Wang et al., 2014). The PHQ-9 (**Supplementary Appendix B**) is the 9-item depression module from the full PHQ, which is a self-administered version of the PRIME-MD (Kroenke and Spitzer, 2002). PHQ-9 satisfies five practical considerations: brevity, easy to score, self-administered, multi-purpose, and in the public domain (Kroenke, 2012). The reliability and validity of PHQ-9 have been examined in prior research (Kroenke et al., 2001; Zhang et al., 2013; Wang et al., 2014). It has been translated into more than 80 languages and is widely used worldwide in different populations (Wang et al., 2014). Subjects were asked to rate how they felt within the past 2 weeks. Each question was scored from 0 to 3 (0 = not at all; 1 = several days; 2 = more than half of all the days; 3 = nearly every day). Scoring 0–4 on PHQ-9 indicates minimal/no depression, 5–9 mild depression, 10–14 moderate depression, 15–19 moderately severe depression, and 20–27 severe depression (Fiest et al., 2016; Gill et al., 2017).

Procedures

Subjects completed the self-rating PHQ-9 after collecting the brainwave data. Specifically, first, before recording the brainwave data, we asked the subjects whether they had practiced yoga, meditation, tai chi, qigong and other attention exercises before. If they had practiced these exercises, they were required not to practice while their eyes were closed, as engaging in these can alter the baseline brainwave pattern. Then, they were asked to wear our single-channel EEG device, close their eyes and remain in a resting state for 3 min. During this process, we asked them to try to relax and not think about anything. After 3 min, the subjects were asked to remove the device and complete the self-rating PHQ-9 questionnaires.

Data Analysis

First, we collected and analyzed the brainwave data of the subjects in the resting state. To avoid subjective bias, we invited two researchers blinded to the subjects' PHQ-9 scores to independently identify the frequency and severity of state depression from the attention and meditation signals, based on the criteria developed in the pilot study. Any disagreements were

TABLE 1 | Comparison of results between our model and PHQ-9, HAM-D, HTP, respectively.

Comparative depression measurement	Total number	Identified state-depression by our model	Identified no state-depression by our model	Consistency rate
PHQ-9 (above 4)				
Identified state-depression	81	59	22	61.4%
Identified no state-depression	77	39	38	
HAM-D (above 7)				
Identified state-depression	43	40	3	63.38%
Identified no state-depression	28	23	5	
HAM-D (above 1)				
Identified state-depression	57	54	3	83.10%
Identified no state-depression	14	9	5	
HTP test				
Identified state-depression	53	51	2	91.2%
Identified no state-depression	15	4	11	

all resolved through discussion and refinement of the criteria. Then, we compared the results with PHQ-9 questionnaires. Subjects were classified as depressed or non-depressed based on their PHQ-9 scores (Zhang et al., 2013). The PHQ-9 scores range from 0 to 27, since each of the nine items can be scored from 0 ("not at all") to 3 ("nearly every day"). Based on commonly used criteria (Fiest et al., 2016; Gill et al., 2017), we chose a cutoff score of 5 as indicating state depression, which is lower than clinical diagnosis of depression.

Study 1 Results and Discussion

The results showed that the overall consistency rate between our model and PHQ-9 was 61.4%[2]. The results of the identification of state depression by our model and PHQ-9 are shown in **Table 1**. Our model identified more depressed individuals compared to PHQ-9 (98 vs. 81). Of note, our EEG model measures transient or current depressive emotions while PHQ-9 measures depressive emotions during the past 2 weeks. Thus, the difference between PHQ-9 results and our brain wave model may be caused by difference in time range. In addition, people can lie when completing self-report diagnostic questionnaires. Therefore, the difference in results may also imply that some of the subjects did not report honestly in the questionnaire or did not have a clear understanding of their inner feelings.

To overcome the limitations of self-report depression questionnaires, we adopted a more rigorous and other-rated depression diagnostic method in Study 2.

Study 2 Electroencephalography Model of State Depression and Hamilton Depression Rating Scale

The 17-item Hamilton Depression Rating Scale (HAM-D) is one of the most widely used measures of depression (Bech, 2015; Bech et al., 2015; Lee et al., 2017) and has been used as a "gold standard" instrument to assess the severity of depression in clinical studies (McIntyre et al., 2002). Thus, we selected HAM-D as the instrument in Study 2 to compare with our EEG model results.

Materials and Methods

Subjects

In Study 2, we recruited 73 adults aged 18–60 years who were suffering from various emotional disturbances and seeking psychological assistance. The sample size was decided prior to the experiments with an effort to recruit as many subjects as possible given the resource limitation within around 2 weeks. Two subjects did not have valid brainwave data, resulting in 71 subjects in our final sample. This study was conducted with approval from the Ethics Committee of the second author's institute. Besides, consent forms were collected from subjects before the experiment.

Procedures

Before the experiment, subjects were asked about relevant medical history, medication history, and basic information such as age and gender. Then, subjects were informed of the purpose of the study and were required to sign an informed consent form. Next, in the experiment, the subjects were required to wear the MindWave mobile headset. Two trained researchers, both of whom had a background in clinical psychology, independently scored the subjects based on the depression part of the Hamilton Questionnaire interview and recorded the brain waves of the subjects during the interview.

Measures

The HAM-D17 consists of 17 items, nine of which are scored on a five-category Likert scale (0–4) and the remaining eight on a three-category Likert scale (0–2), giving a total score ranging from 0 to 52 (Licht et al., 2005). The 17 items of HAM-D are shown in **Supplementary Appendix C** (McIntyre et al., 2002). According to commonly accepted criteria (Hamilton, 1960; Rashid et al., 2021), scoring 0–7 on the 17-item

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[2] Notably, when a cutoff score of 9 is used as the criteria for clinical depression, the percentage of depression was 22.8% (36/158) in the sample. Since this sample was from a boarding high school where students had high pressure to apply for studying abroad, we had a relatively high percentage of moderate to severe depression. Among these subjects, our brainwave model correctly identified 77.8% subjects with state depression (28 out of 36).

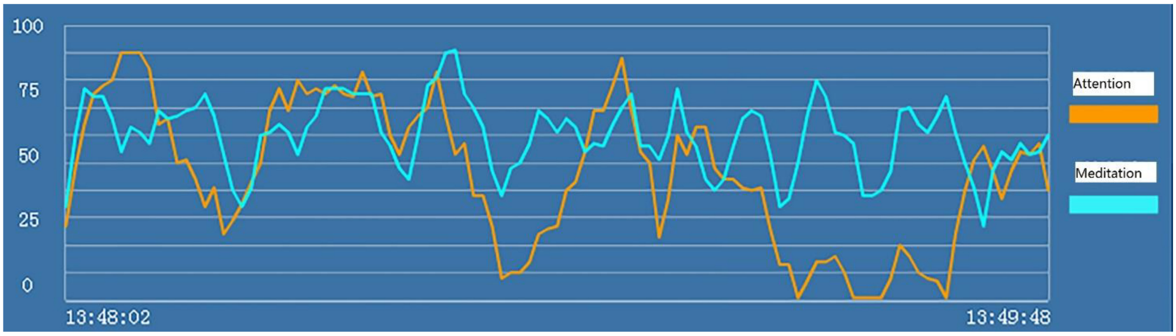

FIGURE 2 | "Attention" (the orange line) and "meditation" (the blue line) signals in the HTP drawing test for subject A3 who did not have state depression.

HAM-D is considered as being normal, 8–16 suggests mild depression, 17–23 implies moderate depression, and over 24 is indicative of severe depression.

Data Analysis

The HAM-D questionnaires were rated by two trained clinical researchers during the interview who were blinded to the brainwave results. The percent of agreement of the two researchers was 97.0% when considering scores above 7 as having state depression. As for the brainwave data, two researchers on our research team independently identified the frequency and severity of state depression from the attention and meditation signals based on the updated criteria from Study 1. Any discrepancies were resolved through discussion.

Study 2 Results and Discussion

According to prior research, full remission of depression is defined as an HAM-D_{17} of 7 or less (Frank et al., 1991). Thus, an HAM-D score above 7 was considered a sign of depression, resulting a consistency rate of 63.38% between our brainwave model and HAM-D[3]. The detailed results of the identification of state depression by our model and HAM-D are shown in **Table 1**.

Moreover, if we also consider the items with some depressive characteristics (including depressed mood, guilt, suicide, work and interest, retardation) above 1 as early stages of depression, then the consistency rate of the two methods is 83.10% (see **Table 1**). In particular, we found two subjects in Study 2 who had severe depressive emotions or thoughts during the experiment, such as crying and conveying suicidal thoughts. During these moments, the M-shaped patterns simultaneously appeared in their brainwaves.

Therefore, to better capture the emergence of depressive emotions/thoughts and to demonstrate the simultaneity of our brainwave model and these transient feelings, we adopted the house-tree-person drawing test in Study 3.

Study 3 Electroencephalography Model of State Depression and House-Tree-Person Drawing Test

Materials and Methods

Measures

The house–tree–person drawing test is a type of projective technique that is designed to obtain information concerning the sensitivity, maturity, and integration of a subject's personality and the interaction of that personality with its environment (Buck, 1948). The HTP drawing test includes two phases. The first phase is drawing, which is non-verbal, creative, and almost completely unstructured. The second phase is describing and interpreting the drawing, which is verbal, apperceptive, and more formally structured (Buck, 1948). Then, the subject's responses are analyzed in diverse manners, such as what was said and on which aspect of the drawing was focused. The results are based on psychodynamic interpretation of the details of the drawing, such as size, shape, and complexity (Gu et al., 2020). Using this technique, subjects can freely express their thoughts and feelings that they find difficult to articulate (Donoghue, 2000; Gu et al., 2020); then, the researcher can enter the subjects' private worlds to uncover their inner perspectives, hidden emotions and internal conflicts (Donoghue, 2000; Gu et al., 2020). According to the literature, the House–Tree–Person drawing test is reliable and valid (Chen and Xu, 2008). Researchers have used it to diagnose neurosis and depression and found certain indicators that are reliable markers for these mental disorders (Kan et al., 2011; Cai et al., 2012; Gu et al., 2020). In addition, the House–Tree–Person drawing test is very helpful in diagnosing emotional disorders (Inadomi et al., 2003), and it has been used in emotional tests, psychological screening, and post-disaster relief programs (Chen and Xu, 2008; Gu et al., 2020).

Subjects

This research was approved by the Institutional Review Board at the first author's university. Consent forms were also collected from subjects before the experiment. The sample size was decided prior to the experiments with an effort to recruit as many subjects as possible given the resource limitation within around 2 weeks. We recruited 69 volunteers aged 18–60, who were healthy, had no neurological or psychiatric illness, did not suffer from emotional

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[3] When a cutoff score of 16 is used for clinical depression, the percentage is 18.31% (13/71). Given that we purposefully recruited study participants who were suffering from various emotional disturbances and seeking psychological assistance, this percentage of depression is not unexpected. Notably, among these participants with mild or more severe depression, our EEG brainwave model correctly identified 92.3% subjects as showing symptoms of state depression (12 out of 13 subjects).

FIGURE 3 | A picture drawn by subject A3 who did not have state depression.

disturbances or who wanted to seek psychological assistance. Because one subject did not have valid brainwave data, the final sample included 68 subjects. Among the 68 subjects, 44.1% were male, and the average age was 31.3 years old. Before the experiment, the subjects were informed about the procedure of the study and agreed to participate in the study.

Procedures

We followed prior research on the House-Tree-Person (HTP) drawing test to make the experimental procedures more standardized (Buck, 1948; Oster and Crone, 2004; Moschini, 2005; Chen and Xu, 2008). The materials for HTP tests include a piece of A4 paper, a 2B pencil, an eraser, and a ruler (if the subject asked for). Subjects were instructed to draw following the rules: (1) Please draw at least three things on your paper, including a house, a tree, and a person. (2) The drawing does not need to be aesthetically pleasant, but you have to draw carefully and draw whatever you want. (3) After completing the drawing, write down your name, age, occupation, and education level at the bottom of the paper. During the drawing test, we simultaneously collected the brainwave data of the subjects.

Although there is no limit on drawing time, it is assumed that 5–30 min is the normal range, and below or exceeding this range is of analytical significance. After the drawing test, an interview was conducted while a psychological counselor interpreted to each participant the type of psychological or emotional states reflected by the drawing. The participants were asked if they agreed on the counselor's interpretations.

Data Analysis

For each subject, we recorded the brainwave data during the HTP drawing test (as shown in **Figure 2**), a picture (as shown in **Figure 3**) and a transcript of the interview. First, to analyze the brainwave data, same as before, we invited two researchers to independently and simultaneously identify the frequency and severity of state depression from the attention and meditation signals in each part. With regard to analyzing data from the drawing test, each drawing was inspected and rated by a team of clinical researchers based on an agreed-upon HTP diagnostic classification table, which includes a series of standardized indicators such as the size of the person, symmetry and position of the tree. The team consists of five senior psychological counselors with rich experience in the application of the HTP drawing test.

Study 3 Results and Discussion

Examples of the brainwave data and pictures of two subjects are displayed. **Figures 2**, **3** show the brainwave data and pictures in the HTP drawing test of subject A3 who did not have state depression. **Figures 4**, **5** show the brainwave data and pictures in the HTP drawing test of subject A4 who had state depression. According to the psychological interpretation of the drawing in **Figure 5**, it mainly presents two depressive characteristics: the brush strokes are shallow, which implies that subject A4 lacks strength and self-confidence; the person in the picture is leaning against a tree, which shows a strong sense of powerlessness.

Study 3 results revealed that the consistency rate of our brainwave model and HTP drawing test was 91.2%. The detailed results of the identification of state depression by our model and HTP are shown in **Table 1**.

To better compare the results of the two methods, we provided specific examples in **Table 2** to show subjects' depressive

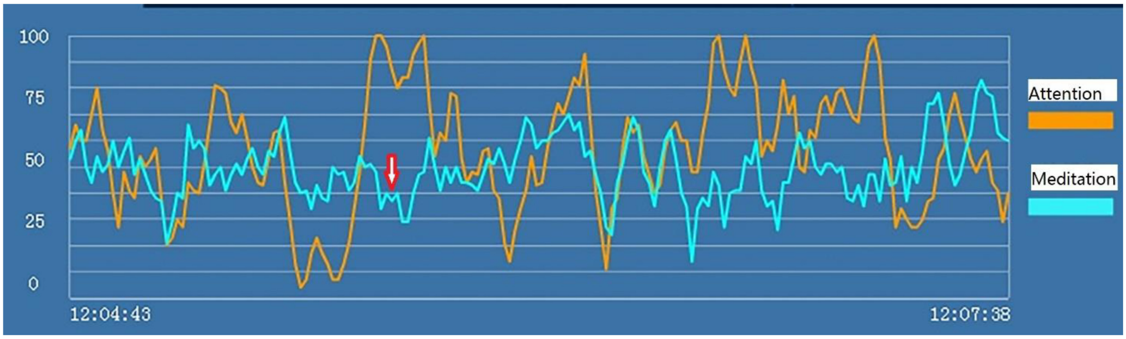

FIGURE 4 | "Attention" (the orange line) and "meditation" (the blue line) signals in the HTP drawing test for subject A4 who had state depression. The red arrow indicates the markers of state depression.

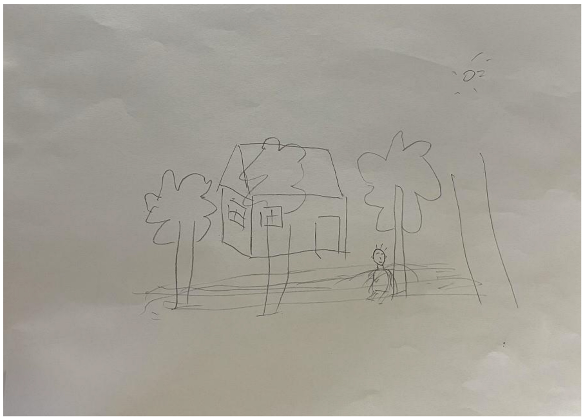

FIGURE 5 | A picture drawn by subject A4 who had state depression.

thoughts/feelings and the corresponding depressive EEG signals. Particularly, for each subject, we compared the time of state depression detected by the single-channel EEG sensor and the corresponding psychological interpretation of the drawing in the HTP drawing test. All subjects endorsed the psychological interpretations. The results again confirmed that our model can effectively identify state depression.

GENERAL DISCUSSION

Results across three studies showed that state depression can be detected using our model building on the "attention" and "meditation" brainwaves produced by NeuroSky's MindWave mobile headsets. When users of the MindWave mobile headset were in a state of depression, an M-shaped pattern appeared in attention and/or meditation signals. We compared the results of our model with other methods to diagnose depression, including PHQ-9, HAM-D, and HTP drawing test, and confirmed the validity of our model.

In addition, to explain the discrepancies in some results, we followed-up with two subjects in Study 2, whose results from the HAM-D questionnaire and the brainwave test were quite different. For example, the brain waves of one subject showed significant state depression in our experiment, but the HAM-D questionnaire did not identify depression. We invited the subject to take another test 2 weeks later, and the severity of state depression in the brain wave test was significantly relieved. We asked the subject and learned that the subject was preparing for job applications a few days before the first test. At that time, she did not know how to deal with the stress and was slightly lost. However, she did not realize her psychological problems during the HAM-D questionnaire interview. Later, with the help of her classmates, she developed plans and began to submit resumes. Therefore, when we tested her again, her depression and anxiety symptoms were significantly reduced. This result further demonstrated that our model of the brainwave test is a sensitive measure of transient state depression.

Depression detection has gained much attention in psychological research, but the detection of state depression using EEG signals has been rarely studied. The key contributions and strengths of this study are three-fold. First, the results of this study can be used for objective, accurate, and rapid diagnoses of depression to help detect depression early and to monitor the stage of depression continuously. Although prior studies have used EEG signals to increase the accuracy to identify depression patients, the rates of underdiagnosis and undertreatment remain high, and there are few methods for early detection of depression.

TABLE 2 | Examples of the depressive thoughts/feelings of subjects and the corresponding depressive EEG signal.

Subject	The time of state-depression detected by the single-channel EEG sensor	The psychological interpretation of HTP drawing test simultaneously
Subject 1	1′24″∼1′28″	Subject 1 was hesitating, which showed his inner struggle as he was trying to find a way out his problems.
Subject 2	(1) 00′53″∼00′57″ (2) 1′23″∼1′27″ (3) 2′59″∼3′03″ and 3′16″∼3′20″	(1) Subject 2 felt pressure from all aspects in his lives. (2) Subject 2 had anxious conflicts about his inner self-cognition. (3) Subject 2 did not have clear knowledge about himself, and he had hidden anxiety and depression.
Subject 3	8′04″∼8′08″	Subject 3 was anxious and worried about the future and did not know how to move on.
Subject 4	(1) 00′58∼1′02″ (2) 6′∼6′04″	(1) Subject 4 had some inner conflicts with family-related matters. She was unwilling to communicate and avoided interpersonal communication. (2) Subject 4 felt anxious and stressed in career and social relationships, and she also had strong psychological defense, self-enclosure and self-protection.
Subject 5	(1) 2′18″∼2′22″ (2) 3′14∼3′18	(1) Subject 5 wanted to find a place to shelter from wind and rain and rest, which caused some negative feelings. She also felt a sense of powerlessness in her heart. (2) Subject 5 drew very small human figures in the picture, which implied weak personal inner strength.

Identifying patients at an earlier stage in their mental illness creates more opportunities for treatments and appropriate care resources. Using the model in our study, we identified depression in a timely and accurate manner. Patients with state depression can thus acquire timely treatment to avoid further aggravation of depression (Dong et al., 2020).

Second, our model is based on single-channel, dry-electrode EEG sensor technology, which largely simplified signals from traditional multichannel EEG sensors. Thus, it is available for common and popular use and may also be helpful for large-scale screening of depression (Ni et al., 2020). Previous research mostly used multichannel EEG sensors to precisely record brain activities and identify depression patients (Mahato and Paul, 2019). But the usage of multichannel EEG sensors was largely limited to clinical and laboratory setups because of the longer preparation time and lower usability. The recent development of the single-channel EEG sensor features higher usability at a significantly lower cost, increasing the possibility of conducting studies in informal environments such as schools and homes. In this case, more people can use our model based on the single-channel EEG device to detect their state of state depression and identify depression at an earlier stage.

Third, the adoption of a multi-measurement method to compare our brainwave model with three currently commonly used diagnoses of depression (PHQ-9, HAM-D, HTP test) greatly increased the validity of our model, given that one method may not be accurate enough to identify depression. Besides, applying the method across three samples ranging from high school students to adults, and including both healthy people and depressed patients, also enhanced the generalizability of our brainwave model to a large population.

Despite the strengths, the current study is not without limitations. Firstly, due to the scope of the study, we were not able to examine the specific mechanism of the relationship between our model of M-shaped patterns and depression. Future study can further explore the underlying mechanism in EEG wave. Moreover, it is a possible direction to analyze the pathogenesis of depression by adopting various analytical methods and techniques and integrating multiple factors into a unified model for analysis to achieve a more objective, comprehensive, scientific and accurate diagnosis and treatment goal.

Secondly, although we included three studies and expanded our effort to recruit more subjects, the sample sizes may not be large enough to generalize to other samples. It would be meaningful for future studies to increase the sample size and conduct tests in a larger population. In addition, researchers can further explore different models to identify other emotional states, such as anxiety, based on “attention” and “meditation” indices from the single-channel EEG sensor. Other efficient methods of processing EEG data will be investigated on a larger database in the future.

Lastly, as a first study using a single-channel, dry-electrode EEG sensor to measure depressive emotions, depressive emotions were only measured once for each subject. But future research can further explore the reliability of state depression and determine whether multiple measurements can improve the accuracy of depression detection. Besides, future studies can identify the factors that promote or inhibit the production of state depression, such as thinking about happy or depressed events, which may help to effectively improve depression symptoms.

In sum, we introduced an EEG brainwave model to identify state depression with a consistency rate from 61.4 to 91.2%, which helps the quick diagnosis and assistance of depression at an early stage. More importantly, research on emotion recognition and adjustment methods based on EEG has very important practical significance and application prospects in the fields of medical health, work life, and human-computer interaction. The root of emotion is in the brain. Electroencephalogram (EEG) can reflect various activity states of the brain and characterize its neural activity during emotional changes. The use of single-channel, dry-electrode EEG sensors to study the recognition and regulation of emotional states and to explore the inner neural mechanism likely would continue to progress in the future.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Ethics Committee at School of Business, East China University of Science and Technology, as well as Shanghai Changning Mental Health Center. Written informed consent to participate in this study was provided by the participants or participants’ legal guardian/next of kin if the participants were under 18.

AUTHOR CONTRIBUTIONS

XL, LC, and XW designed the experimental studies. LC, WJ, HW, XL, and XW collected the experimental data. LC and JG conducted the data analysis. JG, XL, XW, LC, and WJ wrote the manuscript. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyg.2022.850159/full#supplementary-material

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BRIEF RESEARCH REPORT
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The Therapeutic Goals Set by University Students in an Anonymous Web-Based Therapy and Support Setting

Terry Hanley[1]*, Julie Prescott[2†‡] and Aaron Sefi[3]

[1]Manchester Institute of Education, University of Manchester, Manchester, United Kingdom, [2]Department of Psychology, School of Education and Psychology, University of Bolton, Bolton, United Kingdom, [3]Kooth, London, United Kingdom

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****Correspondence:***
Terry Hanley
terry.hanley@manchester.ac.uk

†ORCID:
Julie Prescott
orcid.org/0000-0001-8612-2495

‡Present Address:
Julie Prescott,
Department of Psychology, School of Science, University of Law, Manchester, United Kingdom

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The interest in student mental health and wellbeing has increased in recent years. Additionally, there is a rising volume of students seeking support. Numerous online resources have been developed to meet this need, including anonymous web-based therapy. To date, there has been little focus upon how students may utilise such a service, and this study examines routine evaluation data (solicited from a Goal-based Outcome Measure) from a United Kingdom based service provider. Over the course of one academic year (2018–2019), 211 students articulated therapeutic goals within *Kooth Student*, a web-based therapy and support service for individuals in higher education. These goals were examined for key trends. The students identified a total of 625 goals to work on in therapy, with individuals setting an average of three goals each. The most common goals focused upon obtaining additional support within the service and exploring their emotions. The results suggested that female students were more likely to move towards achieving their goals, with goals that did move shifting an average of 7.74 on a 10-point scale. Practical goals that focused upon getting more help, both inside and outside the service, were most likely to be achieved. In contrast, self-help/self-care goals were less likely to be achieved. These results provide a helpful insight into how students made use of therapy and highlight the importance of the interaction that web-based services have with other provision (web-based and in-person). They also demonstrate the challenge of capturing meaningful outcome data in anonymous services.

Keywords: web-based therapy, therapy goals, goal-based outcome measure, higher education, mental health-state of emotional, social well-being

INTRODUCTION

In recent years, there has been an increasing focus on student mental health and wellbeing (Hubble and Bolton, 2019). Linked to this, within countries such as the United Kingdom (UK), a number of reports suggest that there has been a decline in the mental health and wellbeing of the student population (Thorley, 2017; Hubble and Bolton, 2019). This appears to have worsened during the COVID-19 Global pandemic, with numerous reports indicating that mental health and wellbeing difficulties appear to have increased in student populations during this difficult period of time (Burns et al., 2020). As the impact of mental health issues on students can be serious and lead to academic failure, dropping out of education, poorer career prospects and, in the worst cases, suicide (Hughes and Spanner, 2019), considering the ways in which students can be best supported is high on the agenda. This paper therefore explores the growing provision of web-based therapy to contribute to meeting this need.

The Growth of Web-Based Therapy and Support in Higher Education

Since the 1990s, there has been a steady growth of web-based therapy and support services. These services offer support to individuals and groups in a variety of media, including text-based asynchronous communication (email) and synchronous communication (instant messaging), video conferencing support and self-administered Internet-delivered systems (SAID) of support (Barak et al., 2009). These services have become popular and, although pose many ethical and practical challenges, can arguably meet demands that traditional in-person services cannot always meet (Stoll et al., 2020). For instance, it is notable that web-based services are more appealing for some younger people (Ersahin and Hanley, 2017) and student populations (Hanley and Wyatt, 2021), the Internet making the access of services easier and increasing the anonymity of individuals while using them. Such benefits have particularly come to the fore during the recent pandemic, with web-based services reporting large increases in their service usage as a consequence of national policies such as school closures and social distancing measures (Inkster and Digital Mental Health Data Insights Group, 2021).

Higher education (HE) institutions have started offering a wide variety of services online. These include static resources that provide information and more dynamic resources, such as online therapy (Hanley, 2020). As noted above, web-based services prove a popular idea with student populations (Hanley and Wyatt, 2021). Despite this, research also suggests that engagement with such services might be relatively limited (Musiat et al., 2014; Santucci et al., 2014). For instance, within a study evaluating university implemented computerised cognitive behavioural therapy (CBT), 88% of participants ($n = 43$) did not complete the course of eight sessions (Santucci et al., 2014). High levels of attrition, 61.7% of participants ($n = 1,141$), were also reported in Musiat et al. (2014) paper investigating the efficacy for HE students of a CBT informed transdiagnostic online intervention. There seems to be limited research however that considers how students are engaging and experiencing web-based therapy directly offered by professionals or why levels of attrition appear to be high for web-based support.

Goals in Web-Based Therapy

Self-direction and goals have long been important within therapeutic work (Hanley et al., 2015). Goals have been aligned to theoretical positions that prize individuals having choice in the direction that therapeutic work may head (Cooper and McLeod, 2011) and they have been associated with positive outcomes (Norcross and Wampold, 2018). Further, it is argued that this way of working brings to fore the voice and wishes of younger services users, a factor that has historically been neglected, and increases engagement with therapeutic services (Jacob et al., 2017). Thus, there have been moves to orientate therapeutic work with young people and young adults around goals (Hanley, 2012; Law and Jacob, 2015). In recent years, goal-based outcome measures (GbOM) have been deployed across many Child and Adolescent Mental Health Services (CAMHS) across the UK. Evaluations highlight that these idiographic measures prove more capable than standardised equivalents at capturing relevant change (Edbrooke-Childs et al., 2015) and are now used to indicate the preferential standardised measure for CYP (Jacob et al., 2017). To date however, there has been no systematic research focusing upon goal-focused work with young adults in HE settings.

Given the complex nature of online therapeutic services for younger individuals, using standardised outcome measures has proven both challenging and problematic (Sefi and Hanley, 2012). Much of the challenge has been associated to the specific benefits associated with working in this medium noted above. In particular, the anonymous nature of such contact enhances the complexity of interpreting outcome scores. Idiographic measures, such as GbOM, have therefore been suggested as one means of capturing appropriate evaluative information and increasing engagement in services (Sefi and Hanley, 2012; Jacob et al., 2021). In considering this further, Ersahin (2016) developed a taxonomy of goal categories based upon the goals that young individuals set in web-based therapy sessions. These included goals that were 'intrapersonal goals', 'interpersonal goals' and 'goals on self, related to others'. This taxonomy provides a helpful way a categorising the goals that individuals articulate in online therapy. When compared to in-person therapy, it was notable that the goals generated online appeared to support individuals to access additional support and to address goals that may have been more intimate in nature (Hanley et al., 2017). It is unknown if similar trends are evident in work with students in HE.

Rationale and Research Question

The move to offer web-based mental health and wellbeing support to students needs further scrutiny. While such services provide numerous opportunities, they also highlight many challenges. This brief report intends to contribute to the debates in this arena by examining the types of goals that students articulate when engaging with web-based therapy services. Further, it reflects upon the progress made towards these goals by those seeking support. The following three research questions are considered as,

1. What is the demographic profile of the students who use a web-based therapy service?
2. What categories/types of goals do students set while attending web-based therapy?
3. How do students' progress with goals that are set during a period of web-based therapy?

MATERIALS AND METHODS

This is a practice-based research project (Holmqvist et al., 2015) using anonymized routine evaluation data from the *Kooth Student* web-based therapy and support service. *Kooth Student* is commissioned by HE providers and free at the point of delivery for those who access it. It allows individuals to obtain anonymous support and is completely text-based. While the service is multifaceted, and offers a variety of support pathways, this project focuses solely upon its web-based therapy resource in which trained professionals offer therapy to those seeking support.

The project was granted a favourable ethical review by the institution of the second author.

Participants

During the period of review, notably the 2018/2019 academic year, the *Kooth Student* resource was available to all students at one HE institution within the UK. All the students that made use of the service and articulated goals were included in this study.

In total, 211 students articulated goals during the 12-month period. Demographic information about these individuals is presented at the start of the results section. These students identified 625 goals using the web-based Counselling Goals System (CoGS) embedded within the service. The CoGs follows the same format as pen and paper GbOM (e.g. Law and Jacob, 2015) by requesting individuals to self-define the goals that they currently have. It encourages individuals to identify whether their goals are 'immediate goals', 'therapy goals' or broader 'life goals'. Further, the CoGS was developed so that it is visually attractive and easy to complete online.

Data Generation: Goal Articulation and Routine Goal Monitoring

All individuals who accessed the *Kooth Student* service during the 12-month period were included in the study. This included individuals who organised pre-booked sessions with therapists, and those who use the more *ad-hoc* drop-in service that is offered. During the first contact with the service, each student was asked to identify and articulate what their goals were for the support they were accessing. Those individuals who met with a therapist collaboratively developed their goals through conversations with the *Kooth Student* therapists. These therapists were all trained to work online in a pluralistic, goal focused manner (Hanley et al., 2015). All goals inputted into the CoGS were then categorised by *Kooth Student* therapists using the taxonomy devised by Ersahin (2016). Each time the individual attended a session of therapy, they were asked to monitor any progress towards the completion of the goal, with each goal being assessed on a 10-point scale alongside the online therapists (0 = starting point; 10 = goal achieved). This process may also lead to individuals discarding goals and articulating new goals for their work with the therapist.

Data Analysis

This paper provides a descriptive account of the goals that have been articulated and the subsequent movement towards achievement. In the first instance (and reported here), descriptive statistics were used to explore the type of goals articulated by the students. As noted above, these were coded using Ersahin's taxonomy of goals (Ersahin, 2016) by the service staff. Secondly, the change reported through ongoing session-by-session monitoring is reported for everyone who took part in more than a single session of support.

RESULTS

This section provides an overview of the analysis of 12 months of routine evaluation data. It starts by reflecting upon demographic make-up of those who set goals during this period and what type of therapy they accessed. It then goes on to consider the types of goals set and the chronicled movement of these goals.

Demographic Information and Session Type

Figure 1 provides an overview of the individuals who set goals in the *Kooth Student* service. More than 50% of the student service users were aged between 18 and 22 (59%). 19% of users were male and 79% female. The remaining individuals identified as a gender or gender fluid. 17% of users were from a black, Asian or minority ethnic group. The referral source was predominantly through the university itself (27%) or the Internet (23%). Finally, the therapists chronicled the major presenting issues talked about in the sessions to be anxiety/stress (17%), depression (11%), self-worth (7%), confidence (7%), suicidal thoughts (4%), access to resources (4%), motivation (4%), family relationships (4%), exam stress and self-harm (3%).

The individuals accessing therapy generally spent an average mean of 1 to 2 h accessing the services. **Figure 2** provides an overview of the time individuals spent using the service. This time generally reflected individuals accessing multiple meetings, with structured pre-booked sessions tending to last 50 min while drop-in chats were often around 30 min in duration. 13% of the individuals who used the resource did not go on to meet with a therapist.

The Goals That Students Set

The 211 students set a total of 625 goals, each setting a mean average of three goals. **Figure 3** provides an overview of the top 10 goal categories that were created. As is evident here, getting professional help within the service proved the most common goal, with emotional exploration reflecting the second most common goal.

Progress With Goals Set

Table 1 provides an overview of the goals articulated and the mean average movement towards achieving each of the goal types that had been set. Of the 625 goals set, 383 goals (articulated by 186 individuals) showed no movement during the time period in question—as these did not move, they are

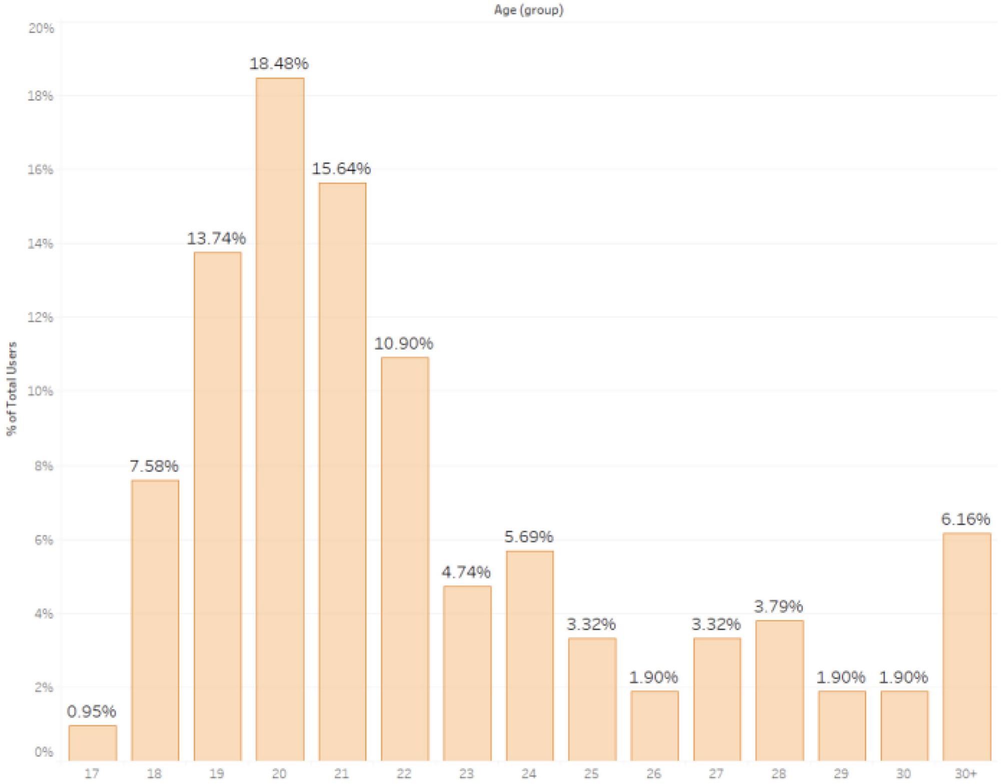

FIGURE 1 | The age distribution of individuals who set goals in Kooth Student.

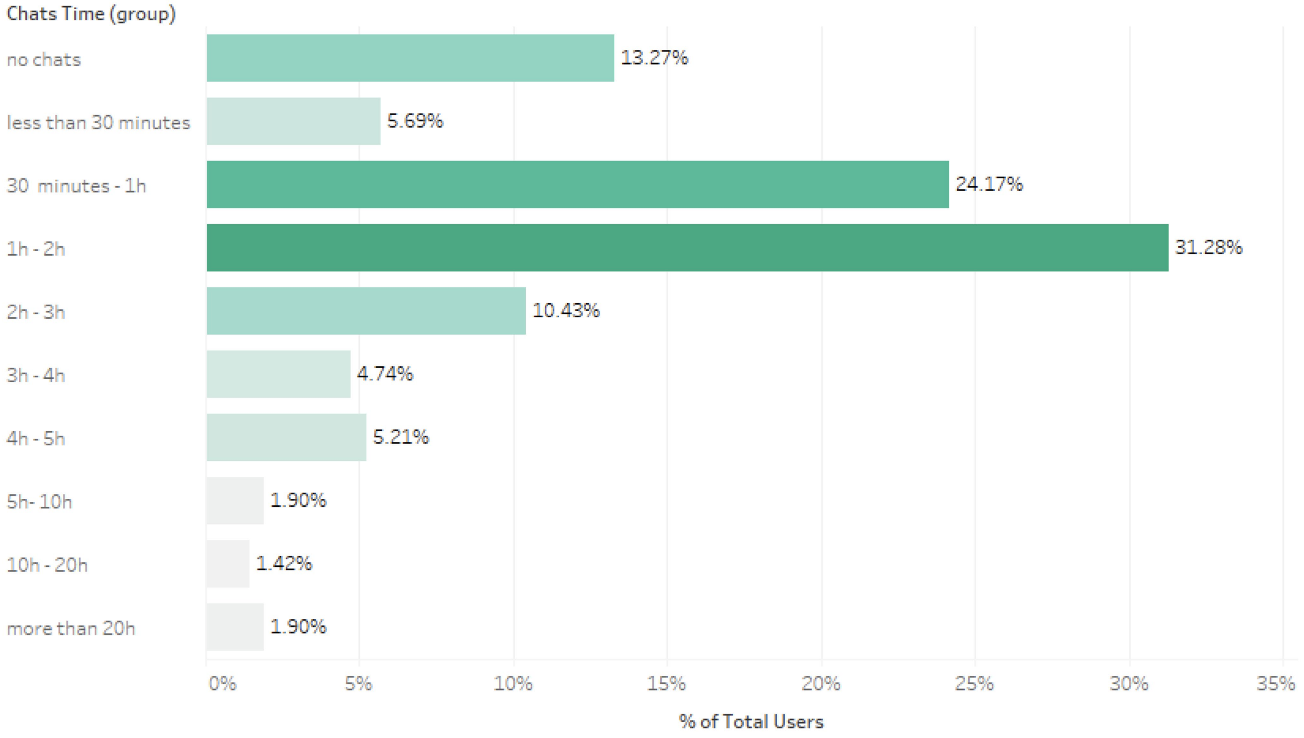

FIGURE 2 | The time period each individual spent chatting to a therapist.

not considered in **Table 1**. A total of 242 goals (articulated by 73 individuals) did show movement towards achievement. The mean average movement of goals on the 10-point scale was 7.74. As is noted on the table, the goals associated with 'Managing depression and Low mood' and 'Feeling happier' were most successfully achieved, while the goals associated with 'Challenging own behaviour', 'Grief' and 'Motivation' moved least.

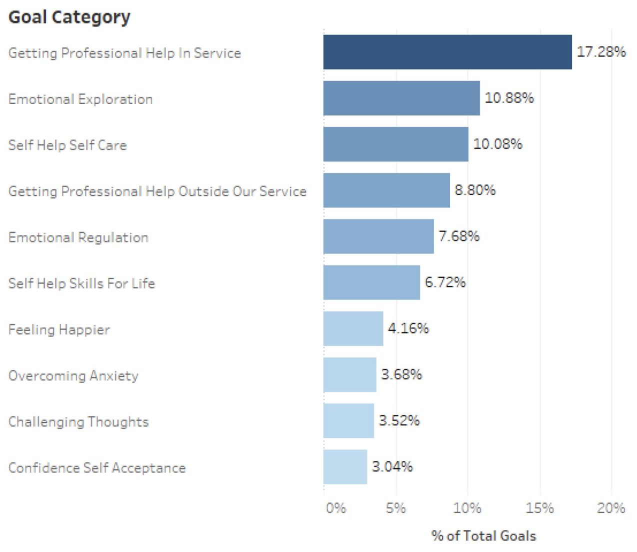

FIGURE 3 | An overview of the top 10 goals set in Kooth Student.

When comparing those who just created goals to those who actually moved towards achieving their goals, there was better engagement with goals from younger individuals (18–22), with 73% of this cohort showing movement in goals set. Further, it was also noted that males were less likely to set goals and less likely to move towards achieving them (15% of individuals), whereas females showed increased movement (84% of individuals).

DISCUSSION

This study set out to explore what type of goals students set within online therapy and whether they were achieving them or not. In this section, we will reflect briefly on each of the research questions in turn.

The individuals who used the online therapy service were predominantly young female students, 22 and under. Such findings prove similar to other studies examining service usage of therapy services for younger people, these appearing to show that therapy is more attractive to female students both in in-person services (Cooper, 2013) and web-based services (Sefi and Hanley, 2012). They also reflect those who may be classed as 'digital natives' (Prensky, 2001), notably individuals who have never lived in a world without the Internet, may find web-based services more appealing than others outside of this age range. The number of students from black, Asian or minority ethnic groups proved relatively modest. The 17% of students identifying in this way does however prove higher than the 10% prevalence reported in

TABLE 1 | Summary of the types of goals articulated and average movement of these goals during therapy.

Goal category	Goals	Users	Avg goals per user	% achieved	Goal movement
Managing depression or low mood	2	2	1.0	100.00	10.00
Feeling happier	6	6	1.0	100.00	10.00
Getting professional help outside our service	29	9	3.2	89.66	9.31
Suicidal thoughts	8	3	2.7	87.50	8.88
Getting professional help in service	55	30	1.8	81.82	8.98
Friendships	4	4	1.0	75.00	7.75
Emotional regulation	14	9	1.6	71.43	8.14
Confidence/self-acceptance	7	7	1.0	71.43	7.86
Self-harm	3	2	1.5	66.67	7.00
Enjoying self	7	5	1.4	57.14	6.14
Emotional exploration	30	24	1.3	56.67	7.17
Self-help skills for life	9	8	1.1	55.56	7.67
Overcoming anxiety	9	8	1.1	55.56	7.33
Speaking up/communicating better	4	4	1.0	50.00	7.50
Sleep issues	2	2	1.0	50.00	5.50
School/college/training	6	4	1.5	50.00	7.17
Career aspirational	2	2	1.0	50.00	5.50
Self-exploration	7	6	1.2	42.86	7.00
Self-help/self-care	17	14	1.2	41.18	6.00
Family relationships	3	3	1.0	33.33	5.33
Challenging thoughts	7	6	1.2	28.57	4.71
Getting more help from significant others	5	5	1.0	20.00	4.40
Motivation	1	1	1.0	0.00	5.00
Grief	1	1	1.0	0.00	2.00
Challenging own behaviour	4	3	1.3	0.00	5.25
Grand total	242	73	3.3	65.29	7.74

statutory Child and Adolescent Mental Health Services (Frith, 2017). Such an increase may be attributed to comforting elements such as the perceived safety provided by the anonymous communication allowed online (Hanley and Wyatt, 2021).

When considering the types of goals that individuals set, it is notable that these are wide ranging. These included goals that were classified as 'intrapersonal goals', interpersonal goals' and 'goals on self, related to others'. In contrast to goals set in similar services for younger age groups, the goals included less focusing upon getting help outside of the service itself (Hanley et al., 2017). Such a difference, may be due to the older age of the individuals accessing support, with these individuals potentially being more aware of services that are available, and making a choice to access support online. When considering the movement towards goal achievement, it is notable that practical goals that focused upon getting more help, both inside and outside the service, were most likely to be achieved. In contrast, self-help/self-care goals were less likely to be achieved. Such a trend appears understandable as the practical goals are likely to be more attainable in a short period of time, whereas achieving self-help/self-care goals are likely to need a longer period of time.

Where the articulated goals moved, it was notable that students reported high levels of goal achievement and that these goals moved further than in comparable data with young populations (Jacob et al., 2021). As with earlier studies in web-based therapeutic resources (Musiat et al., 2014; Santucci et al., 2014), despite aiming to be student focused, the service had a relatively high attrition rate. Only 73 of the 211 service users articulated goals that moved during the time they were engaged with the service. Such a process may demonstrate that individuals take the opportunity to explore the service, before engaging fully. Further, it is important to note that web-based services attract individuals that only use the service once (Chardon et al., 2011). *Kooth Student* proves no exception and, as a consequence, a number of the individuals who articulated goals would not have returned to them to report progress. In accounting for this, some studies only consider those individuals' who return to the goals that they articulate (Jacob et al., 2021), whereas the data reported here included goal scores that both were and were not returned to. Given the varied ways that individuals use web-based services, the importance of developing appropriate means of successfully monitoring such work proves vitally important for service providers such as this.

STRENGTHS, LIMITATIONS AND FUTURE RESEARCH

This paper provides a novel summary of a large dataset generated over a 12-month period within everyday practice in a university therapy service. This is, to our knowledge, the first reflection of data exploring the use of goal-based outcomes within web-based therapy with a student population. While this paper presents the findings in a relatively neat and tidy way, it is important to acknowledge that routine evaluation data are commonly quite complex and uncontrolled. Such a phenomenon is potentially magnified online, with online technologies meaning that information is collated relatively easily and untangling the core elements can prove even more of a challenge (Sefi and Hanley, 2012).

This analysis did not consider the GbOM data alongside other outcomes captured by the service. Further investigation is needed to consider the interplay between idiographic and nomothetic outcome measures in this work. Further, the distance travelled data cannot tell us about single-session usage of such services. Evaluating single-session therapy needs further consideration to understand the reasons for such brief contacts and to assess its value. Additionally, more analysis is required to understand different user journeys in multifaceted online resources. To gain a richer understanding of these web-based mental health and wellbeing ecosystems, qualitative methodological approaches may prove more beneficial.

During the period, the data were collected in web-based therapy with this client group was in its infancy. Offering web-based therapies has however become increasingly commonplace as a consequence of the recent COVID-19 pandemic. Future research may utilise the findings here as a yardstick for comparisons before and after the pandemic. Such work will help to explore the way that therapy services have transformed and evolved during this unprecedented period.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by University of Bolton Ethics Committee (Psychology). The clients/participants provided their online informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

TH: lead author, conceptualization, methodology, data analysis, project administration, writing—original draft, and writing—review and editing. JP: conceptualization, methodology, and writing—review and editing. AS: conceptualization, data analysis and writing—review and editing. All authors contributed to the article and approved the submitted version.

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Conflict of Interest: AS is an employee of Kooth Plc.

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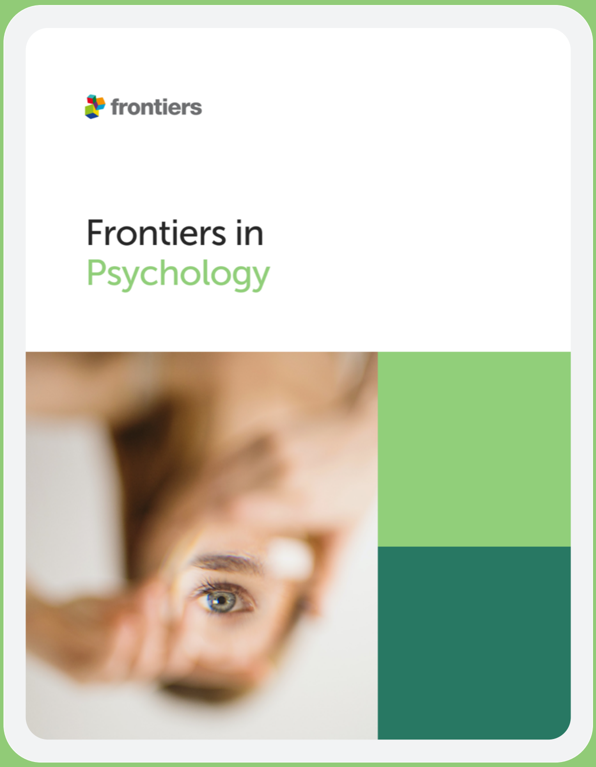
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