JMIR Mental Health

Journal Impact Factor (JIF) (2023): 4.8
Volume 8 (2021), Issue 1 ISSN 2368-7959 Editor in Chief: John Torous, MD, MBI

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Original Paper

Smartphone-Based Self-Reports of Depressive Symptoms Using the Remote Monitoring Application in Psychiatry (ReMAP): Interformat Validation Study

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Abstract

Background: Smartphone-based symptom monitoring has gained increased attention in psychiatric research as a cost-efficient tool for prospective and ecologically valid assessments based on participants' self-reports. However, a meaningful interpretation of smartphone-based assessments requires knowledge about their psychometric properties, especially their validity.

Objective: The goal of this study is to systematically investigate the validity of smartphone-administered assessments of self-reported affective symptoms using the Remote Monitoring Application in Psychiatry (ReMAP).

Methods: The ReMAP app was distributed to 173 adult participants of ongoing, longitudinal psychiatric phenotyping studies, including healthy control participants, as well as patients with affective disorders and anxiety disorders; the mean age of the sample was 30.14 years (SD 11.92). The Beck Depression Inventory (BDI) and single-item mood and sleep information were assessed via the ReMAP app and validated with non–smartphone-based BDI scores and clinician-rated depression severity using the Hamilton Depression Rating Scale (HDRS).

Results: We found overall high comparability between smartphone-based and non–smartphone-based BDI scores (intraclass correlation coefficient=0.921; P<.001). Smartphone-based BDI scores further correlated with non–smartphone-based HDRS ratings of depression severity in a subsample (r=0.783; P<.001; n=51). Higher agreement between smartphone-based and non–smartphone-based assessments was found among affective disorder patients as compared to healthy controls and anxiety disorder patients. Highly comparable agreement between delivery formats was found across age and gender groups. Similarly, smartphone-based single-item self-ratings of mood correlated with BDI sum scores (r=–0.538; P<.001; n=168), while smartphone-based single-item sleep duration correlated with the sleep item of the BDI (r=–0.310; P<.001; n=166).

Conclusions: These findings demonstrate that smartphone-based monitoring of depressive symptoms via the ReMAP app provides valid assessments of depressive symptomatology and, therefore, represents a useful tool for prospective digital phenotyping in affective disorder patients in clinical and research applications.

(JMIR Ment Health 2021;8(1):e24333) doi:10.2196/24333

KEYWORDS

mobile monitoring; smartphone; digital biomarkers; digital phenotyping; course of illness; psychometric quality; mood disorders; depression; affective disorders; mobile phone

Introduction

The phasic development of symptoms over time in the form of disease episodes is one of the key characteristics of affective disorders. These disease trajectories can be used as an informative predictor as well as an outcome measure in psychiatric research and personalized medicine. However, the assessment of the development of symptoms over time is challenging. The value of cross-sectional assessments is limited as they can only capture an excerpt of the symptom history and it is unclear whether this excerpt reflects, for example, the peak of an affective episode or a fully or partially remitted state and whether episodes are recurrent. Collecting this information retrospectively from the patients is one approach to gaining insights into their former symptom history, which is likely to be biased by their current depressive state [1]. Thus, multiple prospective assessments of symptoms are needed for a valid interpolation of the underlying disease trajectory. Although such prospective instruments based on a paper-and-pencil format exist [2], their use is limited due to low cost-efficiency as well as low patient compliance [3]. In recent years, the utilization of smartphone apps for psychological and psychiatric assessment has increased considerably due to the cost-efficiency and practicability of these apps [4-6].

Several proof-of-concept studies have pointed to the utility of smartphone-based data in affective disorder research [7]. Smartphone-based measures can be categorized into passive sensor data (eg, geolocation, distance, steps, acceleration, and app activities) and active self-report. The latter, which entails daily diaries, reiterated questionnaires, and ecological momentary assessments, utilizes multiple assessments per day, thereby acquiring different micro- or macrolevels of affective symptomatology [8]. The focus of this paper is the assessment and validation of active self-report data.

The potential of continuous monitoring of psychomotor activity based on acceleration and location for a differentiation of unipolar and bipolar patients has been demonstrated [9,10]. Recent studies have also indicated that smartphone-based movement parameters allow for a prediction of intraindividual, daily mood state changes [4,11-14]. However, such prospective investigations require in-depth knowledge of the psychometric properties of the acquired data especially when it comes to the validity of smartphone-based measurements. This point appears particularly important in study designs that entirely rely on smartphone-based data.

Consequently, the comparability between smartphone-based and non–smartphone-based versions (ie, conventional paper-and-pencil or stationary computer-based versions) of psychometric instruments has also received increasing attention [15]. Besides the obvious difference in the format in which content is presented, differences in the assessment setting (ie, laboratory or clinical setting vs variable situations in real life) as well as technical reservations could lead to different assessment results. Particularly when using smartphones, potential distractions may become more likely, with the environments of reporting participants being less controllable. Initial evidence suggests that scores derived from digital and paper-and-pencil psychometric instruments seem to be generally comparable, however, with considerable variance in the agreement [16-18]. Yet, a considerable number of previous studies investigating the reliability and validity of digital phenotyping methods have focused on computer-based assessments that might differ from mobile assessments via the participants' smartphones as outlined above. For the Beck Depression Inventory (BDI), interformat reliability between non–smartphone-based paper-and-pencil versions and computer-based versions has been demonstrated across several studies [16], while large-scale validation reports of agreement between smartphone-based and non–smartphone-based versions are currently lacking.

Data from pilot studies indicate agreement between smartphone-delivered, daily self-rated mood and clinician-rated mood via Hamilton Depression Rating Scale (HDRS) scores among bipolar patients [19]; in addition, Juengst et al demonstrated high comparability between mood-related symptoms among traumatic brain injury patients assessed either via smartphone self-reports or via telephone interview [20]. In a systematic review of the literature including data from three studies and a total of 89 bipolar outpatients, significant medium-sized correlations between daily, smartphone-based self-report assessments of depressive symptoms and established clinical rating scales were reported [21]. Regarding smartphone-based monitoring in major depression, Torous et al reported high agreement between daily, smartphone-based self-reports and paper-and-pencil assessments using the Patient Health Questionnaire-9 (PHQ-9) among 13 adult patients with major depressive disorder (MDD) [22]; similarly, Cao et al reported agreement between daily, smartphone-based self-reported mood and the PHQ-9 among 13 adolescent participants [23]. One systematic review that investigated the psychometric properties of mobile mood monitoring among young people concluded that there is enormous heterogeneity in the validity of smartphone-based delivery formats and more high-quality studies are needed [15].

In sum, while the aforementioned findings of overall agreement between smartphone-based self-reported depressive symptoms and established clinical scales is encouraging, it appears important to denote that limited sample sizes in previous reports as well as systematic differences, including sample properties, technical properties, and assessment type, currently limit our understanding of the reliability and validity of smartphone-based assessments of depressive symptoms. It thus remains unclear to what degree validation reports of smartphone-based self-reports are generalizable across assessment instruments, cohorts, and applications; hence, app- or study-specific validation of measurements remains the gold standard.

Therefore, the aim of this study is to assess the validity of smartphone-based assessments of depressive symptoms using the Remote Monitoring Application in Psychiatry (ReMAP) app. To this end, we use smartphone-based depression self-reports using single-item and BDI questionnaire data and investigate their comparability with non–smartphone-based versions of the BDI, a well-established and standardized self-report instrument used among psychiatric patients and healthy control participants. We test the hypotheses that both

delivery formats—smartphone-based and non–smartphone-based assessments—yield comparable results and, therefore, that smartphone-based monitoring of depressive symptoms via the ReMAP app provides valid assessments of depressive symptomatology. Furthermore, we aim to investigate potential differences in the agreement between smartphone-based and non–smartphone-based assessments of depressive symptoms across diagnostic groups as well as across age and gender.

Methods

Participants

The ReMAP study was designed as a prospective, naturalistic observational study. An overall sample of 173 participants was included in the analyses; participants had a mean age of 30.14 years (SD 11.92). The single inclusion criterion for this study was availability of a smartphone-based BDI that was completed within 4 weeks of a non–smartphone-based BDI. The sample included adults that were either healthy controls (n=101) or belonged to one of the following diagnostic groups: MDD (n=43), bipolar disorder (n=5), MDD with comorbid social anxiety disorder (SAD) (n=9), SAD only (n=2), or specific phobia (SP), spider subtype (n=13). Participants were recruited for ReMAP participation in the context of ongoing longitudinal cohort studies over which assessments were parallelized; details on subsamples from all cohorts are provided in the Multimedia Appendix 1.

Participants were informed about the possibility of voluntary additional participation in the ReMAP study in a face-to-face meeting at the time they presented at the Department of Psychiatry, University of Münster, Germany, in the context of ongoing, longitudinal cohort assessments. Interested subjects were extensively briefed about aims; methods, especially type and amount of collected data; details on data security (ie, details on data transfer and storage); and financial compensation. The study was approved by the local Institutional Review Board, and written informed consent was obtained before participation.

Non–Smartphone-Based Measures and Procedures

All measures that were not assessed via smartphone (ie, conventionally administered in interviews or via paper-and-pencil or tablet questionnaires) will be referred to as *non–smartphone-based assessments* and are described below. Presence or absence of a psychiatric diagnosis was assessed in all participants via the Structured Clinical Interview for DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition) Axis I Disorders (SCID-I) [24,25] prior to participation in the ReMAP study. All healthy control participants were free from any history of a psychiatric disorder. As part of the original study assessments, participants from all cohorts provided self-reports of depressive symptoms via the BDI-I [26] or the BDI-II [27]. Both versions of the BDI are standardized and valid instruments for the assessments of depressive symptoms and represent well-established assessment tools in research and clinical routines for assessing the presence and extent of depressive symptoms. Additional assessments of clinician-rated depression severity via the HDRS [28] were available for a subset of 51 participants.

The ReMAP Smartphone App

Development of ReMAP began in mid-2018 at the Institute for Translational Psychiatry in Münster. It is a native app for iOS and Android, based on Apple ResearchKit, Apple Health, and Google Fit. After an anonymous log-in with a provided subject ID, the app works in background mode and monitors the number of steps taken by the user, the distance walked, the accelerometer, and GPS position data. The data are encrypted on the smartphone and sent regularly via REST-API (REpresentational State Transfer application programming interface) to a back end specifically developed for ReMAP, which is provided on university servers. In addition, the app regularly enables the user to fill out various questionnaires regarding sleep and mood as well as to create short voice recordings. Measures used in this study's analyses are described below.

Smartphone-Based Measures and Procedures

After written informed consent was obtained, each participant was provided an individual subject ID (ie, subject code). The participant was then asked to download the developed ReMAP smartphone app and to start the app. At this time, subjects were asked to confirm participation in the study again and to enter their individual subject IDs.

In addition to the continuous assessment of passive data, all participants were asked to provide self-reported ratings of depressive symptoms. To this end, participants filled out a digital version of the BDI-I that was integrated into ReMAP every 2 weeks. Moreover, participants rated their mood and sleep duration by answering single items every 3 days. For the single mood question (ie, "How is your mood today?"), participants provided their responses via touch screen on a scale from 1 (very bad) to 10 (very good). For the single sleep question (ie, "How many hours did you sleep last night?"), participants provided their response on a scale from 0 to 13 hours. For all self-reported data, the app sent out weekly push notifications on a random basis during the daytime with a variance of 2 days or every 2 weeks in case of the BDI. The time of the day when notifications were sent was systematically varied in order to avoid bias from systematically assessing symptom self-reports (eg, only during the morning). Participants were instructed that answering all questions was optional and they were free to choose their time of answering whenever items were made available.

Again, for this study, smartphone-based and non–smartphone-based data were only included if the time interval between completion of the ratings between both delivery formats was less than 4 weeks, in order to minimize potential bias due to temporal change in depressive symptoms. Further, for each participant, the respective BDI, mood, and sleep assessments from the time point with the shortest interval between smartphone-based and non–smartphone-based assessments were included for this study.

Statistical Analyses

Agreement between non–smartphone-based and smartphone-based BDI scores was assessed by absolute agreement using a two-way, mixed-effects intraclass correlation

coefficient (ICC) [29]. To this end, the non–smartphone-based measures were compared with the temporally closest smartphone-based BDI scores available, resulting in the shortest interval possible.

This analysis was further repeated for the over-1-week-interval and the under-1-week-interval groups separately in order to assess the influence of the test-retest interval on the agreement between measurements. In addition, the analysis was repeated separately among healthy controls, affective disorder (ie, MDD, SAD + MDD, and bipolar disorder) patients, and anxiety disorder (ie, SP, spider subtype; and SAD) patients, as well as for the two non–smartphone-based BDI versions (ie, BDI-I and BDI-II). The internal consistency of the smartphone-based BDI was assessed via Cronbach α and compared with the internal consistency of the non–smartphone-based BDIs.

The smartphone-based single mood item was correlated with the non–smartphone-based and smartphone-based BDI scores. Although it covers different levels of symptomatology (ie, the BDI assesses complex symptoms over time, while the single mood item assesses only the current subjective mood [8]), the BDI questionnaire was used for validation based on the assumption that both measures are sensitive for current mood.

For validation of the smartphone-based single sleep item, it was correlated with the smartphone-based and non–smartphone-based BDI item assessing sleeping disturbance. Analogous to the BDI analysis, one mood and one sleep assessment were used for analysis based on the shortest interval to the non–smartphone-based measures. For further validation, the ReMAP BDI and the ReMAP single mood item were both correlated with clinician-rated depression severity using the HDRS.

All analyses were conducted using SPSS, version 26 (IBM Corp). A multiple test correction was undertaken across all significance tests (n=34) in order to avoid α error accumulation using a false-discovery-rate (FDR) correction following the Benjamini-Hochberg procedure [30]. Assuming an FDR q value of .05, this approach yielded a corrected significance threshold of $P<.04$.

Results

Descriptive Statistics

Mean BDI scores and their range across all participants were similar for ReMAP (mean 5.35, SD 8.63; range 0-44) and non–smartphone-based BDI (mean 6.46, SD 9.06; range 0-47). Absolute differences between both measurements were, on average, 3.02 points (SD 3.76) with a considerable range covering 0 to 26 points. The mean test-retest interval was 5.84 days (SD 7.29), ranging from 0.20 to 28.70 days. Detailed descriptive statistics across subgroups of the sample are provided in Table S1 in Multimedia Appendix 1. Among the included participants who completed a smartphone-based BDI within 4 weeks of completing non–smartphone-based measures, the percentages of participants who also provided single items for mood and sleep within a maximum interval of 4 weeks were 97.11% and 95.95%, respectively.

Validity of Affective Symptom Assessment via ReMAP

The overall agreement between ReMAP and the non–smartphone-based BDI was very high (ICC 0.921, 95% CI 0.890-0.942). Separate investigations of the BDI agreement in several subgroups yielded highly comparable ICCs across both BDI versions (ie, BDI-I and BDI-II), across different test-retest intervals, across different age groups, and across males and females—the ICC was over 0.888 for all subgroups. Separate investigations across different diagnostic statuses yielded the highest BDI agreement between delivery formats in the subgroup with affective disorders (ICC 0.912), while healthy controls and participants with anxiety disorders (ie, SP, spider subtype; and SAD) showed moderate agreement between BDIs (ICC 0.639 and ICC 0.736, respectively). Similarly, higher agreement was found among acutely depressed as compared to remitted MDD patients (see Multimedia Appendix 1). ICC statistics for the full sample and all subgroups are presented in Table 1. Scatterplots of ReMAP BDI scores over non–smartphone-based BDI scores are provided in Figure 1.

The internal consistency of the ReMAP BDI (Cronbach α=.944, n=174) was virtually identical to both non–smartphone-based BDI versions (BDI-I: α=.945, n=54; BDI-II: α=.944, n=108). For further validation, the ReMAP BDI was correlated with clinician-rated depression severity using the HDRS in a subset of the sample (n=51). The analysis yielded a strong significant correlation ($r=0.783$; $P<.001$) that was comparable to the association between the HDRS score and the score of the non–smartphone-based BDI ($r=0.682$; $P<.001$).

Table 1. Intraclass correlation agreement of the Remote Monitoring Application in Psychiatry (ReMAP) Beck Depression Inventory-I (BDI-I) with the full sample and stratified subsamples.

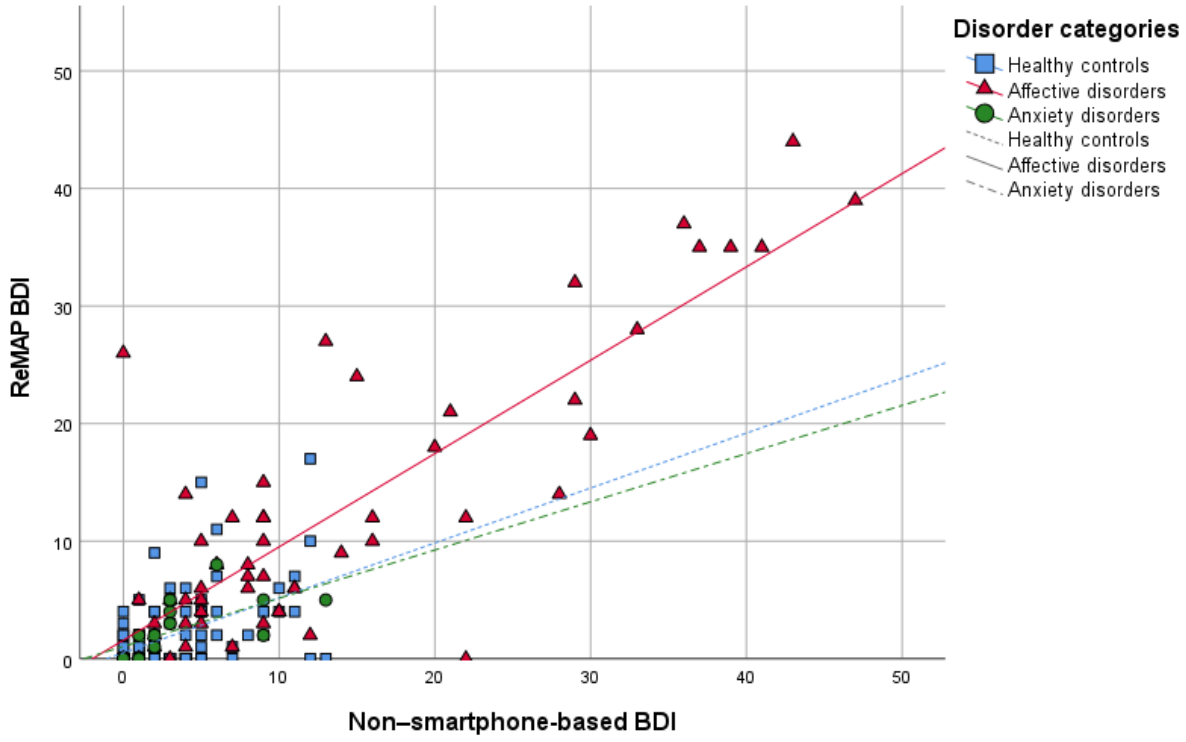
Sample	Number of participants (N=173), n (%)	Intraclass correlation coefficient	95% CI	*P* value[a]
Full sample	173 (100)	0.921	0.890-0.942	<.001
BDI-$I_{non–smartphone\ based}$	64 (37.0)	0.921	0.870-0.952	<.001
BDI-$II_{non–smartphone\ based}$	109 (63.0)	0.919	0.863-0.850	<.001
≤1-week interval[b]	126 (72.8)	0.934	0.890-0.958	<.001
>1-week interval[c]	47 (27.2)	0.888	0.799-0.938	<.001
Healthy controls	101 (58.4)	0.639	0.454-0.760	<.001
Affective disorders	57 (32.9)	0.912	0.851-0.948	<.001
Anxiety disorders	15 (8.7)	0.736	0.252-0.910	.008
Age ≤35 years	131 (75.7)	0.899	0.851-0.931	<.001
Age >35 years	42 (24.3)	0.962	0.930-0.980	<.001
Male	41 (23.7)	0.969	0.919-0.986	<.001
Female	132 (76.3)	0.904	0.864-0.933	<.001

[a]All *P* values below a false discovery rate–corrected significance threshold of *P*<.04 are considered statistically significant.

[b]Participants completed the smartphone-based BDI within 1 week of completing non–smartphone-based measures.

[c]Participants completed the smartphone-based BDI and non–smartphone-based measures more than 1 week apart.

Figure 1. Beck Depression Inventory (BDI) scores via the Remote Monitoring Application in Psychiatry (ReMAP) smartphone app over non–smartphone-based BDI scores across diagnostic groups.



After including all data points with a test-retest interval of up to 4 weeks, the single item for mood assessed via ReMAP correlated moderately with the sum scores of the ReMAP BDI (*r*=–0.538; *P*<.001; n=168) and with both non–smartphone-based BDI versions (BDI-I: *r*=–0.485, *P*<.001, n=61; BDI-II: *r*=–0.504, *P*<.001, n=107). Further, a significant negative correlation between the ReMAP single mood item and the HDRS score was observed (*r*=–0.369; *P*=.008; n=51). Correlations of the single mood item across subsamples are provided in Table S2 in Multimedia Appendix 1.

The single item for sleep assessed via ReMAP was correlated with the BDI item assessing sleeping disturbance. After including all data points with test-retest intervals of up to 4 weeks, this analysis yielded significant negative associations

with the sleep item from the ReMAP BDI (r=–0.310; P<.001; n=166) and with the sleep item of both non–smartphone-based BDI versions (BDI-I: r=–0.279, P=.03, n=63; BDI-II: r=–0.202, P=.04, n=102). Separate correlation analyses of the single mood and sleep ReMAP items across disorder subgroups are presented in Table S3 in Multimedia Appendix 1. The general pattern of results yielded the strongest associations in the affective disorder group.

Discussion

With this study, we demonstrate that smartphone-based monitoring of depressive symptoms via the ReMAP app provides valid assessments of depressive symptomatology. The overall high agreement between the non–smartphone-based and smartphone-based versions of the BDI confirm that digital assessments via the ReMAP app using the participants' smartphones have the potential to offer valid estimates of the trajectory of participants' moods. This notion is additionally supported by the observed correlation of smartphone-administered single-item ratings regarding mood and sleep with corresponding non–smartphone-based assessments. Importantly, the validity of smartphone-based assessments could furthermore be demonstrated by using clinical rating scales as a criterion with a strong correlation of smartphone-based BDI and non–smartphone-based HDRS scores.

The observation of high agreement between self-reported smartphone-based assessments of depressive symptoms and classic non–smartphone-based assessments in this study is supported by previous findings from pilot studies among MDD patients [22] and from a systematic review among bipolar patients [21]. Furthermore, the comparability of the non–smartphone-based and smartphone-based versions of the BDI in our study matches similar results of agreement between paper-and-pencil and computer versions of the BDI [16].

Our findings of overall high validity of smartphone-based and conventional non–smartphone-based assessments of depressive symptoms in a relatively large and heterogeneous sample critically underscores the potential of mobile assessment tools in psychiatric research. Considering that smartphone-based assessments offer valid data on patients' mood states, an expansion of mobile data acquisition in the clinical and research context appears desirable. The cost-efficiency of smartphone-based data might thus allow the acquisition of valid data on patients' long-term disease trajectories at an unprecedented scale. Together with previous studies investigating the comparability of the BDI versions (ie, BDI-I and BDI-II) [27,31] as well as delivery formats [16], our findings add to an increasing evidence base of high comparability of smartphone-based and conventional non–smartphone-based assessments of depressive symptoms.

We furthermore demonstrate that agreement between smartphone-based and non–smartphone-based assessments of depressive symptoms does not depend on the age or gender of participants, which supports the generalizability of smartphone-based assessments of depressive symptoms. This notion appears especially noteworthy considering the relatively large sample size, in comparison with previous reports, as well as the age range of participants included in this study (ie, 18-68 years of age). The inclusion of older participant groups seems relevant, as previous studies have emphasized that smartphone apps for mental health monitoring should meet the needs (eg, easy handling) of older and potentially less technically proficient individuals in order to assure adherence among these group members [32].

An important observation of this study was that higher agreement between smartphone-based and non–smartphone-based assessments of depressive symptoms was found among affective disorder patients compared to anxiety disorder patients or healthy controls. Notably, while the agreement in the affective disorder sample can be estimated as excellent, intraclass correlations indicate a lower, but still moderate to good, agreement in the healthy control and anxiety disorder samples [33]. This might partly be traced back to the much higher variance of depression severity in the affective disorder group. Lower variance in depression scores in nonaffective clinical samples has previously been suggested to account for findings of low reliability among substance addiction patients [34]. Further, small sample sizes of some participant subgroups limit the weight of this finding, particularly for the anxiety disorder subgroup (n=15). These findings may call for a cautious interpretation of findings based on self-reported symptom data in healthy or nonaffective disorder populations. However, they also seem to contradict previous findings. The authors of a meta-analysis investigating BDI reliability concluded that nonclinical samples show a very good test-retest reliability, while only very limited data are available for test-retest reliability in clinical samples [31]. Sporadic reports of lower retest reliabilities as found by one study [35] were explained by the authors as natural changes in depression severity over time [31]. The difference in reliabilities across samples may, in part, stem from differences in statistical analyses, as traditional Pearson correlations that were used by the cited studies can produce substantially different results than ICC agreement estimates, which are now often recommended for retest analysis [36].

Besides validation of a smartphone version of the BDI, this study found moderate to high agreement between mood ratings via smartphone-based single-item assessments and established clinical scores using the BDI, regardless of the delivery format of the BDI. This finding is of particular importance considering that completion of an entire questionnaire is time-consuming and, hence, the usage of single items might provide a valid possibility of assessing mood on a frequent basis. Importantly, these findings are tentative and limited by the fact that the single mood item and the BDI questionnaires may systematically assess differing concepts in regard to the symptom level as suggested by previous scholars [8]. However, although this distinction may account for agreement between both measures, the high agreement also points to substantial overlap between the macrolevel BDI questionnaire and the more microlevel single mood item.

In sum, the associations between questionnaire data (ie, the BDI) and single-item mood self-reports pose the following question: Which measure may be better suited for specific

research contexts and could one of the two be omitted completely? One may argue that single mood items seem to provide a sufficient proxy for the assessment of mood fluctuations that is more time-efficient and could, therefore, be assessed more frequently as compared to a more exhaustive BDI questionnaire. On the other hand, it may be more beneficial to have a more elaborate symptom profile as obtained, for example, via the BDI in exchange for assessment frequency. It remains to be investigated what temporal and content-related resolution is most beneficial for the investigation of the development of depressive symptoms and for specific feature engineering using machine learning algorithms. Likely, the most beneficial trade-off between the two highly depends on the specific research question.

Compared with the single mood item, the single sleep item showed a lower correlation with corresponding non–smartphone-based assessments in the form of sleep disturbance items within the BDI questionnaire. One possible explanation for this low association is that both items measure slightly different aspects of sleep: while the BDI sleep item assesses increased and decreased sleep duration and, depending on the BDI version, also a combination with subjective sleep quality, the single sleep item assesses purely the duration of sleep during the last night. Further, sleep quality or disturbance may be a more heterogeneous construct and, thus, more difficult to assess via a single item. Another possible explanation for this finding could be that variability in the sleep quality, as well as sleep duration, may be less temporally stable as compared to mood changes. Thus, the test interval of up to 4 weeks may be too long in order to validate the smartphone-based assessment of sleep duration. Considering that smartphone-based and non–smartphone-based assessment methods lie several days or weeks apart, the association between them seems to be reasonably high.

Strengths of this study include the relatively large sample of participants and the availability of smartphone-based data along with conventional psychometric and clinical data. Furthermore, this study included participants with differing psychiatric diagnoses and a high variability in age, thus allowing the assessment of generalizability across such participant groups. Further, a wide variety of assessment forms were used for validation, considering multiple sources of information. The application of non–smartphone-based BDI versions (ie, self-report), as well as clinical ratings (ie, HDRS), underlines the validity of the smartphone-based assessments via the ReMAP app. Limitations include the lack of prospective clinical follow-up data. Future large-scale studies are warranted to assess the prognostic validity of smartphone-based self-reports in affective disorder patients.

Smartphone-based monitoring of depressive symptoms remains a timely matter of critical relevance for translational psychiatry. These results demonstrate overall high validity of smartphone-based assessments of depressive symptoms and should, thus, encourage researchers to apply mobile apps toward continuous prospective assessments of depressive symptoms.

Acknowledgments

Funding was provided by the German Research Foundation (DFG) (project No. 44541416-TRR 58); project grants C09 and Z02 of the Collaborative Research Center Transregio (CRC-TRR) 58 were awarded to UD. Funding was also provided by the Interdisciplinary Center for Clinical Research (IZKF) of the Faculty of Medicine, University of Münster (grant Dan3/012/17 was awarded to UD and grant SEED 11/19 was awarded to NO). In addition, funding was provided by the Innovative Medizinische Forschung (IMF) of the Faculty of Medicine, University of Münster (grant OP121710 was awarded to NO and TH and grants LE121703 and LE121904 were awarded to EL). Further, we are deeply indebted to all personnel involved in recruitment and data management as well as to all participants of this study.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Descriptive statistics of subsamples, correlations of the Remote Monitoring Application in Psychiatry (ReMAP) single mood item with Beck Depression Inventory (BDI) scores across subsamples, and correlations of the ReMAP single sleep item with the BDI sleep item across subsamples.
[DOCX File , 32 KB - mental_v8i1e24333_app1.docx]

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Abbreviations

BDI: Beck Depression Inventory
CRC-TRR: Collaborative Research Center Transregio
DFG: German Research Foundation
DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition
FDR: false discovery rate
HDRS: Hamilton Depression Rating Scale
ICC: intraclass correlation coefficient
IMF: Innovative Medizinische Forschung
IZKF: Interdisciplinary Center for Clinical Research
MDD: major depressive disorder
PHQ-9: Patient Health Questionnaire-9
ReMAP: Remote Monitoring Application in Psychiatry
REST-API: REpresentational State Transfer application programming interface
SAD: social anxiety disorder
SCID-I: Structured Clinical Interview for DSM-IV Axis I Disorders
SP: specific phobia

Edited by J Torous; submitted 15.09.20; peer-reviewed by S Steingrimsson, F Bos; comments to author 08.10.20; revised version received 28.10.20; accepted 06.11.20; published 12.01.21.

Please cite as:
Goltermann J, Emden D, Leehr EJ, Dohm K, Redlich R, Dannlowski U, Hahn T, Opel N
Smartphone-Based Self-Reports of Depressive Symptoms Using the Remote Monitoring Application in Psychiatry (ReMAP): Interformat Validation Study
JMIR Ment Health 2021;8(1):e24333
URL: https://mental.jmir.org/2021/1/e24333
doi:10.2196/24333
PMID:33433392

Original Paper

Participant Engagement in a Transmedia Storytelling Web-Based App Intervention for Mental Health of Latina Women: Qualitative Analysis

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Abstract

Background: Stigma, fear, and lack of knowledge regarding treatment options or where to get help create delays for Latina women in accessing needed mental health help. Story-based media interventions hold appeal for Latina women. Thus, we drew upon the Social Cognitive Theory by Bandura to create an evidence-based, transmedia storytelling web-based app for mental health called *Catalina: Confronting My Emotions* to connect Latina women to a curated set of mental health resources. Understanding how Latina women perceive various aspects of the web-based app will help design future expansions.

Objective: A previously published analysis led to the development of a category on how participants related to the lead character (Catalina) in the story line of the web-based app as a real person. However, the purpose of this analysis was to gain an understanding of participants' experiences with the extension of the dramatic story line of the web-based app beyond Catalina to a Latina nurse-therapist character named Veronica, who was featured prominently in the app's interactive content and bonus videos.

Methods: Qualitative analyses were conducted with interview data from a community-based sample of 28 English-speaking Latina women aged between 21 and 50 years who scored above the threshold for anxiety (Generalized Anxiety Disorder-7) and/or depression (Patient Health Questionnaire-9) but were not suicidal at screening. Data were collected 72 hours after participants engaged with our transmedia storytelling web-based app for mental health. Grounded theory methodology guided the analysis and interpretation of data that had been collected telephonically, recorded, and transcribed with identifiers removed. Analyses included initial and focused coding using process codes (gerund form of verbs in codes focused on action), informed by symbolic interactionism, and the development of categories with properties through constant comparison, memo writing, and the use of charts and diagrams.

Results: Our participants experienced a multiphase process that was most heavily related to Veronica, the Latina nurse-therapist character in our web-based app, who led them through a process to a place of action. We conceptualized this process as moving from passive viewer to active participant of a transmedia storytelling web-based app intervention. Overall, 3 new conceptual categories provided insight into women's experiences, including encountering a trustworthy nurse-therapist character, taking in messages that dispel old beliefs, and preparing when and how to take action. Each category has nuanced properties that reflect participants' experiences.

Conclusions: Active engagement with our web-based app led our sample to successfully transition from the viewpoint of the observer to the viewpoint of the experiencer, moving from a passive position of watching to active engagement that involved imagining, thinking, reflecting, and acting. Careful development of dramatic material for health-related web-based apps using

transmedia story extension and bonus videos needs to be based on input from the target group from the start of development through evaluation and testing.

(JMIR Ment Health 2021;8(1):e22575) doi:10.2196/22575

KEYWORDS

transmedia; Latina; mental health; mobile applications; internet; depression; anxiety; storytelling; mobile phone

Introduction

Background

The median delays in seeking mental health care for depression and anxiety in the United States have been estimated to be 9 and 8 years, respectively, even if the person knows that their symptoms are due to a mental health problem; these delays were significantly associated with being Latinx or Black [1]. A meta-analysis on the duration of untreated unipolar depression showed that participants who failed to initiate care within 8 weeks of becoming aware of depression had a lower probability of responding well to treatment or achieving remission [2]. In another study, 70% of the 287 Latina women in a community-based sample delayed seeking needed physical health care; furthermore, having depression or anxiety was associated with 3.1 times greater odds of delaying needed health care (95% CI 1.6-5.9) [3]. Therefore, for Latina women, the consequences of untreated depression and anxiety threaten both physical and mental health.

The prevalence of depression is higher among Latina women than among Latino men in the United States [4,5], as it is globally [6]. Compounding the problem, Latina women have been reluctant to seek care [7] due to fear, guilt, shame, privacy concerns, lack of family support, or distrust of professionals [8]. This includes English-speaking Latinx men and women [9], who have reported higher levels of self-stigma and have more often said they would conceal a potential mental health problem compared with non-Latinx White individuals [10]. Latinx men and women are approximately half as likely as people of other racial or ethnic groups to obtain mental health care [11]. Thus, a dynamic intervention that helps this group overcome barriers to care and identify available resources is crucial.

As mental health literacy is a segue to treatment engagement [12], it is an asset that would benefit Latina women with symptoms who wish to obtain mental health help. Key features include having the ability to recognize a mental health disorder as it develops, being clear about professional and self-help treatment options, and knowing where to obtain resources and information, as well as how to help someone else who is struggling with their mental health [13]. However, the question arises of how to most effectively reach Latina women with this content. This is especially challenging with Latina women, who avoid even talking about mental health due to fear of stigmatizing labels [12]. Nonthreatening strategies are needed to increase the confidence of Latina women and encourage them to seek help and make contact with a provider. A discreet approach to introducing and delving into the topic of mental health is likely to be more acceptable to Latina women; however, for the approach to be effective in helping Latina women achieve the goal of mental health and wellness [14], it should be uncomplicated, engaging, and directly related to getting treatment.

One strategy is to use technology that most Latina women have in their pocket, purse, or desktop, that is, their smartphone, tablet, or computer. Latinx men and women report high levels of internet use both for entertainment [15,16] and for accessing health information [17]. Latinx men and women have high rates of smartphone ownership [18], which supports the idea of a mental health web-based app intervention that is accessible on smartphones or other mobile devices and can be ultimately personalized as well as scalable to maximize reach [19]. However, any endeavor to create a web-based app needs to be guided by theory and based on scientific evidence, as Torous and Roberts [20] have explained. They cautioned that only very few of the 10,000 mental health apps that were available for the public to download in 2017 were actually based on data [21]. With such a large number of available apps, it can be quite challenging for users to find the few evidence-based apps among those that were not developed based on data [20]. In addition to being evidence-based, developers need to take extra steps to ensure that their apps are user friendly, designed with user input [22,23], and respectful of users' privacy [21,23]. Ultimately, if the app is useful for meeting users' needs, it holds promise for raising the otherwise low rates of engagement with mental health apps [21].

When considering a target group of symptomatic Latina women, apps also need to be culturally acceptable, desirable, and enjoyable to them, so that they will be attracted to using the apps. Latinx men and women are considered a mobile-first community with some of the highest levels of smartphone engagement. For example, 90% of all Latinx consumers use their smartphones to perform video streaming. In particular, Latina women report high levels of television watching and movie going [16], spending more than 30 hours per week watching television and more than 22 hours per week using their smartphones while exploring apps, downloading and viewing videos, or surfing the net. Latina women also report using YouTube, Google+, Instagram, Snapchat, and Twitter at higher rates than non-Hispanic White women [24]. For these reasons, we created an evidence-based, storytelling mental health intervention that could link untreated Latina women to the needed care and resources via a smartphone, tablet, or computer using transmedia. Transmedia involves telling stories that unfold and extend across multiple digital platforms, including smartphones, tablets, or computers, which offer users and viewers a media experience that has the potential to go deeper as they gain different points of view related to the story world, plot, or characters through extra scenes or bonus videos [25].

Previous Work

Fueled by input from Latina women, informed by Social Cognitive Theory by Bandura related to media, vicarious learning, and behavior change [26], and inspired by the 1970s edutainment productions by Miguel Sabido on Televisa in Mexico [27], we created a Hollywood-quality web-based app with a responsive design that can be used on smartphones, tablets, or computers. We partnered with a programmer and Latinx media and film professionals, as described elsewhere [28,29]. Our web-based app is character driven in that the momentum of the web-based app is carried forward by the characters themselves. In addition, our characters are messengers of health-related content embedded in the story and bonus videos. This means that the story line is extended by featuring characters in additional bonus videos that are psychoeducational or therapeutic. In this way, the characters present helpful information from within the story world while also enhancing the participants' media experience. For these reasons, we developed the characters with special attention to deidentified input from Latina women struggling with depression who participated in previous research studies [30-38]. In addition, during the design phase, we received critique and input from Latina therapists and non-Latina women therapists who worked with symptomatic Latina women to maximize usefulness from a provider point of view. These sources of input influenced all scripts, directing, and acting. In theater testing, Latina women of the target demographic gave feedback useful for editing and culturally tailoring the content. Latina focus group participants named it *Catalina: Confronting My Emotions.* Our approach heeds advice voiced by Torous et al [22,23] about the importance of a collaborative approach in app development that includes patients and providers.

A mixed methods study with 2 major aims was conducted. The first was to quantitatively analyze the feasibility, acceptability, and efficacy of the web-based app intervention, and the second was to qualitatively explore the experiences and perceptions of 28 English-speaking Latina women in a community sample that engaged with the web-based app. All participants were aged between 21 and 50 years and scored above the threshold for anxiety [39] and/or depression [40] but were not found to be suicidal at screening. Interviews were conducted by phone approximately 72 hours after participants engaged with media in the web app.

Due to the design of the home webpage of our web-based app, participants were led to engage with the videos by starting with the story-based videos about a character, Catalina, portrayed by actress Sandra Parra. These videos included a 11-minute webisode (online television episode) about Catalina struggling with feelings of sadness, frustration, and worry in her daily life. This was followed by a 3-minute video log of Catalina, making a recording for her best friend in which she confides in her best friend that she is thinking of seeking therapy. Users then watch a 3-minute extra scene of Catalina coming out of a community counseling center and follow her as she continues walking down the street while leaving a voice message for her best friend about her positive experience in therapy with a character named *Veronica*. At this point, participants have not yet seen Veronica, but they hear Catalina talk about the therapy session with Veronica as something she values.

The goal of the early videos was to attract and pique the interest of participants in the dramatic story so they would be motivated to click to open the bonus and interactive videos that extended the story through Veronica. Thus, the story involved some drama, some romance, and some tense scenes depicting difficulties Catalina had involving an old boyfriend, her mother, and her emotions. Our strategy was successful, and all 28 participants clicked to open and watch all features of the web-based app [28]. They got their first glimpse of Veronica, portrayed by actress Yareli Arizmendi, in a 4-minute bonus video in which she speaks from her point of view as a Latina and a nurse who is a therapist. Veronica looks directly into the camera as she speaks to the participants. The script allows Veronica to talk about Catalina's situation in an accessible way and to build upon it to share how common depression and anxiety are among women and to provide various points of psychoeducation. She then invites participants to click to open a sequence of interactive videos. Over the course of 5 short 1- to 2-minute interactive videos, Veronica again speaks to the audience directly, posing questions about what is holding them back from getting care [41] to help them consider their own situation, emotional needs, and desires. Finally, Veronica invites participants to click to open her blog, written from her point of view, which contains carefully selected links to hotlines, local clinic webpages, telephone numbers, and websites that provide free or low-cost resources and information about mental health [28,29].

Our team analyzed and published an analysis of qualitative data from our sample about their perceptions of the fictional lead character of the story, Catalina, whom they related to as a real person with a past, present, and future [29]. However, as a major portion of the transmedia web-based app involved Veronica, the nurse-therapist character, it was imperative for us to analyze the qualitative data from participants about Veronica. She was the character who guided participants through all other aspects of the web-based app experience, including the transmedia bonus videos, interactive features, and resource-rich blog.

Objectives

The purpose of this qualitative analysis is to explore, describe, analyze, and interpret the perceptions of English-speaking Latina women with elevated levels of depression and/or anxiety related to the nurse-therapist character in our transmedia web-based app, named Veronica. Through this analysis, we aim to provide knowledge for consideration in the future when developing nurse characters or other health provider characters in mental health apps designed especially for Latina women and other users struggling with depression or anxiety symptoms.

Methods

Design

For this qualitative analysis, we used the techniques of grounded theory methodology [42,43] to analyze interview data that were collected as part of a mixed methods intervention study. As was described elsewhere [28,29], approval was obtained from the

UCLA Institutional Review Board. Symbolic interactionism [44,45] informed our use of grounded theory techniques; symbolic interactionism holds that people make sense of reality through the social aspects of their daily lives and meaning emerges through social interactions. This sensitized us during analysis to focus on what was meaningful to participants about their web-based app experience, with special attention to interactions with the characters in the context of their own lives.

Sampling and Recruitment Procedures

To attract participants, flyers were distributed at 9 community-based sites located in a metropolitan area of Southern California. Interested women called the study phone and were screened. Purposive sampling was used with the goal of recruiting English-speaking Latina women who scored above the threshold for anxiety [39] or depression but were not suicidal [40]. Those who met the inclusion criteria and gave web-based informed consent were aged 21-50 years, could speak and read English, and had access to the internet via a tablet, computer, or smartphone.

Data Collection

Participants completed a web-based baseline survey before engaging with the web-based app. A telephone interview was conducted up to 3 days later. A semistructured interview guide was used [29], which included open-ended questions about the Latina women's experiences with each aspect of the transmedia web-based app, their perceptions of Veronica, and attitudes about help-seeking. Being semistructured, the interview was designed to allow participants to expand on topics as they desired. As is recommended by grounded theory methodology, participants' answers in early interviews influenced questions posed in later interviews. Thus, additional questions that emerged in early interviews about what Latina participants found pertinent were added to subsequent interviews as data collection proceeded. All telephone interviews were conducted by a nurse scientist who is also a mental health nurse practitioner (first author). After completing several steps in the study, including the audio-recorded telephone interview (lasting an average of 45 minutes), participants received a US $60 gift card (via US mail, text message, or email). All digital recordings were password protected and were stored on a server with a firewall. Audio recordings were transcribed verbatim using a professional and secure transcription service. All transcripts were deidentified, checked for accuracy, and uploaded into Atlas.ti (qualitative data analysis; Scientific Software Development GMbH) [46]. All participants who enrolled in the study completed the entire study.

Data Analysis

We engaged in a rigorous qualitative analysis of the data using the techniques of grounded theory methodology. Initial coding of each line of data was performed using process codes (gerunds) to maximize our focus on the actions of each participant (including their thinking and self-talk) and their point of view as an individual. This reduces tendencies to project beyond the data or to make an interpretive leap prematurely based on one particular line of data. Process coding also directed the analysis to take into account multiple participants' perspectives. *Initial codes* were created for each line of 10 of the 28 transcripts. Then, we identified the most significant and most frequent codes (called *focused codes*, which are similar to themes based on grounded theory methodology) and used them to sort codes with similar meanings into groups. Symbolic interactionism enhanced our analysis because it provided guidance for asking ourselves questions during analysis of the data about women's interactions with the characters and with themselves as they experienced the web-based app. This helped us to identify what aspects participants found meaningful. Then, we developed the focused codes into categories. The qualitative software Atlas.ti (qualitative data analysis; Scientific Software Development GMbH) [46] facilitated the analytic process by serving as a platform to organize data so that it could be easily shared between researchers. Excel charts facilitated our use of a constant comparison of data with data and codes with codes. We were limited to only one interview per participant, so we could not perform theoretical sampling. However, the techniques of grounded theory methodology allowed us to scrutinize every line of the very rich data we had collected to perform a systematic and rigorous analysis. Memo writing deepened the analysis, facilitated discussions about patterns in the data, enhanced researcher reflexivity, and led to checking potential biases throughout the analysis. From this, we were able to develop a robust description of categories with nuanced properties. Diagrams were instrumental in illustrating processes and identifying relationships between and within categories.

Results

Participant Details

Demographics and levels of depression and anxiety symptoms at screening for our sample of 28 Latina participants are reported in Table 1 [28]. More than half of our sample reported watching story-based dramas or comedies on television once or more each week and watching videos, movies, or story-based shows on the internet at least weekly, using a smartphone, tablet, or computer.

Table 1. Sample demographics (N=28).

Characteristic	Value, n (%)
Highest education level	
Some high school (but not all)	3 (11)
Graduated from high school or earned a general educational development certificate	7 (25)
Some technical, trade, or vocational school after high school	3 (11)
Attended at least one course in college	8 (29)
Graduated with an associate degree	1 (4)
Graduated with a bachelor's degree	3 (11)
Graduated with a master's degree	2 (7)
Chose not to answer the question	1 (4)
Finances	
Ability to meet weekly financial needs	
Not difficult	3 (11)
Somewhat difficult	6 (21)
Very difficult	19 (68)
Chose not to answer	0 (0)
Mental health symptoms	
Depression and anxiety	
Depression: PHQ-9[a] score ≥10	3 (11)
Anxiety: GAD-7[b] score ≥10	4 (14)
Depression and anxiety scores each ≥10	21 (75)

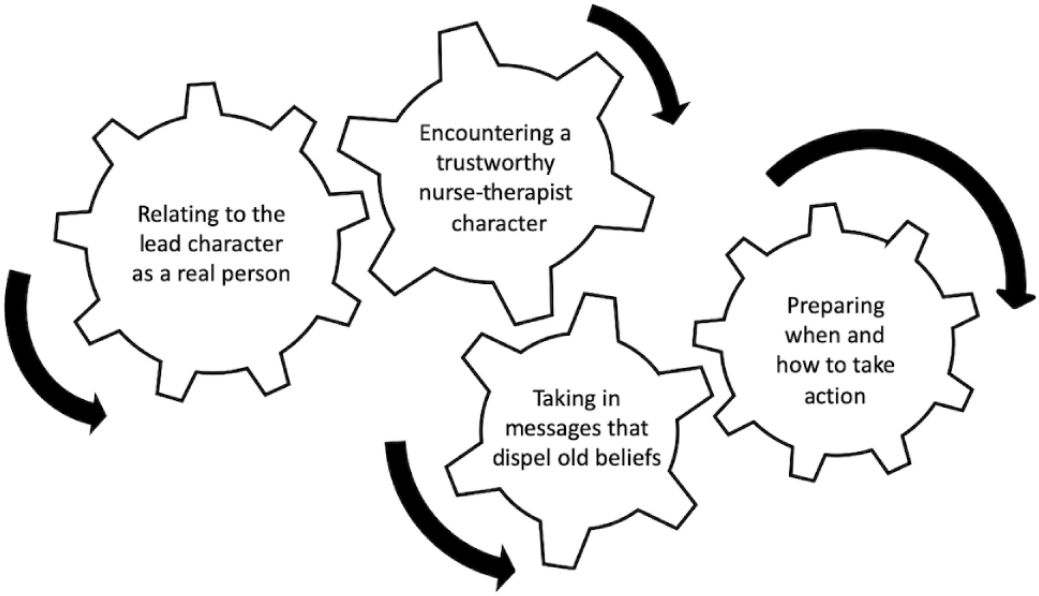
[a]PHQ-9: Patient Health Questionnaire 9-item.

[b]GAD-7: Generalized Anxiety Disorder scale 7-item.

Moving From Passive to Active Participant in a Transmedia Storytelling Web-Based App Intervention

The Latina women in our sample engaged in a multi-phase process that we conceptualized as *moving from passive viewer to active participant of a transmedia storytelling web-based app intervention*. This process is depicted using the metaphor of interlocking gears. The process begins with the movement of the first gear, which, in this depiction, is the symbolic connection to the lead character in the web-based app. Our sample of symptomatic Latina women found Catalina to be highly relatable (Figure 1). The analysis and description of this conceptual category was previously published [29]. We called it *relating to the lead character (Catalina) as a real person*. The turning of the first gear causes the next gear to turn, which then engages the next gear until all the gears are turning.

Figure 1. Depiction of the process of moving from a passive viewer to an active participant of the transmedia storytelling web-based app intervention.

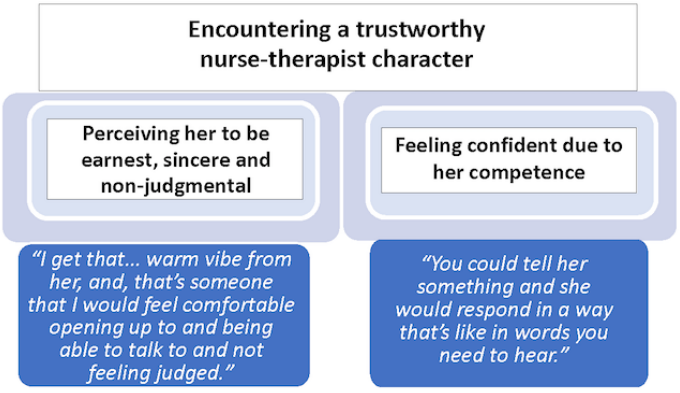


This analysis picks up after the first gear is in motion. In other words, having found Catalina to be relatable, the Latina women in our sample moved on to an active engagement with the second character, Veronica, a nurse therapist. This analysis provides a nuanced description of the second, third, and fourth phases of the process that Latina women went through upon meeting Veronica in the media of the web-based app. These 3 phases are depicted as interlocking gears and are representative of 3 new categories. These 3 categories give clarity to the process of moving from passive viewer to active participant. Each new category has 2 or 3 properties. The categories are as follows: *encountering a trustworthy nurse-therapist character*, *taking in messages that dispel old beliefs*, and *preparing when and how to take action*.

Encountering a Trustworthy Nurse-Therapist Character

All participants clicked the links on the web-based app that extended the story from a focus on Catalina to bonus videos wherein Veronica, the nurse-therapist character, spoke directly to the audience. Our participants spoke at length about their experience of Veronica in interviews. They recognized Veronica as a trustworthy nurse who was also a capable therapist. As participants described their perceptions and reactions to Veronica, it was the element of trust that mattered most to them. This category had 2 properties: (1) perceiving her to be earnest, sincere, and nonjudgmental and (2) feeling confident due to her competence (Figure 2).

Figure 2. Properties of the category of encountering a trustworthy nurse-therapist character.



Perceiving Her to be Earnest, Sincere, and Nonjudgmental

Sincerity was perceived as a crucial aspect of Veronica's trustworthiness. One participant described her as "very genuine" and indicated that Veronica's choice of words and style of speaking conveyed an honest intention to help and a deep sense of caring. This made the media interaction feel enjoyable, comfortable, and safe. She stated:

> *She [Veronica] felt very eager to help. So, her tone of voice was soft but very straightforward but also like there was some love in it. So, I really liked hearing from her. I felt safe.*

Participants did not focus on Veronica as a fictional character. Rather, they described how earnest she was, which impressed them. One woman said, "regardless if she really was a nurse, she seemed very sincere." Participants explained that they felt certain that Veronica would *understand* instead of judging them,

that they trusted her, and perceived her to be the type of therapist who would be *really open to listening*. In the context of their recent emotional struggles, the participants valued her lack of judgment, implying that it was not just important but necessary for them to feel comfortable.

Women described Veronica's manner, how she looked, and how they felt in response to her demeanor. For example, one woman explained that Veronica seemed "warm and approachable," that "her demeanor was very welcoming and very caring," and although this participant said she typically would have preferred a male counselor, Veronica "felt like she was like someone that I could go and just share how I'm feeling" as she seemed to "be neutral and impartial."

Putting the emphasis on the effect Veronica had on her, another participant said, "she seems to calm my nerves." After recounting how she perceived warmth from Veronica, another woman emphasized her personal expectations and then projected feelings she anticipated having in the presence of Veronica:

> *I get, that - for me - warm vibe from her [Veronica], and, that's someone that I would feel comfortable opening up to and being able to talk to and not feeling judged.*

Feeling Confident Due to Her Competence

The second property of trustworthiness in the nurse character was her competence, which inspired confidence. Participants believed that Veronica embodied different facets of competence, which made them feel confident about her. One woman said, "and, that's why I could feel comfortable—the way she sounded confident and [like] someone you can talk to, feel comfortable with." Another said she was "very empathetic, very professional."

Many were impressed by her expertise as a nurse therapist saying, "she's very knowledgeable" and "it looked like she knows what she's doing and talking about." Another summed up Veronica's proficiency by declaring firmly, "she's great at what she does." Participants commented on her presence as a skillful therapist and regarded her as a master:

> *Veronica seemed to be a person that has studied, I guess, human behavior in difficult situations. She seems like she is a person that is capable of helping a person in need and she seems to be trustworthy.*

Participants also viewed her as a capable therapist who had a wide range of skills, able to help "no matter what" type of problem was presented. Her capability engendered confidence as one woman exclaimed, "I feel like she would give me a lot of good advice for my life, and how to deal with situations." Several women expressed assurance that Veronica could handle any sticky or complex situation they might encounter. One woman stated:

> *. . ..because Veronica knows how to deal with problems like that, so I know she would be someone that could definitely help me over the problems, whatever I'm going through.*

Others expressed themselves by describing a hypothetical scenario and then explaining how Veronica could tailor her skills to match the needs of such a person with such a problem at such a moment. One woman imagined confiding in Veronica and said "…you can tell you can trust her. You could tell her something and she would respond in a way that's in words you need to hear."

Taking in Relevant Messages That Dispel Old Beliefs

Our participants reported that the messages in the videos that involved Veronica were meaningful to them. How they described this content indicated that the messages were effective in bringing them new insight and deeper understanding of mental health. Thus, the second category is *taking in relevant messages that dispel old beliefs*. The 2 steps of this process are represented by 2 properties of this category: (1) taking in new messages because they were personally relevant and meaningful and (2) using these messages to dispel old myths and erroneous beliefs about mental health (Figure 3).

Figure 3. Properties of the category of taking in relevant messages that dispel old beliefs.

Messages Were Relevant and Personally Meaningful

When the interviewer asked general questions about participants' thoughts related to seeking help for emotions in general, participants spontaneously answered in a way that integrated Veronica's messages. They personalized the content of Veronica's messages to fit their own situation. Remarkably, they remembered her messages even though the web-based app had not prompted them at any point to memorize or recite any content in the app. Furthermore, when asked how they felt about

Veronica, they responded as if Veronica and her messages were so intertwined that they were the same thing. For example, when asked how she *felt* about Veronica, one participant did not answer by describing a feeling. Rather, she answered by citing one of Veronica's messages that she found relevant in her life and related it to her own family, saying:

> *I liked the point that she [Veronica] brought up, I believe she had said, "First," you know, "you have to make sure you're okay with yourself, and you need to seek help if you want to," you know, "have a better life and also help your family."*

The content delivered by Veronica in the web-based app seemed to be taken in and absorbed by the women. During the interviews, women transposed what Veronica said by putting it into the first person as if it was their own idea, never mentioning that they were using Veronica's words. Sometimes during an interview, women shared something Veronica had said as if they were educating the interviewer. For example, one woman who was pregnant at the time of the interview gave a brief description of Veronica and then quickly went on to paraphrase one of Veronica's messages saying, "...because I matter, and in order for me to take care of bringing a life into this world, you need to make sure you are ready to help others." With conviction, this participant explained the reasons why seeking therapy would be crucial for her and her family. She shared her *own* view but never mentioned that Veronica had said very similar words in the video.

Another participant described how she "wished" she could talk with a person like Veronica when "problems in the home" occurred. She reiterated Veronica's advice from the video and expanded upon it, bringing in how emotional struggles can take a toll on one's body, which she said was why taking action felt specifically relevant to her. She said:

> *She gave really good advice. Like, getting therapy is good. It's good to get help. It helps. You read, you take it out, you take it out of your body. It's not good to be holding things in. It's good to talk to somebody, you know? It helps. It makes things better. You feel it helps you more be less stressful, less nervous, you feel like a different person.*

Using Messages to Dispel Old Beliefs

Through the process of taking in new messages, the women experienced a shift in thinking that spurred new insight. In the process, it dispelled old beliefs and erroneous myths about mental health and mental health care. Women said that Veronica clarified how common mental health challenges were and in doing so "put things into perspective." They explained how Veronica helped them see their symptoms differently, which made them feel more comfortable and less odd or unusual. One woman said, "maybe it's more normal than we think!" and then added, "I like that she [Veronica] made me feel like, OK, this is a thing that happens to a lot of people." Her experience with Veronica dispelled a previous belief that she was the only one, as it did for many participants. Another woman with the same realization summed it up saying, "...we're not alone. There's a lot of other women out there that are going through the same thing."

One woman dispelled an old myth that had prevented her from seeking help "until" she felt it was finally time. She shared her feeling that she had to wait until the right time, but she never seemed to know when the time was right. Referring to how, over time, she quietly endured emotional struggles that seemed to multiply, she said, "I guess I feel like we take it in, we take it in until we finally burst." She then explained how Veronica's messages helped change her perspective about the right time to seek help. She said:

> *I guess after seeing these videos and seeing the way the therapist talks, that's what, made me feel comfortable to know that you don't have to wait until you can't take it anymore. You could get help before so that you won't get to that point.*

Participants described how Veronica's messages brought awareness, saying that she "made me realize" things. In the context of the overall story line in the web-based app, another participant shared how she realized a key point about therapy. Previously, she thought that if she went to a therapy appointment, she would be doing all the talking. Now she realized that actually, "maybe it's more of a combination where we're both talking." This and the other details that Veronica shared about getting mental health care were practical and helpful, as one woman said:

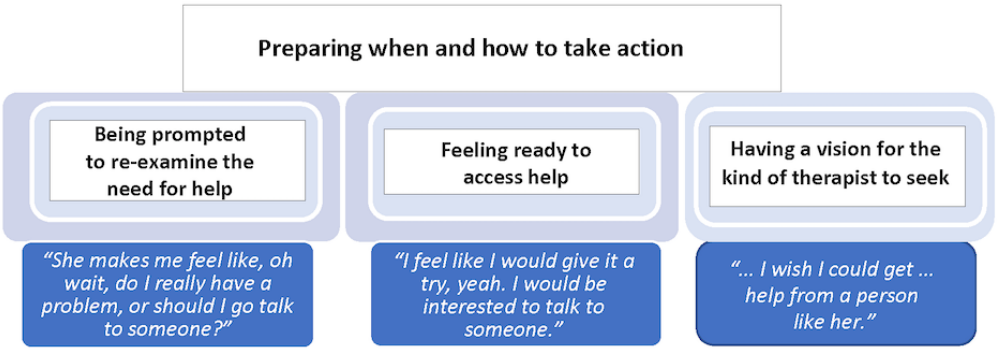
> *...she explained how it would help to get therapy, what the benefits are to talk to someone, how it would make you feel better and possibly change your life or even your lifestyle.*

These details, coming from Veronica, dispelled the idea that getting help was not acceptable, and that, in fact, it could lead to a positive change in their personal lives.

Preparing When and How to Take Action

After the women decided that Veronica was trustworthy and engaged in the process of integrating messages they found to be relevant, they entered a part of the process that involved preparing when and how to take action. This category has 3 properties: (1) being prompted to re-examine the need for help, (2) feeling ready to access help, and (3) having a vision for the kind of therapist to seek (Figure 4).

Figure 4. Properties of the category of preparing when and how to take action.



Being Prompted to Re-examine the Need for Help

After finding Veronica to be trustworthy, participants found that the content of her messages helped them reflect to gain a more enlightened view of themselves. They felt prompted to apply what they learned from Veronica and to step back, take an honest look at their ability to cope with their emotional struggles, and examine it in the context of their life circumstances. One woman with 5 children, who never sought therapy before and always put her children's needs before her own, was moved by Veronica's message. This woman said, "She [Veronica] gives good advice, and I just feel everything she said is true." She went on to discuss the possibility of finding a therapist saying, "I get to thinking, I am thinking about it... They [the videos] give you good information, like the counselor [Veronica], and it's true, it's good to talk to people."

Another participant reflected on how she felt before engaging with the transmedia web-based app intervention saying, "I've never been, 'OK, I'm going to go'." However, she continued to say that now she found herself open in a way that was new for her. Admitting that, thanks to Veronica, she had re-evaluated her need for mental health care, she said, "She makes me feel like, 'Oh wait, do I really have a problem?', or 'Should I go talk to someone?'" Her willingness to be open and inquisitive about her own need for help was key to moving forward in the help-seeking process.

Feeling Ready to Access Help

The second property of preparing to get help involved feeling ready. Some participants, who announced their unequivocal desire to seek help after engaging with the web-based app, attributed their decision to the character, Veronica. This included her presence overall and her insightful messages. One woman, struggling to cope with her life as a single mother said, "I've been having a lot of anxiety due to all my stress, just overall in my life." She expressed her enthusiasm and enhanced readiness to seek therapy by saying:

> *I guess just seeing Veronica and the way that she is and how she brought up good points. So, it's something that I would definitely be interested in doing.*

After coming to terms with Veronica's messages, another participant indicated that she was more prepared to take the risk of seeking help. She said, "I feel like I would give it a try, yeah. I would be interested to talk to someone." Another woman gained hope and optimism that therapy had the potential to improve her life:

> *Actually, all the stuff that she said, it's true. You shouldn't feel alone. You should always get help, especially when you're feeling down or depressed. If you get help, it's going to help you a lot, it's going to help you a lot. I don't know yet, because I haven't gone to get help, but I am pretty sure that if I could get help, I know it's going to help, and I know that's what I need.*

Having a Vision for the Kind of Therapist to Seek

The third property of preparing to get help involved desiring to find a therapist like Veronica. Participants were so moved by Veronica that some not only wanted to seek professional help but also wanted to find a therapist who was like her. One woman, who revealed that Veronica changed her thinking about seeking mental health care, shared that feeling comfortable with a therapist was a priority. She felt that it would maximize her ability to open up and talk more freely. She stated:

> *I was thinking about, I wish I could get in contact or help from a person like her. It makes me feel kind of, you know, when you feel fine about someone, that you can talk?*

Another participant expressed how the web-based app's depiction of a therapist like Veronica actually gave her hope. It provided the impetus to take the initiative to seek help for herself. She stated:

> *I wanted to believe that there will be another therapist like her as well. You know, like, that understands you. So, it just made me feel comfortable to actually take that step.*

Another woman who had thought about seeking help "plenty of times" but never followed through said, "I just worry so much, like, if they're really going to understand me." However, watching Veronica, she said, "If I had a therapist like her, I would not have a problem meeting with a therapist, honestly." This helped generate the motivation to plan for her course of action to enter therapy. As a result, she planned to "talk to my doctor. He'll recommend someone nearby my house."

Discussion

Principal Findings

Our web-based app, *Catalina: Confronting My Emotions*, offered our Latina participants a culturally acceptable digital bridge that ultimately led them to resources for getting the needed mental health care. Although the first step of the process of engagement with our web-based app involved participants identifying with Catalina, it was Veronica, the fictional nurse-therapist character, who served as the catalyst through the remaining steps of the process that led participants to options for action. Our sample became actively engaged with the web-based app and transitioned from the point of view of the *observer* to that of the *experiencer*, moving from a passive position of watching to an active engagement, guided by Veronica. This process included imagining, thinking, reflecting, and acting. No doubt the process of engagement started when participants recognized themselves in the relatable lead character of the story line, Catalina [29]; this put the metaphorical gears of the dynamic process in motion (Figure 1). However, it was engagement with Veronica, the nurse-therapist character, that soon became the focus of their experience as they clicked to open transmedia bonus videos and other features. Through this, participants shifted from a focus on how Veronica helped Catalina in the story to personally experience how Veronica was actually helping them in real time. As such, Bandura's dynamic of social modeling [26,47] was in motion first through Catalina and then through Veronica. By increasing engagement with the nurse-therapist character (Veronica), participants were able to apply her messages to themselves.

As Veronica's messages mattered to them, they digested them. They came from someone they saw as a knowledgeable, competent health professional, who they wanted to listen to and engage with. This messenger, Veronica, also seemed to really care. She was a nurse and a therapist, but, importantly, she was also a Latina woman who understood them. Veronica's messages prompted participants to replace previous assumptions with new perspectives on the healing potential of therapy and other mental health resources. As the old misconceptions about mental health were defused, the gears turned onward. The next phase of the dynamic process led participants to begin preparing themselves to take action. They were able to focus on when, how, and what they could do to make a change in their lives. The potency of Veronica's messages added to the power of our web-based app to become a conduit to care for our sample, over a third of whom took action to use a resource, get information, or make an appointment within one week of engagement [28].

As participants already found the Catalina character to be highly relatable, the bar was set high for any characters who followed in the web-based app's transmedia bonus videos. The results of our analysis showed that Veronica attracted and held the participants' attention, deepening engagement and investment in the web-based app experience. There is no doubt that this is in part due to the talent of the Hollywood actress who portrayed Veronica (Yareli Arizmendi). Participants saw Veronica as welcoming not only because of how she looked or the sound of her voice but also because of the way she conveyed a sense of loving care to participants. From a film-directing point of view, Veronica was meant to be a knowledgeable character who was also compassionate [48]. Data from participants indicated that Arizmedi's performance met the mark.

As we analyzed the transcripts from interviews with Latina women in this study, we found it impossible to tease apart participants' views of the character (Veronica) from the content of the messages she delivered. Participants seemed to perceive them as being integrated as one and the same. Many women incorporated the actual language used by Veronica into their own self-expression. Women voiced her words as their own, which suggests that the things she communicated rang true to them, most likely because they were relevant to their lives. This underscores the importance of partnering with members of the target group to allow *their* concerns to be central to the design of a storytelling mental health web-based app [21,22,49]. It also indicates that casting a talented actress who could powerfully and poignantly embody a character was vitally important.

Our scripts were based on the priorities of Latina women who had struggled with depression that we had identified in previous research [30,31,36-38]. This included Latina women's own past experiences with depression when alone or in therapy sessions with a therapist as well as lessons they learned and found valuable. As noted earlier, well before filming, the scripts were written by a Latinx script writer from Hollywood and revised with input from therapists. After filming, the first cut of the videos was vetted in theater testing by a sample of Latina women who fit the demographics of the target group [28]. This was done before our mixed methods study was implemented with symptomatic Latina women. The input from our participants for this analysis implies that the script indeed reflected what they needed to hear and that content was delivered in a way that they found easy to receive and absorb. Taking the messages from the script into account was not a passive act for them. Rather, the participants took an active role in the web-based app experience, considering its video content, as the story unfolded, clicking to watch each of the bonus videos and engaging in the interactive questions on screen as the story extended from a focus on Catalina to a focus on Veronica to a focus on them.

Participants became aware that distressing symptoms warranted professional help and their engagement with the web-based app expanded their vision of both the kind of help they wanted to find and where to get it. Interestingly, these are similar to the elements of mental health literacy that Jorn [13] described. It is possible that what helped facilitate this process was the compassion that the character, Veronica, expressed in her portrayal of a nurse therapist. Kemp et al [48] performed an analysis of compassionate mental health care delivered in digital form, such as through web-based apps. They defined compassion as having several elements that seem to pertain to the way that Veronica was perceived by Latina women in our sample. For example, through her gestures and words, Veronica conveyed awareness that many women have emotional struggles and need help. Participants saw Veronica as focused on helping by reducing suffering. Veronica also encouraged them to click the next link, engage with the interactive sequence, and think about what was holding them back. Participants could have chosen

to stop the web-based app engagement at any point in time and just turn it off. However, they continued, likely because of their connection to Veronica and because engagement felt useful to their own journey [21]. Although simultaneously being knowledgeable and caring in a way that Latina women welcomed, Veronica also modeled mental health literacy; she shared information about depression and anxiety, options for treatment, and where to get help [13]. Women responded with high interest, trust, and, ultimately, action.

Engagement with this web-based app created a unique space for participants, one that helped optimize mental health contemplation and led to action. It provided our Latina participants with an opportunity to experience what it might be like to have Catalina's therapist interact with them. In the interactive sequence of 5 short 2-minute videos [28], Veronica posed questions from the confidence ruler and the importance ruler based on motivational interviewing [41]. Participants could move through this sequence at their own pace, replay a video, or return to it later. This gave participants the choice to engage with Veronica through a back-and-forth experience of videos and questions. It included ample space for personal introspection, possibly contributing to their feeling that this might be what an actual therapeutic interaction felt like. Participants valued this experience, which further enhanced engagement; it is noteworthy that we had no attrition in this study [28].

Torous et al [14] have called for the creation of digital technologies that lead to increased access to care while fostering a therapeutic relationship. Our character-driven web-based app holds promise for moving in that direction. For example, although our purpose was to engage symptomatic Latina women and then connect them to sources of therapy and help, our results showed that engagement in our web-based app led to statistically significant drops in depression and anxiety scores, both 1 and 6 weeks after engagement [28]. It is possible that this was partially due to a kind of therapeutic alliance that women developed with Veronica. Although she was not providing live therapy to participants, she was interacting therapeutically with them to enhance their self-awareness, confidence, and sense of the importance of getting needed care. Veronica also normalized mental health symptoms and helped women feel less odd, thereby challenging the stigma associated with depression and anxiety. Overall, Veronica met the participants' needs.

Limitations and Next Steps

The findings of this analysis are not meant to be generalizable to all Latina women or to all Latina women with mental health symptoms. In addition, it is not generalizable to users of story-based apps, character-driven apps, or transmedia apps. Nonetheless, the knowledge generated here advances an understanding about important elements of mental health provider characters featured in storytelling web-based apps for underserved groups, specifically, English-speaking Latina women with depression and/or anxiety. Future research with a Spanish version of our web-based app is needed to test feasibility, acceptability, and efficacy with a sample of Spanish-speaking Latina women. In addition, a future randomized controlled trial with a much larger sample that is broader is needed to validate the study with evidence from symptomatic but untreated Latina women, both Spanish and English speakers, in comparison with an attention control. Potential extensions of this work include using a theory-driven approach to create additional character-driven webisodes or bonus videos that extend the story while supporting participants who are engaged in needed therapy (actual or virtual). Other interactive modules that are character-led and therapeutic could be created and tested in English and Spanish. Further exploration, development, and experimentation hold promise for gaining needed insight into the most potent uses of story-based features in mental health web-based apps. Finally, testing the web-based app with women of other ethnic groups or translation of the web-based app into languages other than English and Spanish would provide valuable insight related to helping other populations. Diverse, multidisciplinary teams will be crucial as we advance the science of web-based apps for health that use transmedia storytelling.

Conclusions

As researchers and developers continue to produce mental health apps, research and testing are crucial to identify the areas where we need to focus our efforts to provide effective web-based or app-related tools [23]. Our web-based app was both a useful conduit for mental health resources and an experience that was dynamically experienced by symptomatic Latina participants. Our positive results to date are likely due to many things including the theory-informed [26,45] process of development that we undertook and the multi-layered approach of drawing upon input from Latinx collaborators at every step. This analysis of qualitative data collected after use of the web-based app by the target group about their experience is crucial for informing the next step of app development. Although a theory-driven, collaborative, data-based approach is time consuming, it is key to creating web-based apps that are desirable and acceptable to a target group such as symptomatic Latina women and, therefore, more likely to be successful in meeting their needs.

Authors' Contributions

PS collected all data and led data analysis and interpretation of results; AM collaborated in data analysis and interpretation; MH designed the study and collaborated in data analysis and interpretation. MH was primary in overseeing the entire study. All authors collaborated in writing and editing the manuscript.

Conflicts of Interest

None declared.

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Edited by G Strudwick; submitted 16.07.20; peer-reviewed by H Coats, A Dominguez-Rodriguez; comments to author 28.09.20; revised version received 23.11.20; accepted 05.12.20; published 13.01.21.

Please cite as:
Soderlund PD, Martinez Hollingsworth AS, Heilemann MV
Participant Engagement in a Transmedia Storytelling Web-Based App Intervention for Mental Health of Latina Women: Qualitative Analysis
JMIR Ment Health 2021;8(1):e22575
URL: http://mental.jmir.org/2021/1/e22575/
doi:10.2196/22575
PMID:33439137

Original Paper

Individualized Web-Based Attention Training With Evidence-Based Counseling to Address HIV Treatment Adherence and Psychological Distress: Exploratory Cohort Study

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Abstract

Background: The prevalence of mood, trauma, and stressor-related disorders is disproportionately higher among people living with HIV than among individuals without the virus. Poor adherence to HIV treatment and heightened psychological distress have been linked to symptoms associated with these disorders.

Objective: The objective of this exploratory pilot study was to develop and implement an intervention that combined individualized web-based attention training with evidence-based counseling to promote HIV treatment adherence and reduce psychological distress among people living with HIV. The study targeted African American and Latino young men who have sex with men, two population groups in the US that continue to experience disparities in HIV treatment outcomes.

Methods: Study participants with elevated symptoms of depression and suboptimal adherence to antiretroviral therapy were recruited primarily through referrals from Los Angeles health and social service providers as well as postings on social media. Participants enrolled in the 4-week intervention received weekly counseling for adherence and daily access to web-based attention training via their personal mobile devices or computers.

Results: Of the 14 participants who began the intervention, 12 (86%) completed all sessions and study procedures. Using a pretest-posttest design, findings indicate significant improvements in adherence, depressive symptoms, and attention processing. Overall, the proportion of participants reporting low adherence to antiretroviral therapy declined from 42% at baseline to 25% at intervention completion (P=.02, phi=0.68). Mean depressive symptoms measured by the 9 item Patient Health Questionnaire (PHQ-9) showed a substantial reduction of 36% (P=.002, Cohen d=1.2). In addition, participants' attentional processing speeds for all types of stimuli pairings presented during attention training improved significantly (P=.01 and P=.02) and were accompanied by large effect sizes ranging from 0.78 to 1.0.

Conclusions: Our findings support the feasibility of web-based attention training combined with counseling to improve antiretroviral therapy adherence among patients with psychological distress. Future research should include a larger sample, a control group, and longer-term follow-up.

(JMIR Ment Health 2021;8(1):e18328) doi:10.2196/18328

KEYWORDS

depression; trauma; HIV; attention training; implicit cognition

Introduction

People living with HIV are disproportionately affected by depression and posttraumatic stress disorder (PTSD) [1,2]. Compared to the general population, studies have estimated prevalence rates among people living with HIV at two to three times higher for depression and up to nine times higher for PTSD [3,4]. While both disorders adversely affect adherence to antiretroviral therapy, symptoms of depression and PTSD, even at subclinical levels, weaken an individual's ability to effectively self-regulate the attention and cognitive processes required for consistent goal-directed behavior, such as following a long-term treatment regimen [5-7].

Research indicates that poor antiretroviral therapy adherence and engagement with HIV medical care are connected to difficulties that HIV patients face in controlling negative thoughts, memories, and impulses to effectively manage their attentional focus [8-12]. To meet the challenges associated with attaining their treatment goals, patients must learn to effectively employ cognitive self-regulatory skills, including attention control and the ability to flexibly shift attentional focus from emotionally negative health-compromising thoughts toward those that are positive or neutral and associated with favorable health outcomes [13,14].

Little research has focused on the development of interventions designed specifically to build the cognitive self-regulatory skills needed for optimal antiretroviral therapy adherence. There is, however, a growing body of empirical and theoretical evidence that demonstrates the efficacy of attention training approaches in developing these skills, thereby promoting consistent goal-directed behavior related to a wide variety of health concerns, including smoking, problem drinking, substance abuse, eating disorders, being overweight, and obesity [15-17]. Similarly, attention training procedures have demonstrated efficacy in addressing several mental health problems for both adults and adolescents, including anxiety disorders and major depression [18-21]. Such approaches provide structured training designed to strengthen an individual's ability to shift his or her attentional focus away from stimuli that provoke thoughts and memories associated with treatment avoidance and psychological distress and toward stimuli that promote treatment engagement and emotional well-being. In addition, the indirect nature of attention training approaches makes them appropriate for addressing the implicit or nonconscious thoughts, beliefs, and memories that are related to depression, anxiety, and trauma [22,23].

Despite promising research indicating the value of attention training in addressing both psychological and physical health outcomes, there is a paucity of research focused on the application of attention training among HIV patients with comorbid psychiatric symptoms [24]. Attention training is a clinically relevant approach given that negative attention biases are closely linked to depressed mood and a tendency for threat vigilance in connection with anxiety and trauma. The training of attention away from salient negative stimuli and toward neutral or positive stimuli could be used to improve treatment adherence, increase engagement with HIV medical care, and promote mental health functioning. To enhance treatment outcomes and the durability of attention training effects, individualized stimuli could be presented during each session, thereby addressing the salient thoughts, beliefs, memories, and images that trigger specific types of behavior or emotional responses for a given patient. Research indicates that individualized stimuli trigger stronger attention biases among study participants than general stimuli [25,26].

We conducted an exploratory pilot study to develop and implement an intervention consisting of a 4-week, web-based attention training program combined with evidence-based counseling to improve antiretroviral therapy adherence and reduce psychological distress among HIV patients. Individualized, web-based attention training, in combination with evidence-based counseling, has the potential to serve as an accessible approach that could be widely disseminated to reach individuals at risk for poor treatment outcomes due to suboptimal antiretroviral therapy adherence or psychological distress. As a first step in exploring this potential role, the study sought to develop and determine whether such an intervention approach could be efficiently deployed and conveniently delivered to patient populations disproportionately affected by HIV. African American and Latino young men who have sex with men represent two vulnerable patient populations in the US that suffer from persistent elevated viremia, disproportionately high HIV transmission rates, and low levels of engagement in the HIV care continuum [27]. Given the need for effective cognitive self-regulatory skills in maintaining consistent adherence and engagement with care amid elevated psychological distress and multiple psychosocial stressors (eg, HIV stigma, experiences of trauma, childhood abuse), the study provided an opportunity to evaluate the viability of intervention featuring web-based individualized attention training to reach these vulnerable patient populations.

Methods

Participants

The sample consisted of participants recruited for Project STEP (Steps Toward Embodying Positivity), an intervention designed to address HIV treatment adherence and depressive symptoms among African-American and Latino young men living with HIV in the Los Angeles metropolitan area. Participants in the intervention, which combined individualized web-based attention training with evidence-based counseling, were recruited primarily through referrals from health and social service providers and through postings on social media used by the target population (eg, Adam4Adam, Craigslist, Grindr).

Individuals who expressed interest in joining the study were screened in person or by phone to determine if they met the following 4 eligibility criteria: (1) African American or Latino male living with HIV; (2) 18- 29 years old, inclusive; (3) self-identified as gay, bisexual, or same-gender loving; and (4) depressive symptoms at mild or higher levels of severity based on self-report measures or suboptimal antiretroviral therapy adherence, two psychological and behavioral risk factors for poor HIV treatment outcomes that the intervention was designed to address.

Procedure

Upon meeting the inclusion criteria, participants were administered informed consent and then enrolled in the study. Assessments and interviews with participants were conducted by a study team member during face-to-face meetings. After completing procedures to elicit and assess their individualized stimuli (ie, brief thoughts related to treatment and mood changes), participants were scheduled for a second study meeting in which they were given an attention training tutorial and assessed for baseline reaction time performance. Upon finishing 4 weeks of attention training, participants were scheduled for a posttraining assessment within a week of their final training session. Participants received $50 each for completion of the baseline and final assessments and $5 for each weekly meeting attended. All procedures for recruitment, data collection, and confidentiality were reviewed and approved by the Institutional Review Board of Charles R. Drew University of Medicine and Science.

Measures

Overview

We collected study data through use of a self-administered computerized survey that participants completed during baseline and posttraining study visits. To gauge the preliminary impact of the intervention, the computerized survey included measures of adherence and depressive symptoms. To describe our sample, we administered questionnaires tapping demographic and health-related characteristics, anxiety and trauma symptoms, and psychosocial stressors (eg, HIV stigma and childhood sexual abuse). On average, participants completed survey items within 30 minutes.

Demographics

Participants provided basic sociodemographic data by completing a 22-item questionnaire that requested information related to age, ethnicity, education, employment, income, HIV serostatus, healthcare usage, and other personal characteristics.

Adherence

Self-reported adherence was assessed using a modified version of the visual analogue scale (VAS) [28,29]. In the scale used in this study, participants were presented with a horizontal number line divided into 4 segments to represent the percentage of HIV medication doses missed during the 4 days prior to the assessment (ie, 0%-25%; 25%-50%; 50%-75%; and 75%-100%). Using the number line, participants were instructed to indicate their adherence within 1 of the 4 categories. The final category encompassed moderate and high levels of adherence. Recent research suggests that newer formulations of antiretroviral therapy may allow some patients to achieve virologic suppression and immunological benefits with relatively moderate adherence levels [30-34]. The modified version of the scale was used to enhance its administration and reduce response bias.

Depressive Symptoms

Depressive symptoms during the 2 weeks prior to assessment were measured using the Patient Health Questionnaire-9 (PHQ-9) [35]. The PHQ-9 is a well-validated and widely-used brief instrument for assessing and monitoring depression severity. Depression scores derived from the PHQ-9 correspond to minimal (≤4), mild (5-9), moderate (10-14), moderately severe (15-19), or severe (≥20). Based on systematic reviews and a meta-analysis of the PHQ-9, a cutoff score of 10 or greater has been described as indicative of meeting diagnostic criteria for depression [35,36]. The instrument had a Cronbach alpha of .89.

Trauma Symptoms

The Posttraumatic Stress Checklist-Civilian Version [37] was used to measure trauma symptoms. The checklist is a 17-item self-report measure of PTSD symptoms. Participants were asked to respond to each item using a 5-point Likert scale response format. Scores on the instrument range from 17 to 85, with higher scores indicating greater symptom severity. A score of 30 has been recommended as the minimum threshold for the further evaluation of PTSD symptoms among individuals in a civilian population [38].

Anxiety

The Modified Mini Screen [39] was administered to gauge anxiety symptoms. It is a 22-item scale designed to identify individuals who may have psychiatric symptoms at levels that warrant further evaluation. We used 9 items from the scale to assess anxiety symptoms among participants, with scores of 6 or greater indicating elevated levels of anxiety.

Childhood Sexual Abuse

Two items from the Child Sexual Abuse Index [40] were used to identify participants who had been subjected to sexual abuse during childhood. Specifically, participants were asked to indicate whether before the age of 18 they experienced (1) unwanted sexual events and/or (2) sexual abuse or molestation. The Child Sexual Abuse Index also includes additional items in which participants indicated the type of sexual abuse, whether it involved violence or physical force, their age when the abuse occurred, and their relationship to the perpetrator(s).

HIV Stigma

To assess the presence of HIV stigma, we used the AIDS-Related Stigma Scale [41]. Participants were asked to respond (yes/no) to 6 dichotomous items pertaining to internalized negative beliefs and perceptions about people living with HIV.

Attention Training: Project STEP

The goal of attention training through Project STEP was twofold. First, it was designed to increase treatment adherence by teaching participants how to maintain their focus on thoughts that were approach-oriented with regard to treatment and to direct their focus away from thoughts that were avoidance-oriented. Second, to reduce depressive symptoms, attention training also sought to increase a participant's skill in quickly diverting attention away from those thoughts perceived as having an emotionally-negative valence and directing attention toward thoughts that were perceived as neutral or having an emotionally-positive valence. Attention training, delivered via a web-based app, used the participant's own

thoughts identified during an individualized assessment procedure.

During the assessment procedure, we elicited a wide range of personal thoughts and perceptions about treatment from participants through individual interviews. Thoughts related to positive and negative changes in the participants' emotional states were also elicited. Individual interviews were followed by administration of a computerized program in which participants were asked to quickly rate the similarity of paired combinations of their treatment-related thoughts as they appeared in random order on the computer screen. The computerized rating procedure is consistent with other research designed to identify implicit cognitive processes [42-44]. Ratings were subjected to multidimensional scaling analysis to generate 2D mappings that depicted how a participant's treatment-related thoughts, memories, and mental associations were associated with either treatment adherence or treatment avoidance. Multidimensional scaling analysis has been used and evaluated as an approach for the assessment of implicit cognitive processes [8,43,45]. Both implicit and explicit cognitive processes were captured through the assessment procedure.

Modified Dot-Probe Task

Attention training was delivered through a modified version of the dot-probe task, a spatially oriented computerized procedure employed to retrain attentional focus. Using a web-based version of the task developed for the present study, participants accessed the dot-probe task via their computer or mobile device and completed sessions at home. At the start of a training session trial, participants were asked to view the screen of their device and watch a fixation cross that was situated in the center of the screen. After 1000 ms, two stimuli consisting of contrasting thoughts that were elicited during individualized assessments replaced the cross and appeared simultaneously on opposite sides of the screen for approximately 2500 ms. Then, a dot-probe appeared on the screen in the location of one of the previous stimuli. At this time, participants were required to indicate the location of the dot-probe as quickly as possible by clicking on their cursor or touching the screen of their device. The probe always appeared in the location of the stimuli that were treatment approach-oriented and conveyed a neutral or positive emotional tone, thereby training participants to respond to these types of stimuli rather than to negative and treatment avoidance-oriented stimuli.

Each individualized training session lasted approximately 15 minutes and was presented in 4 blocks. A single training block was composed of 50 trials, with a trial consisting of each sequence from the appearance of the fixation cross to the onset of the dot-probe. Completion of a training session required that the participant finish all 4 blocks. Participants, who received a tutorial practice session on the use of the attention training program prior to beginning the intervention, were provided information on the rationale behind attention training, an explanation of attention training procedures, and explicit instructions in which both speed and accuracy were emphasized. To ensure they understood how to use the computerized program, participants were required to have an accuracy rate of 80% during the tutorial practice session before proceeding to actual intervention training. During the intervention, trial-by-trial feedback in the form of an audible signal alert was provided during attention training sessions to aid participants in reorienting their attentional focus. At the end of each block of training, participants were presented with a screen that showed their reaction time and accuracy rate for that specific training session. Participants were asked to complete at least three individualized training sessions at home on a daily basis for 4 consecutive weeks. With repeated trials, participants were expected to implicitly learn how to redirect or retrain their attentional focus toward neutral, positive, and approach-oriented stimuli and away from treatment avoidance-oriented stimuli associated with negative emotional states and poor health behaviors. To evaluate changes in the amount of time a participant required to shift their attentional focus from avoidance-oriented or negative thoughts toward those that were approach-oriented or positive/neutral (ie, attentional processing speed), we used reaction time measures collected during baseline and posttraining administrations of the modified dot-probe task.

Weekly Counseling

In addition to attention training, participants received weekly counseling related to HIV treatment adherence and cognitive self-regulation. Two intervention counselors, who matched the age, gender, and ethnic characteristics of the sample, were trained and supervised by the principal investigator, a licensed clinical psychologist. The first of the 4 counseling sessions focused on psychoeducational content, such as the role of thoughts in health behavior and affect. Participants were given information on techniques to identify and monitor their thoughts and were encouraged to discuss how attention training could be used to effectively manage their thought processes. During the subsequent 3 meetings, participants were presented with selected modules adapted from the Treatment Advocacy Program [46-48], an evidence-based individual level counseling intervention for people living with HIV. Modules were delivered by counselors in the form of PowerPoint slides via a laptop computer or iPad. Treatment Advocacy Program modules selected for this study provided participants with behavioral strategies and information pertaining to antiretroviral therapy adherence, mood management, and alcohol and substance use. Participants were also given information on local resources and provided with referrals when needed.

Data Analytic Strategy

Data analysis was performed using IBM SPSS 22.0. Due to the exploratory nature of the study and the corresponding small sample size, data analysis focused primarily on descriptive statistics. The full sample consisted of individuals who were enrolled into the study and completed baseline questionnaires. We examined data from the full sample (N=20) to characterize participants who met eligibility criteria and completed baseline measures. Most analyses presented in this report, however, are based on data from participants who completed the attention training intervention and final assessments (n=12). To compare participant characteristics based on study completion status, we used the Chi-square statistic for categorical variables and independent samples *t*-test for continuous variables. The

Chi-square statistic was also used to examine changes in adherence among participants from pre- to posttraining assessments.

We used *t*-tests to examine changes in mean numbers of depressive symptoms, reaction times, and accuracy scores. Reaction time analyses included reaction times only from correct responses. To reduce the influence of outliers, we eliminated reaction times that were 1.5 standard deviations above or below a participant's mean response time. This approach is consistent with other published research [49]. Effect sizes were calculated using the phi statistic for categorical variables (small effect=0.1; medium effect=0.3; large effect=0.5) and Cohen *d* for comparisons of means (small effect=0.2; medium effect=0.5; large effect=0.8) [50].The alpha level for all statistical tests was set at .05.

Results

Sample Description

African Americans comprised the majority of the full sample (12/20, 60%) and Latinos represented 40% (8/20). Mean participant age was 27 years (SD 1.7). Study participants identified as gay (15/20, 75%) or bisexual (5/20, 25%). Sixty-five percent of participants (13/20) indicated that they had completed high school, a high school equivalency credential, or some college, and 20% (4/20) reported graduating from college. Fifty-five percent of the full sample (11/20) had annual incomes below $20,000.

Adherence in the full sample was considerably below optimal levels, with the majority of participants (12/20, 60%) reporting adherence rates less than or equal to 75%. Participants experienced high levels of psychological distress. The mean depressive symptom score was 11.95 (SD 6.6), which is in the moderate range based on the PHQ-9 and is above the threshold widely used to suggest further evaluation for major depression. Fifty-five percent of participants in the full sample (11/20) reported elevated symptoms of anxiety. With regard to trauma symptoms, 40 percent (8/20) had symptoms at or above recommended screening level cutoffs for PTSD. Forty-five percent (9/20) reported unwanted sexual events, sexual abuse, or molestation before the age of 18. Eighty percent (16/20) reported experiencing internalized HIV stigma.

Of the 20 participants enrolled, 6 were excluded as they failed to attend a required study meeting for orientation to attention training procedures. Based on the remaining 14 participants who began attention training, the study completion rate was 86% (2 participants dropped out for unknown reasons before completing the protocol). There were no statistically significant differences between enrolled participants who completed the intervention and those who were excluded or dropped out with regard to demographics, adherence, depressive symptoms, or other assessed variables.

Attention Training

Participants were encouraged to complete at least three attention training sessions on a daily basis, for a total of 84 sessions during the intervention. The median number of training sessions among intervention completers was 48. All 12 study participants who completed the intervention attended each of the 4 weekly meetings with a study counselor.

Table 1 shows changes in attentional processing speed among study participants. Attentional processing was based on mean reaction times scores grouped by assessment period (baseline vs posttraining) and by stimuli pairing type (ie, positive-neutral, negative-neutral, positive-negative, and neutral-neutral). Participant reaction times to correctly identify the location of the dot-probe in each of the 4 stimuli pairings significantly declined from baseline to posttraining assessments, with large Cohen *d* effect sizes ranging 0.78 to 1.0. Participants experienced the greatest mean reduction in reaction times for the positive-negative stimulus pairings (369 ms), followed by positive-neutral pairings (353 ms).

Table 1. Mean dot-probe reaction time to stimuli presented at baseline and posttraining assessments (n=12).

Stimuli pairing	Baseline mean reaction time, ms (SD)	Posttraining mean reaction time, ms (SD)	Test statistic	*P* value
Positive-neutral	2553 (693)	2200 (375)	–3.25	.01
Negative-neutral	2579 (770)	2255 (414)	–2.71	.02
Positive-negative	2561 (677)	2192 (368)	–3.48	.01
Neutral-neutral	2483 (683)	2175 (331)	–3.23	.01

Accuracy scores for each of the 4 types of stimuli pairings during the baseline and posttraining assessments were calculated to provide a measure of the rate at which participants correctly responded when prompted to indicate the location of the dot-probe. The only statistically significant change in accuracy scores from baseline to posttraining assessments, however, occurred when participants responded to positive-negative stimuli pairings (94% vs 98%, respectively; t_{10}=4.05, *P*=.002).

Treatment Adherence

We examined the relationship between attention training and antiretroviral therapy adherence before and after the intervention by examining participant adherence rates based on a threshold of 75%. We categorized participants with adherence at or below this threshold as having "low" adherence and those with adherence above the threshold as having "moderate/high" adherence. In the current study, participants with low adherence reported rates between 50% to 75%. At baseline, 42% (5/12) of participants who completed the intervention had low adherence versus 58% (7/12) with moderate/high adherence. During the posttraining assessment, however, these percentages had shifted significantly with 75% (9/12) reporting adherence in the moderate/high range (Table 2). This change in adherence represented a large effect size (phi coefficient=.68).

Table 2. Changes in antiretroviral therapy adherence and number of depressive symptoms among intervention participants (n=12).

Characteristic	Baseline	Posttraining	Test statistic	*P* value
Adherence rate, n (%)			5.6	.02
≤75%	5 (42)	3 (25)	N/A[a]	N/A
>75%	7 (58)	9 (75)	N/A	N/A
Depressive symptoms, mean (SD)	13.4 (6.8)	8.6 (7.5)	3.71	.002
Symptom severity, n (%)				
Minimal (0-4)	1 (8)	3 (25)	N/A	N/A
Mild (5-9)	3 (25)	6 (50)	N/A	N/A
Moderate (10-14)	2 (17)	0 (0)	N/A	N/A
Moderately-severe (15-19)	4 (33)	2 (17)	N/A	N/A
Severe (20-27)	2 (17)	1 (8)	N/A	N/A

[a]N/A: not applicable.

Depressive Symptoms

Mean depressive symptoms among participants who completed the intervention declined significantly by 36% based on the PHQ-9, from 13.4 (SD 6.8) at baseline to 8.6 (SD 7.5) posttraining, (t_{11}= 4.16, *P*=.002; Cohen *d*=1.2, indicating a large effect size). The mean baseline score, which was in the moderate range with regard to depressive symptom severity, exceeded the cutoff of 10 widely used to suggest further diagnostic evaluation for major depression. The mean posttraining score, which fell below this cutoff, was clinically significant in that it represented an overall downward shift in symptom severity from the moderate to the mild range. As Table 2 shows, compared to baseline levels, there was a marked drop in the percentages of participants who experienced depressive symptoms in the moderate, moderate-severe, and severe ranges upon completing the study.

Discussion

Principal Findings

In this exploratory pilot study, we aimed to develop and implement an intervention consisting of individualized, web-based attention training combined with evidence-based counseling to promote adherence to antiretroviral therapy and reduce depressive symptoms among HIV patients experiencing elevated levels of psychological distress. Findings indicate that web-based attention training in addition to counseling can be efficiently deployed and conveniently delivered to a vulnerable HIV patient population with suboptimal antiretroviral therapy adherence and disproportionately high rates of depressive and PTSD symptoms. The intervention implemented in this study had a high completion rate (12/14, 86%), indicating strong viability as a clinical approach. Participants were able to access an individualized attention training program through their own mobile devices or computers, completing a median of 48 sessions during the 4-week attention training program, or the equivalent of approximately two sessions per day. Attention training combined with evidence-based counseling yielded considerable therapeutic benefits to intervention participants. We found statistically significant improvements among participants in antiretroviral therapy adherence from pre- to posttraining. In addition, we found both statistically and clinically significant reductions in depressive symptoms. Findings also showed notable improvements in attentional processing speed based on reaction time measures. Research suggests that improvements in processing speed play an important role in promoting everyday functioning and quality of life [51,52].

While participants in this study were assessed at only two time intervals, the study effectively employed strategies that could be used to maximize the benefits of attention training and strengthen the long-term durability of intervention outcomes. Our intervention used specific strategies (eg, performance feedback) to enhance the learning experience of study participants, drawing from recent research involving attention training [53-62]. Based on goal setting theory [63], these strategies included providing participants with explicit instructions, a clear statement of the training goal, and trial-by-trial feedback on performance (eg, reaction time changes; response accuracy rate). This study illustrates how individualized, web-based attention training for HIV patients with psychological distress could be employed in combination with psychotherapy.

Participants represented individuals who could most benefit from attention training due to the cognitive burden posed by multiple psychosocial stressors (eg, clinically-significant depressive symptoms, experiences of trauma and abuse, and internalized HIV stigma). Future studies, however, should be based on larger samples that include women and individuals representing a wider range of ages, geographic locations, and behavioral risk groups. Although studies support the validity of self-report measures of adherence [64], findings in this investigation could be bolstered by future research that incorporates biomedical measures of adherence. In addition, future studies should be designed to examine measures of cognitive self-regulation related to attention control, cognitive flexibility, and attention bias. Such measures would be derived based on administration of a standard dot-probe task where all stimuli are targeted with equal probability. This preliminary pilot study did not administer the standard dot-probe task.

Finally, to better understand the role of attention training in HIV patient outcomes, research should be conducted that tracks participants over longer time intervals with a design that incorporates other approaches and a control group.

Attention training has shown much promise as an approach to improve outcomes associated with a range of health behaviors and psychological disorders [15-21,24,65]. This exploratory study contributes to the literature on attention training by showing its clinical applications in addressing the impact of depressive and trauma symptoms on HIV treatment adherence. We were able to provide evidence of the ability of individualized, web-based attention training to yield favorable improvements in adherence and psychological distress in two vulnerable populations of HIV patients. Our findings provide support for additional exploration of this promising application.

Data Availability Statement

The raw data supporting the conclusions of this manuscript will be made available by the authors, without undue reservation, to any qualified researcher.

Acknowledgments

The authors would like to thank Kieran Breda-Hill, Wendell Glenn, Jahmil Lacey, Luis Mancilla, Kelvin Sterling Scott, Alan Stacy, and the Project STEP advisory board (Alonso Bautista, Juan Carmen, Antonio Castaneda, Thomas Davis, Abraham Estrada, Donta Morrison, and Maribel Prosas) for their assistance and support in completing this report.

The first author is supported by a grant from the National Institute on Minority Health and Health Disparities (NIMHD; S21 MD000103; David M Carlisle, MD, Principal Investigator). This research was supported by Grant 5U54MD007598 from NIMHD (Jaydutt V Vadgama, PhD, Principal Investigator).

Authors' Contributions

EH conceived and designed the study, performed data analysis, and wrote the manuscript. JSF and NTH contributed to the writing of the manuscript. CA performed data collection, organized the database, and performed data entry. SM developed attention training software and contributed to data collection activities. All authors agreed on the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

PHQ: Patient Health Questionnaire
PTSD: posttraumatic stress disorder

Edited by A Tsanas, G Eysenbach; submitted 19.02.20; peer-reviewed by I Wani, B Smith; comments to author 17.03.20; revised version received 31.03.20; accepted 03.04.20; published 28.01.21.

Please cite as:
Houston E, Fadardi JS, Harawa NT, Argueta C, Mukherjee S
Individualized Web-Based Attention Training With Evidence-Based Counseling to Address HIV Treatment Adherence and Psychological Distress: Exploratory Cohort Study
JMIR Ment Health 2021;8(1):e18328
URL: http://mental.jmir.org/2021/1/e18328/
doi:10.2196/18328
PMID:33507152

Viewpoint

Workshop on Implementation Science and Digital Therapeutics for Behavioral Health

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Abstract

Digital therapeutics can overcome many of the barriers to translation of evidence-based treatment for substance use, mental health, and other behavioral health conditions. Delivered via nearly ubiquitous platforms such as the web, smartphone applications, text messaging, and videoconferencing, digital therapeutics can transcend the time and geographic boundaries of traditional clinical settings so that individuals can access care when and where they need it. There is strong empirical support for digital therapeutic approaches for behavioral health, yet implementation science with regard to scaling use of digital therapeutics for behavioral health is still in its early stages. In this paper, we summarize the proceedings of a day-long workshop, "Implementation Science and Digital Therapeutics," sponsored and hosted by the Center for Technology and Behavioral Health at Dartmouth College. The Center for Technology and Behavioral Health is an interdisciplinary P30 Center of Excellence funded by the National Institute on Drug Abuse, with the mission of promoting state-of-the-technology and state-of-the-science for the development, evaluation, and sustainable implementation of digital therapeutic approaches for substance use and related conditions. Workshop presentations were grounded in current models of implementation science. Directions and opportunities for collaborative implementation science research to promote broad adoption of digital therapeutics for behavioral health are offered.

(JMIR Ment Health 2021;8(1):e17662) doi:10.2196/17662

KEYWORDS

mHealth; mobile health; digital health; telemedicine; eHealth; behavioral sciences; substance-related disorders; mental health; implementation science

Introduction

The research-to-practice gap is a significant challenge to the health care field, and translation of evidence-based practices for substance use and mental health conditions is no exception [1-3]. Recent data indicate only 11% of people in the United States with a substance use condition received treatment, and fewer than half (43%) of adults with a mental health condition received treatment [4]. Technology offers great promise for addressing many of the barriers to adoption of evidence-based treatments for behavioral health conditions.

Digital behavioral health therapeutics, delivered by way of familiar and nearly ubiquitous platforms such as the web, smartphone mobile applications, text messaging, video conferencing, and remote monitoring, can transcend the time and geographic boundaries of traditional settings so that broad audiences can access evidence-based care when and where they need it. The flexibility of technology and incorporation of mixed media (eg, text, audio, video, animation, avatars, virtual reality) allow for tailoring of content to meet individual needs across a range of learning styles to promote engagement, a key marker of intervention success [5]. Digital therapeutic tools improve consistency of delivery of key intervention components, enhancing fidelity, and usage data allow clinicians and researchers to evaluate whether users adhere to recommended doses. The broad accessibility of digital devices can be used to empower individuals to be more actively self-directed in their care.

There is strong and growing evidence for digital therapeutic approaches for substance use and mental health conditions [6-8]. The empirical literature includes studies of digital therapeutic approaches across the care continuum for a range of patient and client populations and in diverse settings. For example, there are a number of evidence-based digital screening and assessment tools that represent translation of existing validated screening and assessment instruments to web-based or mobile application platforms [9-13]. These tools have been evaluated in studies across a range of settings, including addiction and mental health treatment and primary care settings. Emerging empirical work also highlights the promise of wearable technologies and remote sensing for passive identification of symptoms such as drug craving, stress, depression, and schizophrenia [14-18]. For example, innovations in machine learning and digital phenotyping were used to predict substance use risk [19] and opioid overdose in community regions [20]. The literature highlights the exciting opportunities of digital screening and assessment strategies to identify substance use and mental health symptoms as a first step to timely delivery of appropriate treatment.

There is also strong and growing support for the effectiveness of digital treatment approaches for substance use and mental health conditions, across a range of substances (eg, tobacco, alcohol, marijuana, cocaine, opioids) and mental health diagnoses (eg, depression, anxiety, posttraumatic stress disorder, schizophrenia, bipolar disorder) and across a range of adolescent and adult populations. Digital therapeutic tools developed with foundations in evidence-based principles such as motivational enhancement, behavioral and cognitive behavioral therapies, and mindfulness have demonstrated positive impact on symptom management and behavior change for substance use [21-33] and mental health conditions [34-43]. There is also good evidence for digital therapeutic approaches to support recovery following treatment [44-46].

Yet, despite promising impact, digital behavioral health therapeutics have yet to see widespread uptake in practice. The implementation science with regard to scaling adoption and sustaining implementation of digital therapeutics for behavioral health is still in its early stages. The Center for Technology and Behavioral Health (CTBH) is a P30 "Center of Excellence" supported by the National Institute on Drug Abuse with the mission to promote state-of-the-technology and state-of-the-science related to development, evaluation, and sustainable implementation of digital therapeutic approaches for substance use and related behavioral health conditions. Three CTBH Cores, Treatment Development & Evaluation, Emerging Technologies & Data Analytics, and Dissemination & Implementation (D&I) Science, bring together a diverse team of national and international researchers with expertise in addiction science, behavioral health treatment, computer science and engineering, health economics, health services delivery, and implementation science. To promote transdisciplinary research collaborations, CTBH hosted a series of day-long workshops focused on Core missions, with past workshops in Emerging Technologies & Data Analytics [47] and Treatment Development & Evaluation [48]. In this paper, we summarize a workshop hosted by the D&I Core focused specifically on implementation science as related to digital therapeutics for behavioral health. In this paper, we summarize the proceedings of the workshop and offer directions for collaborative research to propel implementation science and promote broad adoption of digital therapeutics for behavioral health.

Methods

The day-long workshop, "Implementation Science and Digital Therapeutics," was conducted in December 2018 on the campus of Dartmouth College, and 9 CTBH-affiliated scientists were invited to present their work related to digital therapeutics for behavioral health. The presenters were primarily clinical researchers, representing addiction medicine, psychiatry, pediatrics, internal medicine, and behavioral economics. Presenters were encouraged to use implementation science models (eg, Consolidated Framework for Implementation Research [CFIR] [49] and Outcomes for Implementation Research [OIR] [50]) as guiding frameworks for the presentations and discussions. All of the studies presented at the workshop were approved by an institutional review board or were exempt from review (ie, quality improvement project).

Local CTBH faculty, trainees, students, and staff from all Center Cores at Dartmouth College were invited to attend the campus-based workshop. Of approximately 70 invitations, 50 participants attended the all-day meeting, representing computer science, engineering, user experience and interface design, biomedical data sciences, public health, addiction medicine, psychiatry, primary care, internal medicine, digital intervention research, and health services implementation research. The workshop audience was diverse in terms of gender and race/ethnicity representation. Although the majority of the attendees and speakers were from Dartmouth College, the insights from the workshop are broadly applicable.

Principles and Methods

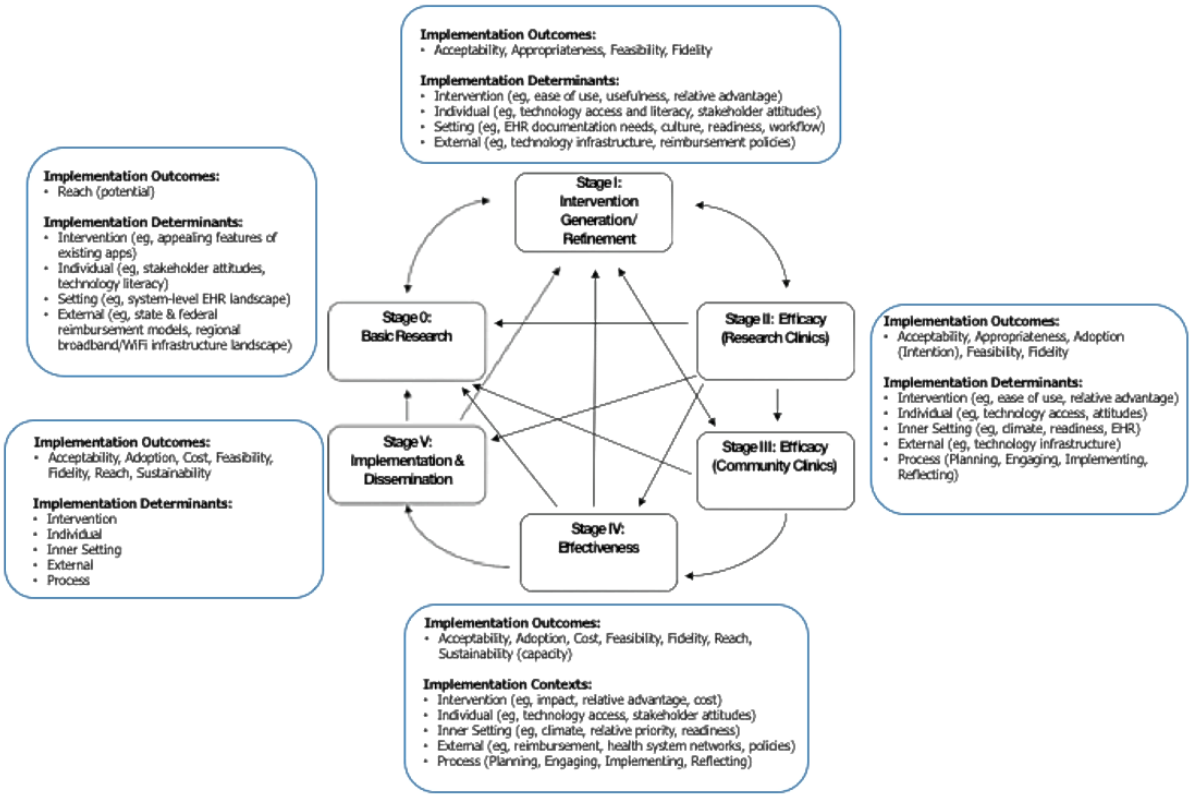
Overview of Implementation Science and Digital Therapeutics

D&I Core director Sarah Lord provided an overview of the CFIR [49] and OIR [50] as related to digital therapeutic research.

The CFIR, a comprehensive framework of contextual determinants associated with successful implementation of innovations in health care settings, can readily be applied to digital behavioral health therapeutics. The CFIR organizes implementation determinants representing characteristics of the innovation (eg, ease of use and perceived usefulness of a mobile app for opioid use and depression), characteristics of individuals using the innovation (eg, self-efficacy for using a mobile app, clinician attitudes about using technology for treatment), characteristics of the setting within which the digital therapeutic is intended to be used (eg, readiness of a primary care practice to use a mobile app with patients with identified opioid use disorder and depression), characteristics of the external ecosystem (eg, limited broadband and wireless infrastructure in rural regions, electronic health record requirements), and characteristics of the implementation process (eg, planning, engagement, execution, evaluation and reflection). The OIR framework outlines 8 outcomes of implementation research, including acceptability, adoption, appropriateness, feasibility, fidelity, reach, cost, and sustainability, that can be applied to digital therapeutic research [50]. Lord described how digital approaches, by nature of technology itself (eg, consistent delivery of intervention components, usage data capture), can enhance achievement and ongoing measurement of implementation outcomes (eg, fidelity, reach) and hold promise for advancing implementation science more broadly.

Lord described a rationale for incorporating an implementation science perspective throughout the stages of digital therapeutic development research to maximize potency of the digital therapeutic while also optimizing implementation, building upon the National Institutes of Health Stage Model of Treatment Development [51]. Lord presented an enhancement to the model that maps salient implementation outcomes and CFIR determinants at each stage of research and outlined what could be learned about implementation at each stage and how the approach could propel translational science of digital therapeutics in systems of care (Figure 1). The enhanced model could serve as an organizing framework and common language for behavioral health scientists, data scientists, implementation scientists, and technology developers to work together on a shared mission to most expeditiously develop potent digital behavioral health therapeutic approaches that can be broadly translated into systems of care. The enhanced model suggests anchors for measurement of implementation-related constructs at each stage to promote cross-study and cross-setting common data to address questions such as, "What characteristics of digital therapeutics, individual end users, health care settings, and the larger ecosystems facilitate or impede implementation outcomes?" A compendium of existing evidence-supported implementation outcome and determinant measures that could be used in digital therapeutic research can be found on the CTBH website [52].

Figure 1. Mapping implementation-related constructs to stages of digital therapeutic development research. EHR: electronic health record.



Implementation in Practice: Innovations in Adaptation and Evaluation

Keynote speaker Aimee Campbell highlighted models for adapting evidence-based digital interventions and evaluating implementation in systems of care. Campbell described adaptation of the evidence-based Therapeutic Education System (TES), a digital substance use treatment program grounded in the community reinforcement approach for substance use disorder [21], for use with American Indian (AI) and Alaskan

Native (AN) populations. As part of the formative work to inform adaptation, Campbell and team outlined key facilitators and barriers to implementation of TES demonstrated in a large clinical trial study in treatment settings [21]. Characteristics of the treatment setting facilitated TES implementation and intention to use TES. Clinicians' perceived social norms regarding use of TES in the agency influenced their intentions to implement TES [53]. Clinician involvement with TES improved clinician attitudes towards digital treatment and increased patient retention and adherence [54].

In a pilot with AI and AN adults seeking treatment, participants reported that TES provided important and relevant information, but lacked cultural relevance in delivery of the information [55]. Campbell described use of the ADAPT-ITT Model [56] to guide adaptation of TES for AI and AN populations. The iterative process involved potential end users in identifying areas for adaptation to improve cultural relevance of program content and delivery. Adaptations included use of AI and AN words and slang terms, use of Native actors in video depictions, and culturally relevant representations (eg, references to and depictions of nature). The process yielded an adapted TES version that was judged by clinician end users as having higher relative advantage and compatibility with treatment provision goals relative to usual care and that was highly acceptable to representative AI and AN patient end users [57]. The work of Campbell and colleagues highlighted the important role of end user engagement in adaptation of digital therapeutics for promoting intervention relevance and adoption.

Integrating Technology Into Practice

Technology Tools for Tobacco Use Disorder in People With Serious Mental Health Conditions: Implementation Factors

Mary Brunette described a program of research to develop and evaluate digital therapeutics for smoking among individuals with serious mental health conditions. Brunette outlined a user-centered design approach to develop a brief digital motivational intervention to promote initiation of the smoking cessation treatment, "Let's Talk About Smoking" (Figure 2) [58,59]. The iterative approach yielded a program that was reported as easy to use by the target population, a group with cognitive impairment and generally less computer experience. The program was also highly acceptable and more appealing than standard tobacco education to the population. In a pilot study of the single-session intervention, over 45% of those who used the program proceeded to enroll in smoking cessation treatment [60].

Figure 2. Feedback screen from the smoking cessation decision support tool, "Let's Talk About Smoking".

Brunette also described results of a web-based smoking cessation program grounded in cognitive behavioral therapy, "Let's Talk About Quitting Smoking" [33]. In pilot testing, 25% of participants reduced smoking, and 10% demonstrated bioverified abstinence at 2 months [33]. Clinician-identified barriers to ongoing implementation of the digital intervention included uncertainty about reimbursement for the intervention, lack of clinician buy-in for use of the technology, and the need for additional training and technical assistance for patient subgroups.

Scaling Up Science-Based Mental Health Interventions in Latin America

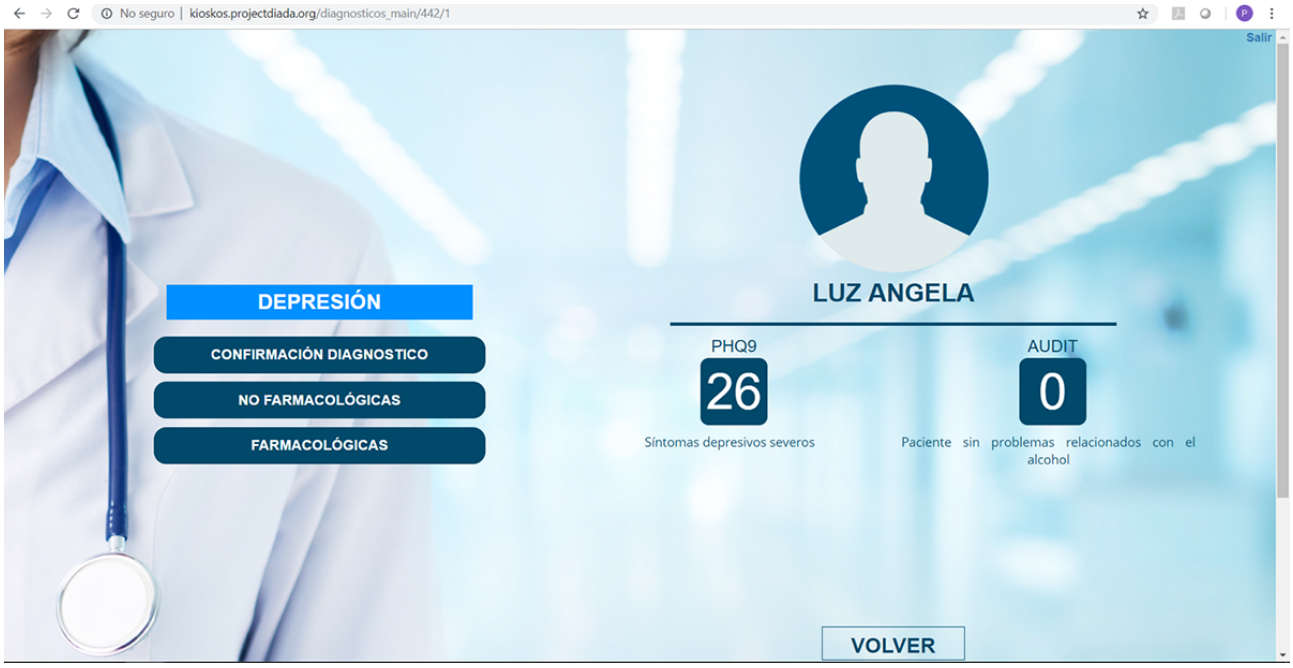
The next set of presentations highlighted a collaborative project, funded by the National Institute for Mental Health, being conducted by investigators at CTBH and clinicians and researchers in Latin America to integrate digital therapeutic services for depression and alcohol use disorder (AUD) in primary care settings in low- and middle-income countries (LMICs) in Latin America. Leonardo Cubillos prefaced the panel with a description of a systematic review evaluating implementation of integrated mental health care in LMICs. Cubillos presented a preliminary review of 58 articles

representing studies evaluating integrated mental health care in primary care settings in LMICs, with evidence to suggest that integration of mental health services improves outcomes for depression and alcohol use and is cost effective. Based on the review, Cubillos outlined a new typology of models of behavioral health integration that have been used in LMICs, including mental health care delivery by skilled and nonskilled mental health and primary care staff [61].

William Torrey and Sophia Bartels presented initial data from an implementation study to scale a technology-facilitated, evidence-based approach to addressing depression and AUD in primary care settings in Colombia. The researchers introduced a suite of digital tools in primary care settings that included (1) digital kiosks in the waiting rooms for patients to self-enter data to promote systematic screening for depression and AUD (Figure 3), (2) tablet-based decision support tools to guide the primary care physicians to use the screening information in their patient assessment for evaluation and diagnosis (Figure 4), and (3) a digital therapeutic for active treatment of patients found to have AUD and depression. The first phase of the implementation study was conducted in primary care settings in 6 regions of Colombia, representing urban and rural communities.

Figure 3. Primary care waiting room kiosk used for the screening of depression and alcohol use disorder.

Figure 4. Decision support tool for primary care physicians displaying patient scores for depression and alcohol use disorder screening.



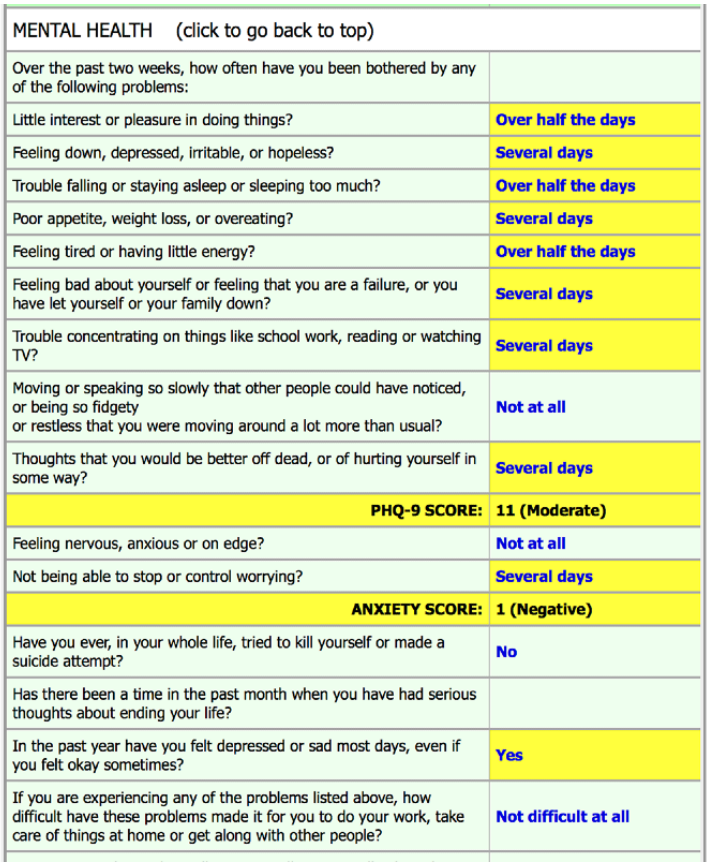
Torrey and Bartels described a methodical implementation process for the rollout of the new model of technology-driven care that included elicitation of patient, provider, and community member input through quantitative and qualitative methods to assess barriers to current processes for identifying and treating depression and AUD and to determine opportunities for integrating technology into the care workflow. Iterative engagement with primary care organization stakeholders informed strategies to build clinical capacities (eg, mental health training, technology training) and to develop technological infrastructure to support the digital components of the service suite. Implementation was evaluated with quantitative surveys and qualitative interviews to measure implementation outcomes and contextual determinants in addition to patient outcomes.

Preliminary results indicated good feasibility and acceptability of the integrated digital care model and positive perceptions of compatibility of the digital care model with current practice at the primary care settings, particularly in the urban communities in which the model was integrated. Primary care doctors increased the percentage of patients diagnosed as having depression and AUD from near 0% to 17% and 2%, respectively [62]. A flexible, supportive organizational climate and perceived fit of the intervention with the clinic practice facilitated integration. Difficulty engaging patients with AUD, low provider self-confidence for making a difference, social norms that support drinking, and physician concerns about labeling patients with a diagnosis were identified as barriers to diagnosing and treating patients in need. Poor technology infrastructure (eg, limited internet or WiFi capacity) in rural regions was also a barrier to uptake of the digital therapeutic tools. The presentations by Cubillos, Torrey, and Bartels highlighted how reverse innovations from research in low-resource countries can advance scientific knowledge for implementation of digital therapeutics in resource-limited regions of the United States.

Integration of Digital Therapeutics in Primary Care in the United States

The next presentations highlighted efforts by clinical researchers to integrate digital therapeutics into pediatric primary care and internal medicine settings. Ardis Olson described the >13-year process involved in the development and implementation of DartScreen, a digital health risk behavior screening tool, in pediatric practices (Figure 5). DartScreen was iteratively developed by primary care clinicians and an academic pediatrician as part of the Dartmouth primary care research network [63,64]. The content and delivery approach of the screener was informed by the American Medical Association Guidelines for Adolescent Preventive Services, including (1) using validated substance use and mental health screening tools (eg, CRAFFT, PHQ-2), (2) addressing patient readiness to change for key health risks, and (3) providing easily digestible results for clinicians to access at the beginning of the patient visit (eg, summary screen of health risks with scoring and risk levels highlighted). The initial DartScreen was administered on personal digital assistants. DartScreen is now available as a standalone web-based version implemented on tablets, as well as integrated in EPIC.

Figure 5. Patient-clinician collaborative review screen from DartScreen.



MENTAL HEALTH (click to go back to top)	
Over the past two weeks, how often have you been bothered by any of the following problems:	
Little interest or pleasure in doing things?	**Over half the days**
Feeling down, depressed, irritable, or hopeless?	**Several days**
Trouble falling or staying asleep or sleeping too much?	**Over half the days**
Poor appetite, weight loss, or overeating?	**Several days**
Feeling tired or having little energy?	**Over half the days**
Feeling bad about yourself or feeling that you are a failure, or you have let yourself or your family down?	**Several days**
Trouble concentrating on things like school work, reading or watching TV?	**Several days**
Moving or speaking so slowly that other people could have noticed, or being so fidgety or restless that you were moving around a lot more than usual?	**Not at all**
Thoughts that you would be better off dead, or of hurting yourself in some way?	**Several days**
PHQ-9 SCORE:	**11 (Moderate)**
Feeling nervous, anxious or on edge?	**Not at all**
Not being able to stop or control worrying?	**Several days**
ANXIETY SCORE:	**1 (Negative)**
Have you ever, in your whole life, tried to kill yourself or made a suicide attempt?	**No**
Has there been a time in the past month when you have had serious thoughts about ending your life?	
In the past year have you felt depressed or sad most days, even if you felt okay sometimes?	**Yes**
If you are experiencing any of the problems listed above, how difficult have these problems made it for you to do your work, take care of things at home or get along with other people?	**Not difficult at all**

The web-based version of DartScreen is being used in 13 pediatric practices throughout Vermont and New Hampshire and has reached over 20,000 adolescents, with demonstrated positive impact on adolescents' and pediatric clinicians' experiences of receiving and providing care. Adolescents who used DartScreen were more likely than controls to report being satisfied with their visit and being listened to by their provider and less likely to report that there was something they wanted to talk about with their provider but did not [65]. In a study of audio-recorded teen health visits before and after using DartScreen, use of DartScreen was associated with decreases in provider data gathering and counseling, increases in provider responsiveness and engagement with their patients, greater expressed attentiveness to patients, and more discussion about mental health topics [66]. Use of DartScreen was also associated with increases in teens' reporting of psychosocial information and engagement in dialogue [66].

In a survey study of clinicians who used DartScreen in their pediatric practice workflow, clinicians rated DartScreen as highly useful in the clinical process and easy to use [67]. Facilitators to adoption of DartScreen in practices included identifying a practice champion; demonstrating DartScreen to practice administrators, clinicians, and staff; and trialing of the digital screening tool by a subset of clinicians before progressing to full adoption into office procedures. Barriers to implementation included desire for integration of the screener with electronic health records, unreliability of technology infrastructure (eg, practice internet connectivity issues), and the screening taking too long for some adolescents.

Steven Chapman described integration of the DartScreen into the Dartmouth-Hitchcock Medical Center electronic medical record (EPIC) as a component of Screening, Brief Intervention, and Referral to Treatment (SBIRT) for adolescents and young adults in primary pediatric care. A multidisciplinary team collaborated in greenbelt sessions using a Six Sigma quality improvement methodology and a Define, Measure, Analyze, Improve, Control process to implement SBIRT. All teenagers from all pediatric practices in the Dartmouth-Hitchcock system were screened using the DartScreen tool. Screening rates were regularly above 80% after implementation. Fishbone analysis examining gaps in screener completion and brief intervention delivery indicated that researchers needed to refine workflow for administration of the screener, incorporate tools and prompts for clinicians, and provide training for clinicians in motivational interviewing and brief interventions. The presentation highlighted the benefits of a systematic approach to integration of an evidence-based digital approach into practice, using an institutional quality improvement framework, leveraging electronic medical records, and using co-design methodologies to promote relevance for stakeholders and buy-in.

Implementation Strategies for Addressing Rural Obesity Using Telehealth: Barriers, Facilitators, and Lessons Learned

Internist John Batsis described an early-stage study to evaluate a telemedicine intervention to increase reach of an evidence-based lifestyle program for adult patients with obesity. Batsis described strategies used to iteratively adapt in-person, group-based lifestyle intervention classes to be delivered

remotely to individuals (not as a group) via videoconferencing, based on clinician stakeholder feedback. Evaluation of implementation of the telemedicine approach demonstrated that a large majority of participants (>93%) found the telehealth platform easy to use and useful and would use the intervention in the future. The intervention reached 8.4% of potential participants referred to the intervention. There was preliminary evidence for efficacy of the 16-week telemedicine intervention for improving body mass index and waist circumference [68].

Clinicians perceived a number of advantages of the telemedicine intervention delivery, including expanded access to individuals from rural regions for whom in-person participation was a barrier and high confidence using the telehealth platform. Implementation barriers included clinicians' perceptions of reduction of patient-clinician rapport due to less face-to-face time, clinician fatigue from individualized delivery format to successive patients, practice-level scheduling and space constraints for delivery of the telehealth intervention, and unreliable patient technology infrastructure (eg, connectivity interruptions). Batsis outlined directions for future work to address barriers, including space and time to accommodate visits, inclusion of a one-on-one, in-person visit, and initial assessment of readiness to change to guide individualized treatment planning.

Economic and Policy Perspectives on Implementation Science for Behavioral Health

The final presenter, health economist Daniel Polsky, discussed the value that economists bring to implementation science, including informing decisions about whether evidence-based practice should be disseminated broadly and helping to determine how incentives can induce behavior change to enable broad dissemination of evidence-based digital therapeutics and improve return on investment for funding agencies. Economists can also lend insight into when to de-implement a practice that does not work in a given setting or with a given population. Polsky highlighted how stakeholder groups and disciplines view problems from different perspectives and noted that economists can help bridge divides between researchers and stakeholder groups, such as policy makers. Stakeholders are all interested in sustainability and access to innovative treatments; there is a significant need for research to be translated in ways that are relevant to all stakeholders. Polsky encouraged digital health researchers to include economists and policy stakeholders on study teams throughout the stages of digital intervention research to optimize potential for sustainability and broad system translation of digital therapeutics.

Discussion

To close the workshop, Edward Nunes, an addiction psychiatrist and Deputy Director for Intervention Studies in the CTBH Treatment Development and Evaluation Core, led a discussion during which panelists and workshop participants highlighted key themes and directions for future research, including accelerating evaluation through innovative development and implementation science methodologies, promoting academic-industry partnerships to accelerate evaluation and translation of digital therapeutic approaches for behavioral health, identifying strategies to promote awareness about and use of science-supported digital therapeutics, harnessing big data and predictive modeling strategies to promote implementation science for digital therapeutics, and addressing system context barriers.

Accelerate Evaluation Through Innovative Development and Implementation Science Methodologies

Workshop presentations highlighted the importance of user-centered development processes and engagement of the range of potential end users and stakeholders (eg, patients, clinicians, economists, policy makers) across all stages of digital intervention research to optimize potential for adoption and successful implementation. For example, the presentations by Olson and Chapman describing integration of the DartScreen in pediatric care demonstrated how early involvement of health system stakeholders, such as through practice-based research networks and Six Sigma quality improvement processes, promoted high buy-in from clinicians and alignment of the digital approach with clinical workflow to facilitate implementation sustainability of the screener in pediatric settings.

The use of small pilot studies to optimize intervention design and implementation with end users encourages engagement and can help avoid large investments in development and research only for an intervention to not be practically implementable. The broad accessibility of digital devices offers opportunities for trialing of digital therapeutics with patients and clients in diverse care settings to identify tailored implementation support strategies. The ability to easily trial an intervention promotes successful adoption and implementation [49].

The flexibility of technologies also allows for use of innovative study designs, such as factorial and microrandomized trials, to test different intervention components and the impact of different implementation strategies for promoting use of a given digital therapeutic [69-71]. Hybrid study designs that support evaluation of clinical effectiveness as well as implementation can more efficiently promote translation of digital therapeutics into practice [72]. These designs can also help to answer important scientific questions related to mechanisms of impact and heterogeneity of effects (ie, what works for whom and how, what determinants are most associated with successful implementation in different settings). Systematic evaluation of relevant implementation outcomes and determinants across the stages of digital therapeutic research can iteratively inform directions for refinement of the digital intervention and targets for implementation support. Use of common measurement tools to evaluate implementation constructs across stages can facilitate study replication and cross-study comparisons and build cumulative knowledge to accelerate development of digital therapeutics that are maximally potent and implementable in systems of care,.

Promote Academic-Industry Partnerships to Accelerate Evaluation and Translation of Digital Therapeutic Approaches for Behavioral Health

The workshop highlighted many examples of innovative and effective digital interventions but with limited broad adoption. There is a need for multidisciplinary teams that include a range of stakeholders (eg, patients, clinicians, researchers, technology developers, business experts, economists, and policy makers) to collaborate to develop effective and scalable digital therapeutics. The Food and Drug Administration, for example, has a new process for authorizing digital therapeutics, including for behavioral health (eg, reSET, Pear Therapeutics), that can serve as one model for fostering partnerships to propel translation.

There is also an abundance of behavior change apps in the commercial market space (ie, app stores) that may be helpful but have not been empirically evaluated. Unlike digital therapeutics developed within an academic research paradigm, commercial apps are often developed by business enterprises and commercial developers, with particular attention to promoting end-user engagement and broad dissemination. Initiatives to incentivize research teams to work with app developers to evaluate efficacy of commercially available apps can harness existing dissemination channels to promote scalability of evidence-supported digital therapeutics, particularly in direct-to-consumer markets (eg, app stores). An important component of such partnerships, however, is the ability to access internal usage data to understand how participants are using the apps. Since academic and industry stakeholders may have different motivations for a partnership, establishing clear guidelines for academic-industry partnerships at the outset to set expectations about issues such as roles, intellectual property, and access to and ownership of research-related usage data and algorithms may help to avoid later tensions and perceptions of conflict of interest for researchers.

Identify Strategies to Promote Awareness About and Use of Science-Supported Digital Therapeutics

Participants acknowledged the potential usefulness of a curated space for useful apps for clinicians to recommend to their patients or clients. There are now evidence-supported rating schemas for mobile apps [73]. CTBH also supports a continuously updated curated repository of summaries of empirical studies of digital therapeutics for behavioral health [74], and other organizations are developing rating repositories for mobile apps for mental health conditions [75]. Studies are needed to determine how to facilitate broad adoption and sustainable implementation of existing evidence-supported digital therapeutics with patient populations in diverse care settings.

Harness Big Data and Predictive Modeling Strategies to Promote Implementation Science for Digital Therapeutics

Recent studies highlight the potential of big data sources, such as Google and social media platforms (Twitter, Instagram), and innovative data analytic methods, such as deep neural networking, to predict substance use risk [19,20]. There is tremendous opportunity for collaborative research in the space of big data and novel analytics to identify individual needs and deliver personalized, “just-in-time” interventions using digital therapeutics. Social media platforms can be used to rapidly and inexpensively recruit representative patient and care setting stakeholders to test digital interventions as they are iteratively developed and to study optimal models for implementing digital therapeutics on these platforms.

Address System Context Barriers

Common system-level barriers emerged in the workshop presentations. The interface of digital therapeutics with the array of electronic health records remains a significant barrier. To facilitate uptake of digital therapeutics within health systems, there is important work to be done to identify what information from digital therapeutics is clinically relevant to include in electronic health record systems, what information is best suited for access by end users as desired outside of the electronic health record, and how to optimize the intersection of digital therapeutics with electronic health records. A focus on alignment of digital therapeutics with the documentation needs of electronic health records early in development can accelerate translation.

Technology infrastructure also continues to be a source of significant access disparity, particularly in rural regions. Broadband is still not available in many rural regions of the United States, and mobile WiFi infrastructure is often unreliable. Federal and state initiatives to improve technology infrastructure in rural communities would help to reduce access disparities in these regions and promote opportunities for scaling digital behavioral health approaches to individuals in these often medically underserved areas.

Conclusions

Digital therapeutic approaches to treatment of behavioral health conditions offer great potential for overcoming traditional barriers to widespread delivery of evidence-based care. Digital approaches have the potential to reach broad audiences with highly individualized care that can respond to an individual’s needs, preferences, culture, learning style, stage of recovery, and clinical trajectory over time. Individuals can control the pace of their treatment, and clinicians can augment their treatment practices with digital therapeutic tools to allow them to work at their highest level of training, to work with more patients or clients, and to focus more intensively on high-need clientele. This workshop highlighted important directions for digital behavioral health intervention research to promote broad adoption and optimize implementation of digital therapeutics for behavioral health conditions across diverse care settings and populations. CTBH, as an interdisciplinary community of researchers and practitioners, serves as an important resource to promote implementation science related to digital therapeutics. We encourage researchers and community and policy stakeholders to engage with us in this exciting work.

Acknowledgments

The workshop described in this manuscript and preparation of the manuscript itself were supported by the Center for Technology and Behavioral Health, a P30 Center of Excellence funded by the National Institute on Drug Abuse (P30: #5P30DA029926-05; PI: Lisa Marsch, PhD). reSET is a registered trademark of Pear Therapeutics.

Conflicts of Interest

SL, AC, MB, LC, SB, WT, AO, SC, JB, DP, and KS have no conflicts of interest. LM is affiliated with Square2 Systems Inc, HealthSim LLC, and Pear Therapeutics. These relationships are extensively managed by LM and her academic institution. EN served as unpaid consultant to Alkermes, Braeburn-Camurus and Pear Therapeutics, and has received in-kind medication for studies from Reckitt/Indivior, Alkermes, and a digital therapeutic for studies with Pear Therapeutics.

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Abbreviations

AI: American Indian
AN: Alaska Native
AUD: alcohol use disorder
CFIR: Consolidated Framework for Implementation Research
CTBH: The Center for Technology and Behavioral Health
D&I: Dissemination & Implementation
DMAIC: Define, Measure, Adapt, Improve, Control
LMIC: low- and middle-income countries
OIR: Outcomes of Implementation Research
SBIRT: screening, brief intervention, and referral to treatment
TES: Therapeutic Education System

Edited by J Torous; submitted 01.01.20; peer-reviewed by N Karnik, D Sugarman; comments to author 24.01.20; revised version received 22.05.20; accepted 24.05.20; published 28.01.21.

Please cite as:
Lord SE, Campbell ANC, Brunette MF, Cubillos L, Bartels SM, Torrey WC, Olson AL, Chapman SH, Batsis JA, Polsky D, Nunes EV, Seavey KM, Marsch LA
Workshop on Implementation Science and Digital Therapeutics for Behavioral Health
JMIR Ment Health 2021;8(1):e17662
URL: https://mental.jmir.org/2021/1/e17662
doi:10.2196/17662
PMID:33507151

Viewpoint

It Is Time to REACT: Opportunities for Digital Mental Health Apps to Reduce Mental Health Disparities in Racially and Ethnically Minoritized Groups

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Abstract

The behavioral health toll of the COVID-19 pandemic and systemic racism has directed increased attention to the potential of digital health as a way of improving access to and quality of behavioral health care. However, as the pandemic continues to widen health disparities in racially and ethnically minoritized groups, concerns arise around an increased reliance on digital health technologies exacerbating the digital divide and reinforcing rather than mitigating systemic health inequities in communities of color. As funding for digital mental health continues to surge, we offer five key recommendations on how the field can "REACT" to ensure the development of approaches that increase health equity by increasing real-world evidence, educating consumers and providers, utilizing adaptive interventions to optimize care, creating for diverse populations, and building trust. Recommendations highlight the need to take a strengths-based view when designing for racially and ethnically diverse populations and embracing the potential of digital approaches to address complex challenges.

(JMIR Ment Health 2021;8(1):e25456) doi:10.2196/25456

KEYWORDS

digital health; app; public mental health; health disparities; COVID-19; pandemic; mental health; disparity; behavior

Introduction

The dual public health crises of systemic racism and COVID-19 have significantly increased mental health needs while simultaneously limiting access to traditional models of in-person care [1,2]. The pandemic has critically strained an already overburdened system, magnifying existing shortcomings of the mental health system, including inequitable availability, access, and quality of care for the Black, Indigenous, and people of color (BIPOC) community. BIPOC continue to be disproportionately affected (emotionally and physically) by the virus, experiencing more hospitalizations and greater mortality rates as well as increased emotional distress [3,4]. Concurrently, these losses are occurring against a backdrop of inequities due to systemic racism including long-standing disenfranchisement from the health care system, historic traumas, stigma, high cost, and cultural insensitivity, which may put BIPOC communities at highest risk for not receiving mental health care [5,6]. These barriers have persisted in the wake of prior disasters, preventing BIPOC communities from accessing and utilizing mental health treatment after national tragedies [5]. Given the complex and intersecting clinical and social-contextual vulnerabilities that contribute to behavioral health inequities, an urgent need exists for innovative behavioral health approaches that support effective and accessible care to overcome, rather than perpetuate, existing health disparities.

Digital mental health (DMH) tools like mobile apps could play a key role in expanding access to care for those most impacted by COVID-19 and systemic racism by providing remote assessment, support, or intervention; lowering the cost of mental

health care; reducing transportation challenges; and providing care in a private and destigmatizing manner [7,8]. However, challenges remain including a lack of culturally grounded DMH interventions, minimal implementation data, low provider and consumer confidence in DMH quality, variability in provider competency in DMH, and lower digital access and literacy in groups at the highest risk for experiencing health care inequities. Digital inequalities span a multidimensional continuum that includes socioeconomic status and location [9], age [10], level of education [11], quality of social support network [12], immigration status [13], location, and health literacy [14]. These inequalities align with social determinants of health [15,16]; therefore, as reliance on digital health approaches increases, digital inequalities may further exacerbate existing health disparities and reduce health care access for those most likely to be affected by the ongoing crises.

In this viewpoint, we first provide a "pulse check" on the DMH field amidst the ongoing pandemic and provide five key corresponding recommendations to ensure optimal leveraging of DMH apps for increasing health equity and ensuring that innovation does not inadvertently widen the digital divide.

The Current DMH Landscape

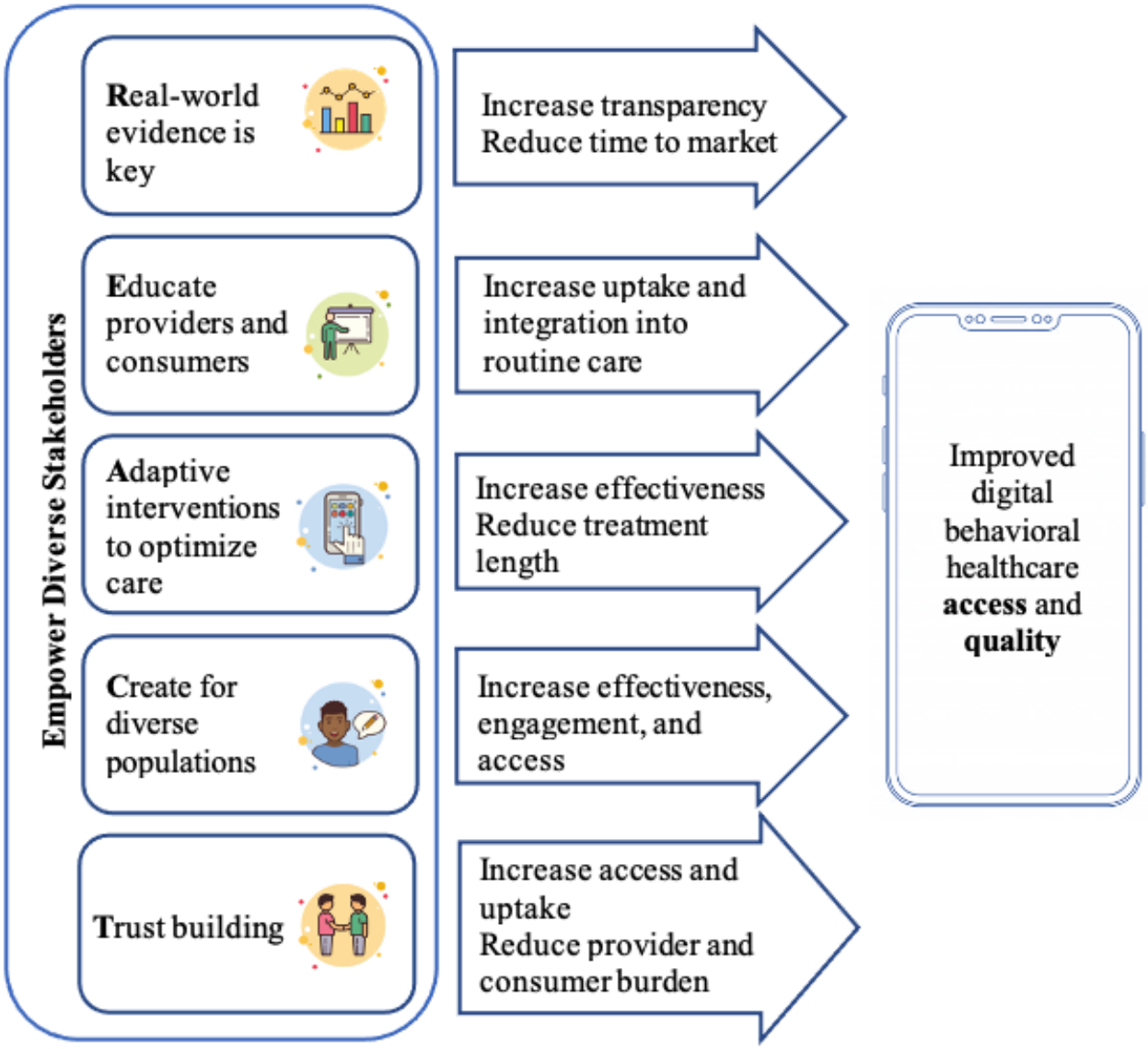
Given widespread availability and scalability, DMH apps have been lauded as a potential first line of defense for responding to the increase in behavioral health concerns precipitated by COVID-19 and systemic racism. Recognizing the need to increase access to effective and safe technologies that promote physical distancing, the US Food and Drug Administration (FDA) issued an Enforcement Policy on April 14, 2020, allowing the "…distribution and use of computerized behavioral therapy and other digital health therapeutic devices for psychiatric disorders…" without the requirement that those products comply with traditional regulatory policies. Additionally, the guidance reiterates and clarifies that low-risk wellness and digital health products—including apps that promote mindfulness, meditation, sleep, exercise, or manage mental health symptoms without providing a specific treatment—will continue to be exempt from FDA oversight. This important policy is consistent with the FDA's previously published emphasis on increasing access to inherently safe digital products for mental health and other medical conditions [17]. FDA guidance regarding mental health apps has the potential to spur innovation, but it can also increase ambiguity in a marketplace already marred with concerns of real-world engagement [18] and a limited evidence base [19,20].

The COVID-19 pandemic has stimulated continued interest and investment in digital health approaches. In the first half of 2020, digital behavioral health startup companies reported record funding of over $588 million, roughly the annual funding for this market in any previous full year, reflecting an industry-wide perception of growing demand for DMH products [21,22]. Continued growth, however, portends continued saturation of the marketplace with apps that make unwarranted claims, offer minimal protection of user data, or are ineffective [23-25]. Health care providers, patients, and their families are at once faced with the promise of leveraging easy-to-access digital tools such as apps, and the daunting challenge of choosing from the 10,000+ DMH apps available [26,27]. The lack of reliable, easily accessible efficacy and safety data around these products continues to impede clinician and consumer ability to make effective health care choices. Reliance on the "wisdom of the crowd" to guide decision making is not advised since, among other reasons, user ratings do not correlate well with clinical utility or quality [27].

Recommendations

We offer five key recommendations on how the mental health care and technology fields can "REACT" to ensure the development of approaches that increase health equity by increasing *real-world* evidence, *educating* consumers and providers, utilizing *adaptive* interventions to optimize care, *creating* for diverse populations, and building *trust* (Figure 1). As highlighted in Figure 1, these recommendations will only be effective through increased representation of and collaboration with BIPOC researchers, policymakers, educators, providers, developers, and payers, requiring the removal of structural barriers in academia and industry.

Figure 1. Ecosystem-wide recommendations to increase digital mental health access and quality.



1. Real-World Evidence Is Key

DMH apps developed for both underrepresented and majority populations have been hindered by a lack of real-world effectiveness data and a paucity of implementation trials [28]. The lack of timely effectiveness data prohibits consumers and medical providers from making informed choices, reducing trust and uptake. Implementation science offers frameworks and methodologies applicable to both increasing sustained use of new technologies and more rapidly evaluating digital products [29]. Drawing on implementation science and human-computer interaction, the Accelerated Creation to Sustainment model [30] offers an alternative approach to traditional clinical evaluation methods that can take over 10 years to move an intervention from conceptualization to implementation [31]. This approach proposes an iterative process of design and evaluation across three phases (create, trial, sustain) and may be facilitated by real-time engagement and outcomes data gathered by the device itself. This approach highlights the need to utilize user-centered design [32,33] to support both the development of a product and an associated implementation and sustainment strategy. In the trial phase, products and implementation strategies are concurrently tested in "real-world" settings utilizing Optimization, Effectiveness, and Implementation studies that explore effectiveness and implementation outcomes. Outcomes such as fidelity, adoption, uptake, and cost are particularly important to track to ensure new technologies are acceptable to a diverse population of consumers. Finally, in the sustainment phase, ongoing passive or low-effort data collection informs continued optimization as the research team transfers responsibilities to clinical or organizational staff.

2. Educate Providers and Consumers

As the field moves toward generating a more robust and easily interpretable evidence base for specific apps, providers and consumers must be empowered with alternative strategies to make informed decisions on which apps to utilize in clinical practice. The American Psychiatric Association's app evaluation framework offers a guiding framework for providers and consumers to self-evaluate apps [34]. In principle, this framework offers a much-needed solution to a complex problem, but it also places a potentially high burden on providers to

evaluate digital therapies, which the framework itself notes is "not what psychiatrists and mental health clinicians are classically trained to do [provide]" [35]. Given these challenges, it is unclear how provider evaluation of mental health apps will practically fit into the workflow for clinicians.

Moreover, given that a substantial proportion of mental health services is rendered through primary care [36], additional steps need to be taken to help provide primary care providers with the necessary information to make informed decisions about app selection for their patients. It is therefore critical to train both primary care and mental health professionals in digital technologies to support patient care. Frameworks for digital competencies in mental health have primarily focused on telehealth and do not fully address integration of broader products including the prescription of digital therapeutics or integration of apps to support treatment [37,38]. There must be a synergistic balance between providers being empowered to effectively choose and evaluate digital products on an individual basis for their patients, and more transparent and accessible information on individual products. The balance may be facilitated by the inclusion of a digital specialist or "digital navigator" [39]. Finally, broader provider and stakeholder education is critical as lack of understanding or knowledge of digital approaches is a key barrier to DMH uptake and adoption [40].

3. Adaptive Interventions to Optimize Care

Digital approaches offer the opportunity to develop adaptable interventions that provide tailored content based on individual characteristics, such as race, gender, sexual identities, family structure, and language preferences [41]. The pandemic has further highlighted the potential for external stressors to exacerbate previously managed chronic mental health concerns and the need to flexibly ramp up care. We can leverage novel clinical trial methodologies (eg, the Multiphase Optimization Strategy [42] and sequential, multiple assignment, randomized trials (SMART) [43]) to develop adaptive DMH interventions that adjust the type or dosage of the intervention based on patient characteristics. SMART trials facilitate this development by randomizing patients to different treatment options across time based on predetermined decision points, allowing for an assessment of effectiveness for different interventions at each stage. These novel designs allow for the evaluation of the tailoring variables and intervention components in the same trial. Moreover, they support the development of decision rules for assigning treatments based on patient characteristics and response to interventions, rather than a priori decisions. This can result in shorter and more targeted interventions.

4. Create DMH Apps for a Diverse Population of Users

Considerable work is required to ensure the availability of DMH products that fit a wide range of user needs and preferences. Efforts have been hampered by the underrepresentation of BIPOC researchers and developers, calling for fundamental shifts to address structural barriers in academics and industry. In order for digital technologies to recognize their full potential to mitigate widening behavioral health disparities exacerbated by the COVID-19 pandemic and ongoing cultural-based traumas, they must be designed with those who are both at most risk for mental health concerns and who face the greatest barriers to health care engagement. At risk of oversimplification, this fundamentally calls for us to follow the core principle of designing for the end user [32]. This includes both the type and way we utilize technology to deliver care and the intervention content we deliver. Human- or user-centered design approaches that ask the question, "What are the barriers to receiving effective behavioral health care and how can technology help overcome them?" must be used to develop strategies that mitigate disparities. However, such approaches must engage consumers whose voices are traditionally underrepresented in care settings. Culturally salient recruitment strategies [44], which include addressing community mistrust, participant resource constraints, and potential risks (eg, community stigma), could help researchers and developers more effectively integrate the input of those consumers most likely to benefit from their products [45].

BIPOC underrepresentation in the product development process has potentially reinforced structural inequalities in our health care system by limiting the availability of products that are culturally inclusive and effective [8]. The lack of culturally appropriate tailoring, stakeholder input, and broader community-partnered implementation plans limits the effectiveness of DMH tools, leads to decreased uptake, and may contribute to lower rates of DMH utilization in BIPOC populations despite equal or higher preferences for using DMH apps compared to White peers [46,47]. To increase potential effectiveness and uptake, cultural tailoring must go beyond language translation to incorporate cultural values, norms, and references [48]. This tailoring offers the opportunity to capitalize on community or cultural resiliency factors offering opportunities to increase efficacy of interventions in addition to improved engagement. Finally, digital technologies offer the opportunity to develop intervention approaches that are not as inherently embedded in cultural paradigms or at minimum are language agnostic (eg, attentional bias modification) [49].

5. Trust Building Through Monitoring and Independent Vetting

As we work toward the development and rapid real-world evaluation of DMH approaches for diverse populations, there is a strong need for a sustainable ecosystem to increase consumer and provider confidence, and empower users and providers to effectively choose appropriate and effective DMH interventions based on their specific needs and context. At an aspirational level, there are several approaches that could help increase this confidence.

Increase Industry and Marketplace Self-Monitoring

Across all DMH products, there must be increased industry pressure to self-monitor, conduct rigorous research, and disseminate results in a manner that is interpretable by both consumers and providers. A potential short-term step toward this end is clear reporting of digital products released under the COVID-19–related FDA guidance to ensure company accountability to consumers and facilitate uptake of new low-risk products. On the open app marketplace, the inclusion of clear, easily interpretable statements regarding potential efficacy and risks, including data security, must be encouraged.

A review of 73 popular apps found that none of these evaluations or membership in app libraries were noted in their app store descriptions [27], suggesting a potential lack of awareness of these schemes outside academic communities or that accreditation could benefit companies. App stores could therefore provide a more standardized way to include reporting of clinical testing results [50]. It is recognized that these recommendations introduce burden to companies and, without enforcement-related contingencies, are unlikely to be fully effective. Nevertheless, continued dialogue among stakeholders, including patient and advocacy groups, providers, and DMH companies, will help advance the field.

Independent Vetting and Structured Dissemination of DMH Products

The lack of reliable, easily accessible efficacy and safety data impedes clinician and consumer ability to make effective health care choices. Digital formularies that provide a curated list of clinically supported DMH products could be an important mechanism for enabling dissemination of products including apps into clinical care [51]. Formularies could integrate into electronic health records and associated patient portals, allowing both patients and providers to know which products are supported by their health care organization. Indeed, some steps have been taken in this regard, and lessons learned from these efforts will be important to refine the approach [52,53]. Similarly, the development of independently curated app libraries [54,55] takes a clear step toward increasing transparency around the safety and potential efficacy of apps outside of a formalized health system. However, attempts are hindered by the vast quantity and rapidly changing nature of products on the market. Conscious of the challenges of keeping up with this massively expanding and growing field, the FDA's Digital Health Precertification Pilot Program [56] shifts regulations toward the app developers and manufactures themselves, allowing for products to be developed efficiently through rapid iteration more appropriate for digital products, therefore reducing the need for burdensome hurdles to be cleared with frequent software changes, etc. For this to be successful, there must be an understanding between regulators and developers of a consensus framework for product evaluation. In addition, there must be adequate incentives for engagement in any regulatory programs, as prior voluntary certification attempts have failed [57].

Conclusion

COVID-19 and increased awareness of systemic racism have highlighted the promises and pitfalls of DMH. As interest in DMH grows, we have the opportunity and responsibility to increase the availability of safe, effective, and accessible products that reduce rather than perpetuate health disparities. This will require synergistic collaboration among researchers, policymakers, educators, providers, developers, payers, and patients. As researchers and clinicians, we are well positioned to lead this charge; however, we must embrace the rapid nature of technological innovation and development. Concerns around the increasing digital divide must serve as a "wake up call" for the DMH field to ensure products and mHealth (mobile health) approaches are tackling health care disparities rather than contributing to them. Rather than "designing down" to reduce the complexity of interventions for populations with more limited digital literacy, we must take a strengths-based view of designing for diverse populations [8]. By embracing these strengths, digital health has the opportunity to increase access to care for the most vulnerable populations. Finally, fundamental shifts to address structural inequalities in academics and industry, including the underrepresentation of BIPOC researchers and developers, are needed to revolutionize our field.

Acknowledgments

This work was supported in part by the Multi-Health Systems-Conners Fellowship in Digital Health.

Conflicts of Interest

SHK has received research support and/or consulting fees from a number of digital health companies, including Akili Interactive, BehaVR, Limbix, Luoms Labs, OnDosis, Sana Health, and Tali Health. SHK has stock options in Akili Interactive.

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Abbreviations

BIPOC: Black, Indigenous, and people of color
DMH: digital mental health
FDA: Food and Drug Administration
mHealth: mobile health
SMART: sequential, multiple assignment, randomized trials

Edited by J Torous; submitted 02.11.20; peer-reviewed by T Cosco, J Torous; comments to author 03.12.20; revised version received 23.12.20; accepted 23.12.20; published 26.01.21.

Please cite as:
Friis-Healy EA, Nagy GA, Kollins SH
It Is Time to REACT: Opportunities for Digital Mental Health Apps to Reduce Mental Health Disparities in Racially and Ethnically Minoritized Groups
JMIR Ment Health 2021;8(1):e25456
URL: http://mental.jmir.org/2021/1/e25456/
doi:10.2196/25456
PMID:33406050

Original Paper

Considerations in Designing Digital Peer Support for Mental Health: Interview Study Among Users of a Digital Support System (Buddy Project)

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Abstract

Background: Peer support is an approach to cope with mental illness, and technology provides a way to facilitate peer support. However, there are barriers to seeking support in offline and technology-mediated contexts.

Objective: This study aims to uncover potential ways to design digital mental health peer support systems and to outline a set of principles for future designers to consider as they embark on designing these systems. By learning how existing systems are used by people in daily life and by centering their experiences, we can better understand how to design mental health peer support technologies that foreground people's needs. One existing digital peer support system is Buddy Project, the case study in this paper.

Methods: This paper reports on an interview study with Buddy Project users (N=13). Data were analyzed using the constant comparative approach.

Results: Individuals matched through Buddy Project developed supportive friendships with one another, leading them to become each other's peer supporters in their respective journeys. It was not only the mental health peer support that was important to participants but also being able to connect over other parts of their lives and identities. The design of Buddy Project provided a sense of anonymity and separation from pre-existing ties, making it easier for participants to disclose struggles; moreover, the pairs appreciated being able to browse each other's social media pages before connecting. Buddy Project has an explicit mission to prevent suicide and demonstrates this mission across its online platforms, which helps reduce the stigma around mental health within the peer support space. Pairs were matched based on shared interests and identities. This choice aided the pairs in developing meaningful, compatible, and supportive relationships with each other, where they felt seen and understood. However, the pairs were concerned that matching based on a shared mental health diagnosis may lead to sharing unhealthy coping mechanisms or comparing themselves and the severity of their experiences with their peers.

Conclusions: The results of this study shed light on desirable features of a digital mental health peer support system: matching peers based on interests and identities that they self-identify with; having an explicit mental health–related mission coupled with social media and other web-based presences to signal that discussing mental health is safe within the peer support ecosystem; and not matching peers based on a broad mental health diagnosis. However, if the diagnosis is important, this matching should account for illness severity and educate peers on how to provide support while avoiding suggesting unhelpful coping mechanisms; allowing for some degree of anonymity and control over how peers present themselves to each other; and providing relevant information and tools to potential peers to help them decide if they would like to embark on a relationship with their matched peer before connecting with them.

(JMIR Ment Health 2021;8(1):e21819) doi:10.2196/21819

KEYWORDS

mental health; peer support; technology; design; digital peer support; mHealth; digital health; internet

Introduction

Mental health is a topic of utmost importance to public health. Nearly 20% of US adults live with a mental illness, with the majority never accessing care [1]. Every day, an average of 129 Americans die by suicide [2]. In 2017, it was estimated that 18.9% of all US adults had a mental, behavioral, or emotional disorder [1]. More specifically, young adults aged from 18 to 25 years had the highest prevalence of mental illness (25.8%) among other age groups; however, the percentage of young adults who received mental health services was lower (38.4%) than adults of other age groups [1]. Although young adults tend to be one of the most vulnerable groups with respect to mental illnesses, their mental health care needs often remain unmet [3]. As a result of mental illness, suicidal ideations are estimated to affect 25% of young adults, with helplessness being the most reported motive [4].

The major barriers to accessing and seeking mental health care include stigma associated with mental illness, shortage of trained professionals, treatment costs, concerns about confidentiality, lack of knowledge of resources, and inaccessibility of services [5,6]. Furthermore, the United States is projected to have shortages in most types of mental health care providers by 2025 [7]. As such, new approaches that can complement or expand the capacity of mental health care are needed. One such approach is to facilitate seeking and finding social and peer support.

Social support and peer support are well-established approaches to cope with illnesses, including mental illness [8]; however, when struggling with mental illness, seeking and finding appropriate support is difficult [9]. One key mechanism through which social and peer support may be accessed is through technology and the internet [10]. Peer support, typically exchanged between individuals who share an experience, can facilitate accessing social support by providing information support regarding professional help [11] and emotional and esteem support by boosting one's self-esteem [11], increasing hope [12], reducing the feeling of isolation [13], and allowing peers to feel that they belong to a community [14].

Previous work [10,11,14-16] has established the benefits of creating technology-mediated support systems, including the option to use pseudonyms, an opportunity for social interaction, increased accessibility to a wide range of coping mechanisms and support tools, an increased likelihood of seeking help, a better chance of finding a destigmatized conversation space, and being part of a positive and supportive community of similar individuals. In addition, individuals experiencing mental illness often face unique barriers to build friendships or other social connections [15,17]. An example is social anxiety, which may lead to lower friendship quality or the fear of being rejected or embarrassed [18]. Therefore, using the internet as a way to develop these social connections has proved to be helpful. More broadly, young adults are reluctant to seek professional face-to-face help for their mental health conditions [19]. Therefore, examining other mechanisms that might be helpful to their coping and engagement with peer support is important.

Reports show that approximately 90% of American adults use the internet [20]. In fact, a growing portion of young adults use the internet to access mental health resources [21]. The moment an individual takes the first step to find support and connect to others is a critical point in their illness journey [22], whether that is seeking peer support or other types of care. However, with some exceptions [15], design guidelines for mental health technologies have mostly focused on systems that bring individuals with mental illness in contact with their providers rather than peers [23]. In fact, technology design for peers to support each other has lagged behind other technological innovations for mental health [24]. Although we know that peer support is helpful in coping with and managing mental illness [16] and that technology has the potential to facilitate this coping process [13], there remains a need to interrogate existing peer support systems for their success or lack thereof and learn from them to contribute to our knowledge about how technology-mediated mental health peer support may be designed. By learning how existing systems are used by people in their natural settings and by centering on their experiences, we can better understand how to design peer support technologies that center people's needs. We address this gap by taking Buddy Project [25], an online peer support system for mental health and a nonprofit organization, as a case study. Buddy Project is a peer support system interested in fostering friendship, peer support, and connection, which is one aspect of mental health care. Buddy Project is not a replacement for formal treatment or a place to monitor mental health.

Buddy Project

For this study, we turned to Buddy Project, an online peer-to-peer support system that aims at fostering relationships that provide support to those struggling with mental illness. Buddy Project was founded in 2015 by Gabby Frost, a young person who wanted to prevent suicide and self-harm while advocating for mental health. Buddy Project's mission to prevent suicide is now displayed on the website's home page and in its Twitter and Instagram biographies (Figure 1). So far, the nonprofit movement has paired more than 236,000 adolescents aged between 12 and 25 years. Participants are matched based on age difference and shared interests and connected using their social media accounts (Twitter or Instagram). The sign-up process is shown in Figure 2, where users choose the social media account they want to use. Peers are then redirected to a Google form. On the first page, they provide their email address, first name, and Twitter or Instagram username, depending on the sign-up process they selected. On the second page, peers rank their first to fifth *interests*. A complete list of the interest options is included in Multimedia Appendix 1. We developed higher-level themes for these interests to gain a better sense of what they include. Interests categories include arts and entertainment (eg, musicians, television shows, books), identity (eg, religion, political ideologies, gender, and sexuality), and time zones. The third page prompts peers to provide their age.

The last page informs peers what to expect once they submit the Google form. It states that they will receive an email once paired with their buddy, that their selection is not automatic, and that peers are welcome to sign up for multiple buddies, along with the links to Buddy Project's website, Instagram, Twitter, and Facebook accounts.

Buddy Project's founder manually pairs all of the buddies using a Microsoft Excel spreadsheet. When pairing buddies, they take into consideration the interests they selected when signing up and their age. If someone wants to refuse a buddy, they can simply do so by not connecting with them once paired, and they can sign up to be paired with someone else. There is currently no formal training offered to buddies because buddies sign up to make friends who understand them (and thus can provide them with peer support), not provide or receive any type of professional help or crisis counseling.

We conducted in-depth semistructured interviews with 13 Buddy Project users.

Figure 1. Buddy Project mission statements on Instagram biography.

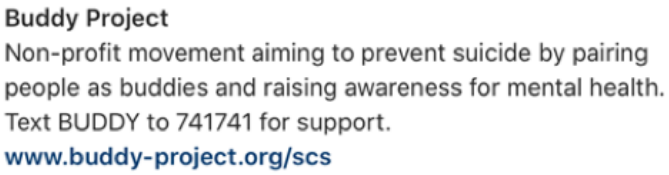
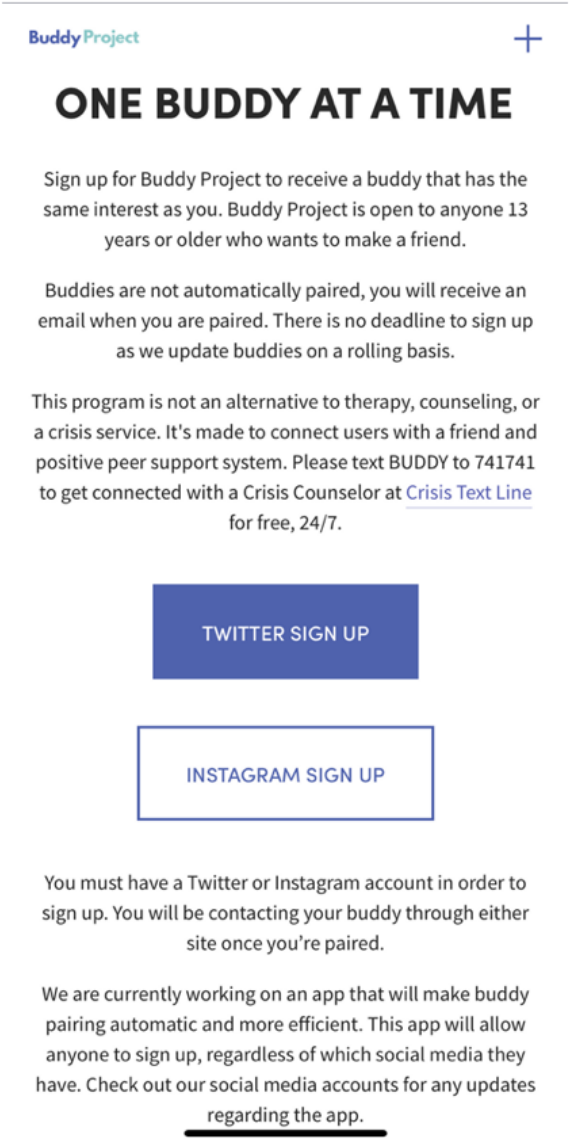


Figure 2. The sign-up page on the Buddy Project website.



Literature Review

Social and Peer Support for Mental Health

Social support is crucial for maintaining well-being [8]. Broadly defined, social support is characterized by meaningful interactions that provide some sort of support [26-28]. Social support can take many forms, such as emotional (communicating care and compassion), esteem (communicating confidence in one's ability), informational (providing information, advice, and tips), network (communicating that one is not alone and that there are many others who understand them), and tangible or instrumental support (providing tangible help and services) [29]. Receiving adequate and appropriate social support improves mental health and well-being [30]. For example, emotional and esteem support are successful in reducing the impact of a negative, unhealthy view of oneself by providing individuals with a higher sense of self-worth [31].

Gaining mental health support poses challenges because it can be time consuming, draining, and costly, and those affected by mental illness may have additional personal or social barriers to build friendships or connections [22]. For example, some may feel uncomfortable or unequipped to approach people or communicate in person to receive support or may have cognitive or social impairments, hindering their ability to seek and receive social support [22]. A main challenge in coping with mental illness is the stigma surrounding it, which is the idea that if one seeks or receives help, they are weak, incapable of taking care of themselves, or are inferior to people who can cope with mental illness on their own [11]. Stigma creates a barrier that prevents people from accessing or acquiring information about mental health resources [13]. Increasing communication about mental health–related topics, coping mechanisms, and common emotions reduces the perceived embarrassment associated with these conversations [32]. Although seeking help online can be beneficial in part because it can limit the consequences of stigma, there is still space to remove barriers to seeking help.

The dominant method of promoting mental health is providing clinical mental health services via professionals such as psychologists, psychotherapists, or social workers. However, most people with mental health disorders receive no treatment [33]. A complementary approach to seeking formal treatments is engaging in peer support. Peer support refers to the support that people with lived experience of an illness or condition (eg, mental illness) can provide to one another [34]. The key principles of peer support include respect, shared responsibility, and an agreement of what is helpful [35]. Peer support's importance as a key recovery service for people with mental illnesses has been established globally [36].

Digital Peer Support and Mental Health

Technology is increasingly applied to deliver peer support to individuals with mental health conditions [37]. Digital peer support is defined as peer support mediated through technology [38]. Technologies such as support forums and groups, mental health–focused mobile apps, and more broadly social media, have the potential to facilitate finding social and peer support and coping with mental illness. Along with increasing the amount of social support one receives [39], peer support can complement other resources (eg, professional therapy) one may use to cope with mental illness. The support one can obtain from a trained professional is qualitatively different from the type of support that one can receive from similar others with comparable lived experiences [40].

Research has focused on developing and evaluating mental health apps. Mental health apps provide features such as information, monitoring medications and symptoms, telepsychiatry, cognitive behavioral therapy, and support groups [41]. However, interest in using mental health apps does not mean actual high usage of these apps [42-47].

Extant research also shows how people turn to online communities to seek and exchange social support with many similar others [48,49] and express themselves [50]. Some online spaces also afford one-on-one peer-to-peer support, which allows peers to connect over personal experiences [51]. Regardless of whether conversations are one-to-many (ie, one post from one person to many recipients) as in the case of forums or one-on-one as in the case of private chats, because of this shared experience, individuals feel more connected, less alone, and less ashamed of what they are going through [13]. Moreover, finding support online can be crucial for some more than others; for example, individuals with intersecting marginalized identities often find safe online communities *necessary* to receive social support [48]. Some degree of anonymity present in some peer support technologies (eg, allowing the use of pseudonyms rather than enforcing the use of physical world identities) removes barriers to seek support when facing stigma, making social support a more attainable coping resource for some in comparison with nonanonymous settings (eg, in other online spaces) [22].

Online and offline, peer-to-peer support unites individuals with mental health conditions, providing them the opportunity to engage in sharing experiences, feelings, coping mechanisms, advice, and support to improve their mental health condition [15]. Although traditional face-to-face communication cannot be replaced with technology [49], connecting with peers via the internet allows for widespread accessibility and often an easier way for users to engage with one another [13].

In summary, digital peer support for mental health is an emerging and promising research space that has the potential to help improve mental health conditions, self-management skill development, social functioning, hope, and empowerment [38]. A systematic literature review on digital peer support interventions found that digital peer support interventions are feasible and acceptable, with high potential for clinical effectiveness [52]. Furthermore, peer support has the potential to improve and change not just how we approach mental health but also social change more broadly [53].

It is important to learn from existing services and platforms that employ technology for mental health peer support in settings outside of controlled research studies (in the real world) to examine users' perceptions and inform the design of future digital peer support systems. We turn to Buddy Project (described earlier) as a case study to do exactly that.

Methods

Recruitment

The recruitment process began with a screening survey that the Buddy Project organization shared on their Twitter and Instagram accounts. To participate in the survey, participants needed to (1) be a social media user, (2) live in the United States, (3) be at least 18 years old, and (4) be a current or previous user of Buddy Project. Being a social media user was important for us to situate Buddy Project within other online support systems that participants may have used. If they met these qualifications, participants were asked to complete the second portion of the survey that asked questions about demographics, social media use, length of longest relationship with buddies, number of buddies they had matched with, month and year when they first used Buddy Project, and overall experience with their buddies. We did not screen participants on the basis of mental health status or diagnosis, as we were interested in learning experiences with Buddy Project, and Buddy Project does not match buddies based on the diagnosis. The survey was open from June 12 to 25, 2019, and received 123 responses. From the responses, 63 participants met the initial criteria, 38 were invited to participate in the study, and 13 were interviewed. We sent an interview invitation to all qualified participants who had consistent survey responses (eg, the time of their longest relationship with a buddy did not extend past the date of when they started using Buddy Project) and had used Buddy Project within the last 2 years. We also purposefully recruited participants from diverse demographics to the extent possible. The invitation included study details and an online consent form. A total of 13 individuals completed these forms and participated in the interview. Table 1 includes the details of participants. We continued recruiting participants through the interview process and stopped when no new themes emerged. We offered a US $15 gift card to interview participants. This study was approved by our institutional review board.

Apart from assisting with recruitment, Buddy Project had no other role in any part of this study. We plan to share this paper with the founder after peer review.

Table 1. Participant details.

Participant[a]	Age (years)	Gender	Race	Education	Living area	Social media	User status	When they joined BP[b]	Total buddy count	Longest relationship	Overall experience
P1	19	Woman	Latina	Some college	Urban	TW[c], SC[d], TB[e]	Previous	2015	1	4 years	Both positive and negative
P2	19	Woman	Black	Some college	Urban	FB[f], TW, IG[g], SC, TB	Previous	2017	4	A few months	Mostly positive
P3	25	Man	White	Some graduate school	Urban	FB, TW, IG	Current	Mid-2018	1	Almost a year	Mostly positive
P4	20	Woman	South Asian	Some college	Urban	FB, TW, IG, SC	Current	2018	2	6 months	Mostly positive
P5	23	Man	White	Some graduate school	Urban	FB, TW, IG, SC, TB	Previous	Mid-2014	5 to 10	4 years	Mostly positive
P6	24	Woman	White	College	Rural	FB, TW, IG, SC	Current	Mid-2018	1	1 year	Mostly positive
P7	20	Woman	White	Some college	Urban	FB, TW, IG, SC	Previous	2018	1	A few months	Mostly positive
P8	18	Woman	White	High school	Urban	FB, TW, IG, TB	Current	April 2019	1	1 month	Mostly positive
P9	18	Nonbinary	White	High school	Rural	TW, SC, TB	Current	2014	4	2 years	Mostly positive
P10	20	Woman	White	Some college	Rural	FB, TW, IG, SC, TB	Previous	2017	2	4-5 months (still check in once in a while)	Mostly positive
P11	19	Woman	White	Some college	Rural	FB, IG, SC	Previous	Mid-2018	3	6 months	Mostly positive
P12	19	Gender-fluid	White	Some college	Rural	TW, IG, SC, TB	Current	2017	5	9 months	Mostly positive
P13	20	Woman	Asian	Some college	Rural	FB, SC, TB, RD[h]	Previous	2015	6	A couple of months	Both positive and negative

[a]Participants typed their gender and race, and we report the terms they used to describe themselves.

[b]BP: Buddy Project.

[c]TW: Twitter.

[d]SC: Snapchat.

[e]TB: Tumblr.

[f]FB: Facebook.

[g]IG: Instagram.

[h]RD: Reddit.

Interviews and Data Collection

Participants included 10 women, 1 man, 1 nonbinary, and 1 gender-fluid person. The average age of participants was 20.3 (SD 2.25) years (range 18-25 years). In total, 6 participants lived in rural areas, and 7 lived in urban areas; 9 participants were White, 1 was Black, 1 was Latina, 1 was Asian, and 1 was South Asian. A total of 7 participants had previously used Buddy Project but were no longer active users and 6 were current users. The number of buddies ranged from 1 to 10, and the length of contact with a buddy ranged from 1 month to 4 years. A total of 11 participants described their experience with Buddy Project

as being positive overall, whereas 2 described it as both positive and negative.

We conducted in-depth semistructured interviews that allowed participants to provide details about their experiences with their buddies while still covering topics regarding their experience with Buddy Project. The interviews were conducted via participants' preferred method of voice or video call, and the audio was transcribed for analysis. The average length of the interviews was 47 min (range 28-56 min).

The interviews began with the interviewer sharing the goals of the study and asking for permission to record the conversation. The participants were then asked about internet and social media use before diving into their stories and experiences with Buddy Project. We asked to hear the story of how the participant found Buddy Project, why they started participating, why they continued or stopped connecting with their buddies, what the relationship with their buddy was like, and what topics they discussed. We asked questions about perceptions of the shared interest feature and their best and worst buddy experiences. We continued with questions regarding how their buddies compared with other friends, online and offline, and when relevant, they were probed about how they used Buddy Project to cope with mental illness or distress and how this compared with their other coping mechanisms (if any). It was important to us that participants only discussed experiences they felt absolutely comfortable with; therefore, we only probed on specific mental health experiences only if they mentioned the topic organically. We paid particular attention to a unique feature of Buddy Project, that is, the way buddies are matched based on the *interests* they select when they sign up. The interview protocol is available in Multimedia Appendix 2.

Analysis

We started coding the data with an open coding procedure using Dedoose—a software for analyzing qualitative data. We followed the constant comparative approach [54], where we looked for patterns, consistencies, and differences in the data in an iterative manner. Specifically, one author coded one interview. Then, the 2 authors met with each other to discuss and refine the codes. The same author then coded 4 more interviews, for a total of 5, and the authors met to sort codes into themes and to further discuss and refine each code and theme. The same author then coded the next 8 interviews with these codes in mind, and the 2 authors met frequently to continue refining the themes. No further codes or themes emerged in the latter process.

Results

We provide an overview of how participants connected with their buddies. Overall, participants used a variety of communication tools to connect with their buddies, including social media, text messages, video calls, and phone calls, with the most common being messaging and social media, which was most convenient for long-distance buddies so they did not have to pay data and messaging rates. These channels also protected buddies from releasing their phone numbers. One participant (P5) spent 2 weeks in person visiting her buddy. Communication frequency varied from multiple times a day to just enough interaction to stay in contact.

In the remainder of this section, we report 4 key themes that were derived from our analysis of participants' experiences that contribute to Buddy Project's success: building a support system for buddies, a stated and visible mission to prevent suicide in Buddy Project's official online presence, matching buddies based on shared interests and identities, and not matching buddies based on shared diagnosis.

Building a Peer Support System for Buddies

Buddies Providing Peer Support

Participants shared reflections on how buddies provided peer support. For example, P11 emphasized the importance of peer support and how Buddy Project contributes to making meaningful supportive connections:

> *I think [Buddy Project is] one of the most amazing things that there is, especially in terms of promoting your mental health...and having friends [that] actually are there for you and [Buddy Project is] trying to connect you to people with those interests [so that] you have those friends.*

P11 gave an example of what the friendship with her buddy is like and how they exchange social support when she said the following:

> *They [the buddy] were definitely always trying to make sure the other person was happy no matter what the situation they just went through was… they were actually just very good about everything no matter how difficult a situation. They wouldn't go to bed unless you were okay and they were always there. That's just, I think, something everyone needs.*

P8 touched on how her friendship with her buddy counteracts loneliness when she said: "I did feel more lonely before [having the buddy] ... But now I feel, I think, like I'm friends with someone."

Referring to buddies as *friends* and these connections as *something everyone needs* are important demonstrations of what important gaps buddies fill in participants' lives.

Buddies found that having the *option* to talk about mental health was important but not a necessary part of daily conversations with their buddies. Having someone who is simply there to talk about their struggles *as needed* is something that P5 found beneficial. She described the supportive relationship that she had with her buddy as follows:

> *Being there for each other when we need it, when we're both low. Knowing how to help each other feel better but just knowing that the other person is there if you just need to vent completely. They'll listen and understand and if they have anything to say, being able to say something that might help.*

Similarly, P6 said:

> *I think it's important to have someone that doesn't have a bias, that shares in your issues. Her and I*

> *actually don't talk about mental health that much, but we both have this understanding that we both have issues, and we both want someone just to talk to when we need to.*

Participants did not talk to their buddies about mental health challenges all the time nor did they want to; however, *knowing* that they *could* do so should they wish, was comforting and a unique aspect of buddies' relationships with one another compared with their other relationships. These examples illustrate buddies providing emotional support (ie, communicating care and compassion) to each other.

Participants also noted sharing advice and tips, a type of informational support, to their buddies. For example, P9 described their relationship with their buddy as follows:

> *They got from the very basic, where do you live and whatnot, to asking about family life and being able to talk about like, "Oh, this is going on in my mental health region," and giving each other advice on how to deal with it. And if things got too bad, they would stop me and be like, "Hey, you should talk to your parents about this or someone around you."*

Similarly, P13 noted the following:

> *I was giving the type of advice or comfort that I was trying to seek from other people. . .it's how I help my friends. . .I did the same for my buddies.*

Sense of Anonymity and Separation From Existing Known Ties

Participants noted that difficulties in disclosing mental health or other sensitive information with peers or friends (not buddies) included privacy concerns and not trusting that the other person would keep their information confidential. In contrast, with buddies, a sense of anonymity and separation of buddies from networks of known ties eased difficulties in feeling safe to share intimate information with others. P4 described it as follows:

> *If I were to come out to a friend, even if they're a friend I trust, there's still a part of this bigger circle that I'm in. They could always tell other friends, or they could accidentally slip up and tell a classmate, or a coworker, things like that. Whereas, my buddy, we're geographically is in a different realm. I know it'll stay between us and if it doesn't I don't have to worry about who they're sharing things with.*

Peers may be unwilling to disclose their struggles with mental illness with known (not anonymous) peers in their social circles for a variety of reasons, such as the stigma surrounding mental illness (or talking about it), lack of helpful skills to effectively do so [55], or privacy concerns [56]. Buddies were often desired, in part, because they were perceived to likely be outside of one's network of existing ties and without connections to one's existing social network.

Although for some the separation from one's network of known ties was helpful and provided a sense of desired anonymity, there were still other cases where the amount of afforded anonymity with buddies was insufficient. For example, P13 described how she used a completely anonymous forum as a mental health resource:

> *If I had a whole long thing that I needed to just rant about or get advice on but I wasn't comfortable talking to anyone in my life or even a buddy, I would go on the forum.*

We see how although buddies were helpful, participants still felt the need to seek other resources to find the support they needed sometimes. Nevertheless, in this example, we see the unique position the buddy had in participants' lives such that they could not talk about certain things *even* with a buddy. In this sense, a forum provided more anonymity than the buddy, whereas a buddy provided more anonymity compared with one's in-person friends. As such, following previous work [57], we conceptualized anonymity as a continuum rather than a binary.

Although human connections can be supportive and helpful, they can also cause harm. Buddy Project provides participants with the Twitter or Instagram username of their peer match, which participants often used to ease worry about connecting with a total stranger. P10 noted the following:

> *It's an easy way to connect to people that's safer [than connecting with a random stranger] because you're connecting me to social media so you can see who the person is and you can know a little about them just by scrolling through profiles and it's not you're just talking to a random stranger.*

Connecting with strangers on the internet is often a concern for those who seek online support [15]. When participants were able to gather cues on social media to assess the buddy, they felt safer to begin a conversation with them.

A Stated Mission to Prevent Suicide on Official Buddy Project's Online Presence

Mental illness can prevent people from feeling included and connected with peers, often categorizing those diagnosed as minorities, creating even more disconnection from one's broader social environment. Overcoming stigma is often the first step to seeking and receiving support for mental illness [58]. Creating a safe space for discussing mental illness often requires a commitment to destigmatization, and Buddy Project is doing exactly that with their explicit mission to prevent suicide and commitment to raise awareness for mental health via their social media outlets. When asked what she thinks about the positive messages on Buddy Project's Twitter and Instagram, P10 responded as follows:

> *I think it's great that they do that because not many people on social media are willing to just openly post about [mental health] so seeing the Wallpaper Wednesdays and all the positive messages... I think it's great that there is an organization out there that's willing to do that.*

Relatedly, P3 described Wallpaper Wednesday as "weekly wallpapers for your phone and your mobile devices." He continued as follows:

> *I think those are really awesome because you can set those up right away if you like the message, and you can set that as your screensaver or your background, and you have that positive message with you every day and at every single point that you need it.*

He added the wallpapers remind him that his feelings were valid:

> *My feelings are valid. That's what I need this week.*

Buddy Project's mission and how it was exemplified in the organization's social media accounts in practice had immediate importance to many participants.

The mission statement is the first piece of information that one sees upon entering the website, and the statement is embedded in both their Twitter and Instagram bios. P5 testified to the need for a safe conversation space when she said:

> *There's such a stigma around [mental health] to not talk about it with the people around you because you don't want to be judged. So, finding somebody on a platform where they advocate for mental health awareness just makes it different, and made me more comfortable to talk about it.*

Echoing a similar point, P4 described how having a mission related to suicide prevention, or mental health, allows discussion of it to become less of a taboo topic with her buddies compared with other people she may meet online.

She said the following:

> *I feel like there are different boundaries in that ... The mission of Buddy Project is very directly related suicide prevention, that's not a taboo topic.*

The explicit framing of Buddy Project allowed less perceived stigma between buddies to discuss mental health, resulting in more discussions of mental health compared with participants' other social settings online and offline. We see how having a mission to raise mental health awareness and demonstrating that in action (eg, through providing resources or social media posts) is an important characteristic for technology-mediated peer-to-peer support systems that want to encourage participants to discuss mental health and exchange support.

Matching Buddies Based on Shared Interests and Identities

We found that another feature that participants deemed helpful with Buddy Project was how peers are matched on the basis of shared interests and identities (eg, music, television shows, identity). Our analysis suggests that shared interests act to promote conversation between new buddies who are otherwise technically 2 strangers at the time of being paired. In addition, salient shared identities help with ensuring that one will be understood when discussing mental health and intersections of their identities with mental health.

Shared Interests as Conversation and Compatibility Aid

Matching buddies on the basis of shared interests had several perceived benefits and functions for participants, which stem from the central theme that shared interests act as support for better conversations, leading to deeper connections at a higher pace. This way of being matched acted as a means for starting conversations, as P3 described:

> *I think [the shared interest is] good because it gives you something to talk about. If you didn't have a shared interest I think it would be a little harder to start up conversations whereas if you have that common interest you can be like, 'What did you think about this part of our common interest?' And then you can start a conversation from there and then it can drift off into other things about your life.*

Similarly, P10 described her experience with using the shared interest to start conversation:

> *It made it easier to talk to them because you went in with this baseline interest that you can both just start talking about and it wasn't awkward icebreaker conversations... you get that instant connection and you understand already why you are talking to this person as opposed to if you're meeting somebody in person for the first time you don't always know what to talk about*

She continued to describe the process:

> *If I message them first, I'll just go in with, "Hey, our interest is this. What do you like about it or what do you know about it?" And just to start the conversation where it's not awkward back and forth like, "Hi, how are you?" Because those conversations can get tedious and boring.*

In this way, shared interests mitigated the risk of potentially losing out on relationships that have the potential to be helpful because buddies can begin their relationship with discussing topics that are meaningful to them (and are not necessarily related to mental health) rather than topics that they do not share an interest in.

Participants also noted that the shared interest feature improves the likelihood that one will find a compatible companion. P1 described this as follows:

> *If I saw something that I thought was cool I could send it to her to also see, or if she saw something she could send it to me and then that would just keep our conversation going.*

The shared interests made it more likely that participants were matched with a compatible buddy. They acted as optional conversation prompts and facilitated the formation of deeper connections between buddies.

Shared Identity to Ensure Being Understood When Discussing Mental Health

Participants noted that it was more helpful to connect with someone who shared a salient identity with them—identities that they perceived to shape their mental health experiences. For example, P6, a self-identified neurodiverse person, said as follows:

> *I think it's definitely easier [to connect to another neuro-diverse individual to discuss mental health]... I have one friend in real life [also neuro-diverse] that*

> *her and I say people who are neuro-typical … just don't understand necessarily sometimes the issues that we have or that we're going through.*

She continued:

> *I think it's easier to talk to someone who kind of gets it a little bit, given I would talk to anyone that had any issues... I think it's really helpful to talk to someone, and have someone else just get it.*

P6 found it easier to talk to neurodiverse peers, especially about mental health, compared with others who did not share this identity facet with her. In fact, many neurodiverse individuals consider neurodiversity as part of their identity, not an illness [59].

As another example, P12 described how Buddy Project "helps you find people ...Especially with pan[sexual], it helped me find people that are like myself." As a result of having a buddy with similar identities, participants felt that they would be understood and seen within their buddy relationship.

Not Matching Buddies Based on a Shared Mental Health Diagnosis

Participants' accounts suggest that shared mental health diagnosis may not always be the best way to match peers who need social support to cope with mental illness. We found that buddies typically base their first conversations off their stated shared interests. As previously described, buddies' experiences have been positive with the shared interest feature, whereas the mental health orientation of Buddy Project creates a shared understanding that discussing mental health with buddies is not taboo. Participants noted that when the shared diagnosis replaces the shared interest, the dynamic of the relationship changes. The friendship aspect is lost, as discussing mental health diagnosis is not how people begin to form friendships with one another; of course, once a relationship exists, discussing mental health is something participants feel more comfortable with. In this section, we describe how participants reflected on the perceived benefits and drawbacks of being matched with someone that shares their same mental illness diagnosis. These include concerns about differences in the severity of buddies' experiences, engaging in self-comparison, and sharing unhealthy coping mechanisms.

Comparing Self and Severity

According to participants, one of the perceived drawbacks of being matched with someone based on a diagnosis is that mental illnesses can vary in severity. P11 described this drawback as follows:

> *The cons would be just the different levels of each different type of mental illness. Anxiety has so many different levels that sometimes you really can't connect because someone's [level of severity] could be so low and then someone else's [level of severity] could be so high.*

As a result of different severities of anxiety, participants' symptoms can be so varied that it could hardly look like the same condition. It is likely that if 2 people are paired with the same mental illness, they are expected to be able to connect over the diagnosis and experiences. When this does not happen because of different severity levels, participants may become discouraged from using peer-to-peer support or not find the validation and support that they need, making mental health support resources scarce.

Participants also noted that matching based on diagnosis might lead to self-comparison on coping and wellness between buddies. For example, P12 described the competitiveness that self-comparison may cause:

> *I guess if you're talking to someone who's had a similar diagnosis as me but their experience was still different, I feel like sometimes it would become a game of "Oh, mine is worse" or that kind of game.*

When individuals compare the severity of their mental illness with that of someone who seems to be coping more effectively than they are, one is subject to negative self-talk [60], which is not helpful in coping.

On the other hand, when participants share the same diagnosis and the same severity level, they will often share similar experiences that allow for a deeper understanding of each other. P6 spoke to the point that anxiety varies in severities and that a benefit of connecting based on shared diagnosis and severity is that one is more likely to find someone who truly understands their experience. P6 said that she would rather connect with someone that has the same diagnosis *and* severity level than someone who just has the same diagnosis broadly:

> *I think it's better to be able to just connect with someone on that [severity] level, just because they do truly understand what you're going through or how you're feeling...*

Variations in severity can lead one to compare their mental state with their peers, which is not always a helpful coping strategy. However, sharing the same severity of mental health diagnosis can result in a deeper understanding for one another and less competitiveness. Overall, for participants wanting to connect with others over a similar diagnosis, severity level was a criterion to ensure the connection would be helpful. Further research is required to examine how the design of peer support technologies would account for fluctuating severities. In this study, we provide preliminary evidence that is a relevant criterion to consider.

Sharing Unhealthy Coping Mechanisms

Another potential downfall to matching buddies based on shared diagnosis is the risk of sharing unhealthy coping mechanisms. P10 gave an example of sharing unhealthy coping mechanisms when asked about being matched with a buddy with the same condition:

> *If you sleep all day to help you cope with something, telling the other person that they might try sleeping more to see if that helps them. Not the healthiest option, but it's what you do.*

Other unhealthy coping mechanisms may include self-harm, substance abuse, changes in diet, and a disconnection from reality. These negative changes can result in decreased mental

health [61], which defeats the purpose of any peer support system.

Overall, participants' accounts highlight the nuances that shared diagnosis matching may have, sometimes leading to more understanding and sometimes leading to unhealthy coping mechanisms or otherwise unhelpful behaviors such as self-comparison.

Discussion

Principal Findings

Although Buddy Project is not the most technically sophisticated peer support system, we found that its design principles are effective in facilitating relationships that help young adults cope with mental illness by engaging in peer support. By taking Buddy Project as a case study that uses technology to pair up young people to cope with mental illness, we provide insights into the qualities possessed by effective technology-mediated peer support systems. We found that designing a technology-mediated peer-to-peer support system with a commitment to mental health awareness is an effective way to create a coping tool for young adults facing mental health challenges. This clear commitment lowers the stigma attached to mental health discussions between buddies and provides a shared understanding that sharing mental health–related experiences is a legitimate need that can be met within this peer support system.

Future digital peer support tools for mental health can use a combination of the features that Buddy Project users found helpful: (1) semiguided chat spaces made possible through matching based on interests and identities that peers self-identify with and having an explicit mental health–related mission coupled with social media and other online presence that makes it clear that discussing mental health is safe within the peer support ecosystem; (2) not matching based on broad mental health diagnosis; however, if diagnosis is important to peers to incorporate such matching with educating peers on how to provide helpful support and how to avoid unhelpful coping mechanisms and accounting for symptom severity in matching; (3) allowing for some degree of anonymity and control over how peers present themselves to each other; (4) allowing potential peers to assess the fit and whether they would like to embark on a relationship with their peers based on browsing public social media profiles of one another or innovating privacy-preserving means of assessing initial fit and trust. We describe these in detail in the remainder of this section.

Semiguided Chat Spaces for Mental Health Coping and Developing Meaningful and Supportive Relationships

Mental Health–Related Mission

We found that having an explicit message such as Buddy Project's mission to prevent suicide creates a space where peers feel safe to talk about mental health; however, mental health is not all that they feel compelled to talk about. Removing people's fear of being judged by their illness not only contributes to more fluid communication but is an essential element of a trustworthy relationship [62]. Once people recognize their condition and are able to communicate their experiences with others, they are taking the first step to recovery and are more likely to seek further help [16]. We recommend that future peer support systems and organizations aiming at facilitating mental health peer support make it an explicit point to advocate for mental health destigmatization through all their outlets in practice.

Shared Interests and Identities

Although the mental health mission provides a stigma-free space to discuss mental health among peers, buddies found that being matched based on shared interests and identities (and not diagnosis) provided complementary context for them to develop deep meaningful friendships in which discussing mental health *and* other topics were welcome.

Semiguided Conversation Space

Taken together, shared interests and identities and the mental health mission statement create what we call a *semiguided* conversation space: an open and flexible yet somewhat guided conversation space, ideal for connections that are both deep and supportive. We describe how we came to this notion in the remainder of this section.

O'Leary et al [24] designed a chat system in Google Docs to study the impact of guided and unguided chats for technology-mediated mental health peer support. In their study, the guided chats followed a script, whereas the unguided chats had no prompts at all. They found that guided chats resulted in deep connections, where peers provided solutions to problems and new perspectives. Unguided chats resulted in smooth conversations that offered personal connections. Their participants referred to unguided chats as *pleasant and relaxing* acting as a distraction, or temporary relief, from one's problems. We found that chats with buddies fell somewhere in between what O'Leary et al [24] referred to as guided and unguided chats, which we call a *semiguided* conversation space.

We describe semiguided chats as those that have the characteristics of both guided and unguided chats to some extent. Semiguided chats are similar to guided chats because of the way the shared interests or identity and mission statement guide conversations among buddies; they are different in that they do not use explicit prompts for buddies to engage in conversations about as guided chats do. Unlike a fully unguided chat space where this shared understanding is missing, the sociotechnical space with semiguided chats is not completely void of possible topics that peers would know they can safely speak to their buddies about (eg, shared interests or identities, mental health). We found that the semiguided conversation space provided by Buddy Project facilitates the development of meaningful friendships and personal connections and a supportive context within which discussing mental health was safe and comfortable and where buddies would exchange stories and perspectives to help each other. However, buddies did not feel that they needed to discuss mental health all the time nor did they feel that they absolutely needed to provide actionable advice to their peers in contrast to what a guided chat space would require. We suggest that a semiguided chat space will allow peers to not only gain the benefits of both guided and unguided chats but will also

likely not evoke unwanted feelings for buddies (eg, an unwanted sense of responsibility to help their peers, as was the case in the study by O'Leary et al [24]).

Semiguided chats offer buddies the option to fluidly switch between deep and light conversations, whereas unguided and guided chats [24] were focused on one or the other. Semiguided chats allow peers to find the middle ground between exchanging social support and problem solving, which could allow peers to use both mechanisms in one resource (ie, relationship with the buddy). We suggest that semiguided chats are a good design principle when creating a sociotechnical space for mental health discussions and peer support. They allow peers to have freedom in what they talk about so the conversation does not feel forced, yet they are free flowing. Combined with a message about mental health, the conversation will still likely gravitate toward becoming an effective coping tool, as it did for Buddy Project users participating in our study.

Previous research has recommended connecting peers in online communities on the basis of similar features other than diagnosis in contexts such as breast cancer [63], various cancer diagnoses [64], and caregivers of individuals with cognitive illnesses [65]. Specifically related to mental illness, recent work [24] suggests that technology can enhance peer support for mental health by matching peers based on similarities that go beyond diagnosis. However, this previous research begs the questions of what this peer support might look like in practice, what peers' attitudes toward it might be in practice, or what other features are important to make peer support matching helpful to peers. Buddy Project's design, as we found, fills this gap in our knowledge.

Striking a Balance: Matching Peers Based on the Mental Health Diagnosis or Not

The participants in this study expressed concern about the potential costs of being matched based on shared diagnosis—comparing one's self and severity of illness and sharing unhealthy coping mechanisms. In fact, individuals with mental illnesses do not always prefer for their peers to have the same diagnosis as theirs [15]. This finding resonates with previous studies, suggesting that sharing unhealthy coping mechanisms is one of the most likely disadvantages of online support groups and peer support [38,55,60,66]. This can include suicidal ideations being shared among peers, and even the possibility of a suicidal pact, and an overall diminished self-esteem and well-being [55]. In the case of depression, which affects an estimated 25% of young adults [67], hearing a peer's depressive thoughts can cause a downward spiral [56]. Being matched based on the same diagnosis can also lead to lower self-esteem and hope when people engage in self-comparison and feel as though others are doing better [16], which counteracts the peer support that one should be receiving [17].

However, with the right system and the right peer match (eg, facilitated through shared interests and identities), sharing healthy coping mechanisms could be a positive experience for participants as it acts as an outlet to seek and provide helpful mental health resources and provide a sense of solidarity and connection to peers [22]. For example, if a participant has been seeking help from a therapist, they could suggest their peer to do the same and support their claim with personal experience, making it more likely that their peer seeks additional mental health support. For this to be possible, we argue that individuals would have to be educated on what healthy and unhealthy coping mechanisms are. In addition, when matched based on diagnosis, peers can provide support to each other around common stressors, symptoms, stigma, and other challenges, resulting in them feeling less alone [58].

A useful approach that addresses the concerns and allows users to receive the benefits of shared diagnosis pairing could be offering educational material to peers that explains to them the potential dangers of these unhealthy actions and instead educating them on healthy coping mechanisms. There is further evidence for an unmet demand for such educational programs, as many individuals express interest in training to become a peer counselor [68]. For instance, the 7 Cups of Tea website educates users on active listening and support provision; similarly, Crisis Hotlines trains their volunteers.

Technological spaces such as Buddy Project or other services dedicated to mental health advocacy and awareness can use their online presence (eg, social media posts) to provide such educational material. They can also provide a set of resources to buddies once they are matched, educating them on healthy coping mechanisms and how to be a supportive, compassionate buddy. The effectiveness of any such approach should be investigated in future research. Our study provides initial insights that there is room for improvement when it comes to engaging in healthy behavior in technology-mediated peer support systems for mental health when a shared diagnosis is a factor in matching peers.

Anonymity, Privacy, Intimacy, and Safety in Relationships Between Buddies

Privacy concerns and the risk associated with sharing information are key challenges for internet users because they can make them more reluctant to sharing information, asking for support, and building connections with other users [69]. It can also be difficult to reach out to strangers with whom one has no pre-existing ties to find support. One of the reasons Buddy Project is a popular choice among young people seeking online peer support is the sense of anonymity and separation from participants' existing and known networks (eg, family, classmates). They are not completely anonymous, as buddies have access to their peers' Twitter or Instagram account and share varying levels of personal information with each other; however, there is a sense that they are unlikely to have a pre-existing tie with their buddy. Therefore, their buddy would also not know anyone in their existing social network. There are also no requirements for sharing physical world names or identities, as they are in platforms such as Facebook. As a result, buddies feel they can safely share their mental health struggles in confidence, without worrying about others' undesired access to their personal information and struggles.

A sense of anonymity facilitates openness in self-expression, support seeking, and support provision around sensitive topics [70-72]. Our findings suggest that control over how to present oneself (eg, using a pseudonym or just the first name) coupled with separation from networks of known ties (ie, existing social

connections such as friends and family) and some contextual information through access to the prospective buddy's social media accounts, or shared interests, helped peers to take the first steps in a relationship with a buddy. Once there was more trust developed in the relationship, participants revealed more and deeper information about themselves, consistent with the social penetration theory [73]. This theory suggests that relationships develop and become more intimate over time as people share more intimate information with each other and move away from solely shallow information [73]. Here, we see how access to prospective buddies' social media profiles before conversing with them for the first time in tandem with the mental health mission and shared interests matching provide a fruitful sociotechnical space for developing deep supportive relationships with buddies.

Giving individuals who sign up to be paired an option to add their social media information is how Buddy Project conducts its matching process; however, users do not *need* to have *public* profiles. We learned that being able to assess their proposed buddy before connecting with them through the availability of some signals on their social media was helpful to participants. However, this would be harder for those whose online profiles are private or do not include much information. We suggest that Buddy Project or similar systems provide ways for their users to assess their buddies before deciding to connect; this does not have to occur using social media platforms. For example, an alternative would be creating a profile within the system that has an *about me* page, how long the person has been a user, buddies paired with, and any other information that users choose to share about themselves.

Some drawbacks of connecting online to find peer-to-peer social support are privacy concerns and cyberbullying [31]. Our findings demonstrate privacy concerns but not much about cyberbullying concerns—an important area for future research. In summary, our findings suggest that peer support systems should consider allowing some degree of anonymity, separation from existing social networks, and control over presentation, along with providing tools to assess and maintain safety and initial fit with prospective buddies before connecting with them.

Conclusions

We contribute to an understanding of desirable features for digital mental health peer support systems: (1) matching peers on the basis of interests and identities they identify with; (2) having an explicit mental health mission coupled with other online presence to signal that discussing mental health is not a taboo within the digital peer support system; and (3) not matching peers based on broad mental health diagnosis; however, if diagnosis is crucial to account for, accounting for illness severity and educating peers on how to provide support while avoiding suggesting unhelpful coping mechanisms; (4) allowing for some anonymity and control over how peers present themselves to each other; and (5) providing relevant information and tools to potential peers to aid in their decision in connecting with the proposed peers before connecting with them.

Limitations and Future Work

As is common in interview studies, this study's sample was not representative of Buddy Project users or their experiences with the service, even though we sought a diverse participant group in demographics and experiences. Future work is needed to evaluate our findings with a larger and representative population, possibly through other methods (eg, survey of Buddy Project users). Nonetheless, following best practices in interview research, our goal is not generalizability [74], rather generating conceptual insights. The challenges faced by individuals with multiple intersecting marginalized identities are worthy of future exploration. For example, although we note that connecting over identities is helpful, future research should explore what an ideal connection would look like when multiple identity facets are concerned.

Our study does not account for all kinds of mental illnesses, and further research is needed to examine the similarities and differences in designing for various mental health peer support systems. Nevertheless, we identify the factors that such designs should consider.

Within our interview participants, we did not encounter anyone who mentioned that they had encountered fake profiles or those with malicious intentions. However, this does not mean that such harmful interactions do not happen. It is possible that those willing to interview with us had more positive experiences. For example, Buddy Project shared our study link on their social media accounts. It is possible that those who follow Buddy Project on social media have had better experiences with the platform (although we attempted to recruit individuals with both positive and negative experiences). However, examining how to design technologies to facilitate trust and safety while reducing harmful behavior is an ongoing area of research that is beyond the scope of this study.

Acknowledgments

The authors wish to thank the participants in the study and the founder of Buddy Project, Gabby Frost, for assisting with recruiting participants. The second author was partly supported through the University of Michigan's Undergraduate Research Opportunity Program, to which the authors are thankful.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Buddy Project's interests and identity options.
[DOCX File , 16 KB - mental_v8i1e21819_app1.docx]

Multimedia Appendix 2
Interview guide.
[DOCX File , 17 KB - mental_v8i1e21819_app2.docx]

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Edited by G Eysenbach; submitted 30.06.20; peer-reviewed by J Amann, K Machin; comments to author 26.08.20; revised version received 08.10.20; accepted 25.10.20; published 04.01.21.

Please cite as:
Andalibi N, Flood MK
Considerations in Designing Digital Peer Support for Mental Health: Interview Study Among Users of a Digital Support System (Buddy Project)
JMIR Ment Health 2021;8(1):e21819
URL: https://mental.jmir.org/2021/1/e21819
doi:10.2196/21819
PMID:33393909

Original Paper

Effects of ACT Out! Social Issue Theater on Social-Emotional Competence and Bullying in Youth and Adolescents: Cluster Randomized Controlled Trial

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Abstract

Background: Schools increasingly prioritize social-emotional competence and bullying and cyberbullying prevention, so the development of novel, low-cost, and high-yield programs addressing these topics is important. Further, rigorous assessment of interventions prior to widespread dissemination is crucial.

Objective: This study assesses the effectiveness and implementation fidelity of the ACT Out! Social Issue Theater program, a 1-hour psychodramatic intervention by professional actors; it also measures students' receptiveness to the intervention.

Methods: This study is a 2-arm cluster randomized control trial with 1:1 allocation that randomized either to the ACT Out! intervention or control (treatment as usual) at the classroom level (n=76 classrooms in 12 schools across 5 counties in Indiana, comprised of 1571 students at pretest in fourth, seventh, and tenth grades). The primary outcomes were self-reported social-emotional competence, bullying perpetration, and bullying victimization; the secondary outcomes were receptiveness to the intervention, implementation fidelity (independent observer observation), and prespecified subanalyses of social-emotional competence for seventh- and tenth-grade students. All outcomes were collected at baseline and 2-week posttest, with planned 3-months posttest data collection prevented due to the COVID-19 pandemic.

Results: Intervention fidelity was uniformly excellent (>96% adherence), and students were highly receptive to the program. However, trial results did not support the hypothesis that the intervention would increase participants' social-emotional competence. The intervention's impact on bullying was complicated to interpret and included some evidence of small interaction effects (reduced cyberbullying victimization and increased physical bullying perpetration). Additionally, pooled within-group reductions were also observed and discussed but were not appropriate for causal attribution.

Conclusions: This study found no superiority for a 1-hour ACT Out! intervention compared to treatment as usual for social-emotional competence or offline bullying, but some evidence of a small effect for cyberbullying. On the basis of these results and the within-group effects, as a next step, we encourage research into whether the ACT Out! intervention may engender

a bystander effect not amenable to randomization by classroom. Therefore, we recommend a larger trial of the ACT Out! intervention that focuses specifically on cyberbullying, measures bystander behavior, is randomized by school, and is controlled for extant bullying prevention efforts at each school.

Trial Registration: Clinicaltrials.gov NCT04097496; https://clinicaltrials.gov/ct2/show/NCT04097496

International Registered Report Identifier (IRRID): RR2-10.2196/17900

(JMIR Ment Health 2021;8(1):e25860) doi:10.2196/25860

KEYWORDS

cyberbullying; bullying; social-emotional learning; SEL; social-emotional competence; RCT; randomized controlled trial; outcome; emotion; bully; prevention; school; intervention; assessment; effectiveness; implementation; fidelity; reception; children; young adults; adolescents

Introduction

ACT Out! Social Issue Theater

The ACT Out! Ensemble was founded in 1995 and is currently operated by Claude McNeal Productions (CMP), a professional theater troupe incorporated as a not-for-profit [1]. The ensemble uses scripted content (scenarios) generated to meet an audience's needs and transforms it into improvisational, interactive theater performances. The actors deliver performances focused on a variety of topics salient to youth and adolescents, including bullying, diversity, inclusion, and substance use [1]. A facilitator pauses the action at the end of each scenario and enables discussion between attendees and the actors, who remain in character for the discussion [1]. For example, a scenario about bullying may instruct the group to create a scene with "an example of a male student making a female student physically uncomfortable." After the actors present an interpretation of that scene, the facilitator pauses the action and asks the audience "whether the male character meant to make the female character uncomfortable," with the actors participating, in character, in the audience discussion.

The premise behind the ACT Out! Social Issue Theater intervention, outlined in the trial protocol, is that dramatic performances can enable emotional catharsis, thereby allowing new ways of feeling and thinking about behaviors and attitudes [2]. In other words, there is likely a difference between students discussing or attending a lecture on an issue like bullying in their own lives (where their own identity has weight and affects perceptions) and students' emotional responses to a scenario that seems real and familiar (eg, bullying) but that is occurring with characters rather than with themselves or their peers. The latter case would theoretically enable students to process their reactions to bullying separately from their own or their peers' identities. This is facilitated by the high caliber of talent involved in the intervention performances; shows by CMP have received positive reviews from, among other venues, the *New York Times*, *NBC*, and *Time* magazine [3]. For this trial, CMP developed and revised 15 vignettes (5 per participating grade level) addressing bullying and cyberbullying using principles of social-emotional learning (SEL) and reviewed the content with the research team. A presentation of the 5 psychodramatic vignettes was planned to last approximately 1 hour, including student interaction with the characters, and these performances constituted the intervention for this trial. This paper describes a rigorous evaluation, through a cluster randomized controlled trial, of the ACT Out! Ensemble's theater performance, addressing bullying and SEL.

Social and Emotional Learning

In the United States and internationally, schools, school-based professionals, and policymakers have begun focusing on positive development models as a means of addressing the numerous, complex, and detrimental behavioral patterns and associated outcomes (eg, bullying, mental health problems, self-harm, and substance use) observed among youth and adolescents [4]. Such approaches deliberately avoid a deficit approach ("fixing what is wrong") and emphasize the development of assets or protective factors in youth. Among the most common and conceptually similar positive development models are positive youth development [5], which emphasizes skills development, healthy relationship development, supportive community systems, and SEL. SEL focuses on the instruction of skills such as social problem-solving, recognizing emotions in others, and emotional self-regulation [6]. There have been numerous SEL programs implemented and evaluated in schools in recent years; a summary of over 300 studies contained in 4 meta-analyses identified generally positive short-term outcomes [7] across multiple domains (eg, substance use). In general, performances by the ACT Out! Ensemble are structured to model aspects of SEL, such as healthy relationships, regardless of the additional topic being addressed (eg, bullying). We have summarized additional content related to SEL and social-emotional competence (SEC) as it pertains to this study in our published protocol [2].

Bullying and Victimization

School bullying is frequently mentioned among the detrimental behaviors addressed by SEL programs [8,9]. Bullying is an unfortunate reality for youth attending US schools; a meta-analysis of 80 studies (youth aged 12 to 18 years) found a 35% student-level prevalence of traditional bullying and a 15% prevalence of cyberbullying [10]. Being bullied in childhood and adolescence has been associated with long-term, negative consequences that persist into midlife in areas such as mental and general physical health and lower socioeconomic status attainment [11]. Further, bullying victimization appears likely to cause notable increases in anxiety and depression among those victimized [12].

A recent meta-analysis of traditional bullying identified 65 school-based bullying prevention programs, but only 8 had been

evaluated more than once [13]. In general, such programs tend to be slightly more effective in reducing bullying perpetration and less effective in reducing victimization [14]. Mean values from meta-analyses have been somewhat consistent in terms of victimization, reporting reductions of 15-16% [14] and 17-20% [15]. A separate meta-analysis, focused only on cyberbullying, reported a mean reduction in victimization of 14-15% [16]. However, a meta-analysis of victimization studies limited to randomized controlled trials with a high level of rigor reported a rather small effect size (standard mean difference of -.09) [17]. Each of the cited meta-analyses note high levels of heterogeneity in the types of programs and outcomes across included programs and studies; importantly, these differences extended to study design and rigor, with some scholars noting that beneficial effects appear to be weaker when measured as part of randomized controlled trials [18].

As one might expect, reductions in victimization tend to be larger for more intensive and multifaceted programs, but implementing such programs can be both expensive and complicated [11,19,20]. For example, a summary of nontargeted (general population), relatively efficacious bullying prevention programs for US elementary schools found that program durations ranged from 11 weeks to 3 years [21]. Even efficacious programs described as "brief" prevention curricula can last 1 week or more and involve multiple interlocking components [22]. Further, several programs that have reported favorable results in efficacy trials have not always produced the same results in effectiveness ("real world") trials, potentially due to issues with implementation fidelity and existing, confounding antibullying programming [23,24]. In concluding their report from a recent effectiveness trial, Rapee et al [24] noted, "clearly, producing a sizeable impact on school-based victimization is extremely difficult." Therefore, there is a demonstrated need for inexpensive, simple-to-implement bullying prevention programming, but achieving positive outcomes from such interventions is likely to be especially challenging. For this reason, we believe that innovative or out-of-the-box strategies to address bullying merit serious consideration.

Psychodrama and Professional Acting as Innovation

Given the difficulty in addressing school-based bullying with lengthy and multipartite curricula, one might wonder why a short (1-hour) dramatic performance would be hypothesized to have even a short-term effect on SEC or bullying. A small body of literature has examined psychodrama as a prevention or behavior-change mechanism in youth, but these studies have covered diverse behaviors [25], have involved multiple, separate components such as teacher training [26], or have used students or school employees rather than professional actors as *dramatis personae* [27]. ACT Out! Social Issue Theater is different than each of these examples because it uses trained, professional actors and requires no involvement from schools outside of planning the visit (when implemented outside of a study). We were unable to find a precedent for this intervention structure in the literature.

Our decision to analyze this intervention was based on our a priori understanding of the value this brief intervention might yield as well as the remarkable community- and school-level support for the program. Prior to this study, more than 500,000 individuals had viewed a performance by the ACT Out! Ensemble [1], providing a notable depth of informal, qualitative evidence supporting the program. Uncontrolled evaluations of the program from 2015 also suggested substantive behavioral benefits [1]. Thus, given the importance of both SEL and bullying prevention in schools, and the unique position occupied by the ACT Out! Ensemble, we determined that an independently conducted, randomized controlled trial of this intervention was a valuable contribution to the prevention literature.

Study Objectives

This study primarily aims to assess whether a 1-hour exposure to ACT Out! Social Issue Theater is superior to treatment as usual for developing SEC and reducing bullying (both bullying behavior and victimization) in elementary, middle, and high school students at a 2-week posttest. Secondarily, the study aims to determine whether the same intervention is superior to treatment as usual in developing specific subdomains of SEC (social awareness, emotion regulation, relationship skills, and responsible decision making) among middle and high school students at a 2-week posttest. Finally, the study also aims to assess student receptivity to ACT Out! Social Issue Theater using previously validated measures indicating student agreement with positive (eg, "enjoyable") and negative (eg, "boring") adjectives. Additional details are available in the trial protocol [2]. All outcomes were measured at the individual participant level, but randomization occurred at the cluster level (classroom) because performances are intended to be delivered to groups and because research literature [23,24] has indicated that pre-existing school-level programs addressing bullying and SEC often vary between schools and may contribute to statistical noise in randomized trials using school as the cluster (eg, treatment as usual may not be consistent between schools).

Methods

Trial Design

The ACT Out! trial was a proof-of-concept cluster randomized superiority trial with 2 groups and 1:1 allocation. The unit of measurement was individual students, but the unit of randomization was the classroom, stratified by school (with 1 exception, Multimedia Appendix 1). For each school, half of the classrooms were randomly assigned to the intervention arm and half to the control arm. Schools with an odd number of classrooms had a single classroom randomly selected for exclusion (though if the school requested, that classroom was permitted to complete the survey for appearance's sake, and the results were then discarded by the study team).

Participants and Recruitment

The ACT Out! trial was conducted among 12 public and charter schools in Indiana: 4 schools in Marion County, 3 in Ripley County, 2 in Boone County, 2 in Lawrence County, and 1 in Monroe County. For reasons described in the protocol, clusters were selected only from grades 4, 7, and 10 [2]. All students in the selected classrooms and schools were eligible to participate. As planned, we recruited schools until meeting a threshold of

approximately 80 participating classrooms (around 1594 students) across both conditions.

Schools were selected based on their willingness to participate in the project as described, which included classroom-level randomization and inclusion of all eligible classrooms in the study's allocation processes. Authorizing officials for schools or school corporations were required to provide a signed letter of agreement prior to participating in the study. At the individual level, the project used a waiver of parental consent (opt out), as approved by the institutional review board. Parents and legal guardians were permitted to review study procedures and were provided with a description of the study a minimum of 2 weeks prior to any individual-level interaction with subjects, along with instructions for how to opt out; students, their parents, and their guardians all had the ability to opt a student out from participating either formally or by survey noncompletion. The rationale for this approach was a combination of the low risk posed by the study as well as the desire to avoid unintentional exclusion of underrepresented minorities and high-risk populations, as described in the protocol [2]. This study and all consent procedures were carried out according to, and approved by, the Indiana University Institutional Review Board.

Intervention

ACT Out! Social Issue Theater

The intervention was a psychodramatic, improvisational performance that was delivered to classrooms (separately, except in 1 case where 2 small classrooms attended together) by members of the CMP professional theater company. Interventions were scheduled to last approximately 1 hour and were delivered during the school day. Each 1-hour performance consisted of 5 vignettes focused on bullying and cyberbullying and was designed to be interactive; after each scenario, the student audience was invited to converse with the performers, who remained in character. In each case, a moderator from CMP also managed the overall performance (eg, calling on students to ask questions of the characters). While the scenarios were improvisational in nature, they were designed to remain true to core concepts that were prespecified and agreed upon by CMP and the research team (eg, the identity of the characters, the nature of the conflict, and methods of bullying). To ensure this, fidelity data were captured from all performances (described in the *Quality Control*). The written specifications for each vignette, by grade level, are provided in Multimedia Appendix 2.

Treatment as Usual (Control)

Classrooms randomized to treatment as usual were provided with the preparation materials for the survey (see *Data Collection*) and completed the survey tools in the classroom during the school day (both at baseline and 2-week posttest). Students were not otherwise informed about the ACT Out! intervention by study personnel. Within schools, we were not aware of any systematic differences between intervention and control classrooms aside from the ACT Out! intervention itself, though schools themselves likely had different SEL and bullying programs at the school level (our statistical models incorporated random effects at both the classroom and school level).

Outcomes

All measured outcomes were prespecified in the clinical trial registration and the published protocol [2], along with the rationale for their selection, and have been validated. Unfortunately, certain outcomes were not possible to collect due to the COVID-19 pandemic, which led to mandated school closures in the state during part of the data collection period (Multimedia Appendix 1). However, we do not have reason to suspect that the data we collected prior to closures were substantively affected.

Thus, this study collected the following 2 primary outcomes: (1) social-emotional competence and (2) bullying behavior and bullying victimization. Overall social-emotional competence was measured at baseline and at 2-week posttest using the Delaware Social-Emotional Competency Scale (DSECS-S) [28]. This scale prompted students to "Please read each statement and mark the response that best shows how much it is like you," with response options of 1=*Not like me at all*, 2=*Not much like me*, 3=*Somewhat like me*, and 4=*Very much like me*. An example statement from the scale is, "I can control how I behave." This scale demonstrated good internal consistency [intention-to-treat (ITT) pretest α=.78] for the study sample. Bullying behavior and experiences of being bullied (victimization) were measured at baseline and at 2-week posttest using the Bullying and Cyberbullying Scale for Adolescents (BCS-A) [29]. These questions measured the number of times (between 0 and 4+) in the past 2 weeks that students "bullied another school student" or, separately, "had been bullied." These sections were further separated into subsections for "online/on the internet or mobile phones" (eg, cyberbullying behaviors) and "offline/face-to-face" (including physical, verbal, and relational behaviors).

Further, the study collected the following 2 secondary outcomes: (1) receptiveness to the intervention and (2) prespecified subanalyses of social-emotional competence for seventh- and tenth-grade students. Student receptivity to the intervention \was measured at 2-week posttest (intervention arm only) using questions to assess the degree to which they found the intervention to be enjoyable, interesting, a waste of time, boring, understandable, difficult to understand, believable, important, and helpful [30]. Social-emotional competence subdomains (social awareness, emotion regulation, relationship skills, and responsible decision-making) were measured at baseline and 2-week posttest (seventh and tenth grades only) using scales from the Washoe County School District Social-Emotional Competency Assessment (WCSD-SECA) [31]. These scales prompted students to "Please tell us how easy or difficult each of the following are for you," with response options of 1=*Very difficult*, 2=*Difficult*, 3=*Easy*, and 4=*Very easy*. An example item from one scale is, "Getting along with my teachers." Though the scales were previously developed to be reliable and valid [31], the items are relatively heterogeneous, perhaps contributing to their rather mediocre internal consistency with this sample [ITT pretest α=.57 (social awareness), .65 (emotion regulation), .68 (relationship skills), and .66 (responsible decision-making)].

Sample Size

The rationale for choices made in preparing the sample size calculation is provided in the protocol [2]. We estimated the sample size required to detect a moderate effect (Cohen *d*=0.30) with a 2-sided significance of .05 and a power of .80 to be 340 participants. We estimated an intraclass correlation of 0.153 based on a prior school-based cluster study on cigarette smoking with a similar methodology [2] and assumed approximately 20 students per classroom, yielding a design effect of 3.907. We took the resultant estimate of 1328 students and multiplied it by 1.2 to account for attrition and potential loss of matched pairs due to survey matching procedures, producing the final sample size target of 1594 students across approximately 80 classrooms.

Randomization and Allocation

Sequence Generation and Type of Randomization

Simple randomization occurred at the cluster level using a smartphone app produced by Random.org [32]. Randomization of clusters occurred within schools with a 1:1 allocation. In the specific instance where clusters first had to be created (a single school), the website version of Random.org was used to randomly assign students to evenly sized clusters and then to assign clusters to a study arm.

Concealment, Implementation, and Blinding

Since the generation of the allocation sequence was computerized, it was concealed to all members of the research team until the moment of assignment. Because of needs driven by school planning, there was some variability in the generation and assignment process. Decisions were made as follows: Schools that agreed to participate were asked to identify all clusters within the selected grade level (eg, fourth, seventh, or tenth). If schools were willing and able to accommodate it, allocation sequences were generated by the fidelity checker immediately prior to the intervention (eg, on-site, in the schools). However, most schools (10/12) were unable to accommodate this method. Subsequently, most schools were asked to list classrooms by a fixed characteristic (eg, the time the homeroom met, teacher's name) at the time of school enrollment. One of the researchers generated a random sequence, applied it directly to classrooms, and shared the sequence with school administrators, identifying which classrooms would be allocated to which arm; the researcher asked the administrators not to share this information with teachers until necessary for planning efforts.

Consent was obtained from an administrative authority at participating schools at the time of enrollment and prior to randomization. Students and their parents or legal guardians were notified at least 2 weeks in advance of the intervention and provided an opportunity to opt out of the study but were not informed about their classroom's allocation. Due to the nature of this study, blinding of participants, school officials, and researchers was not feasible. However, multiple independent statisticians were involved in conducting and reviewing analyses, and some were blinded to the meaning of study arm coding.

Data Collection

Survey Administration

Once a school enrolled in the study, each classroom was provided with a study packet containing surveys and response forms, a manila envelope, a white envelope, and an administrator checklist [2]. Each classroom was also assigned a unique code consisting of the grade level, study arm, and a randomly generated cluster ID. This code was prefilled on the back of each survey form and on the front of each envelope to facilitate data quality control.

Classroom teachers administered the surveys by following the step-by-step administrator checklist. Surveys that were handed out to students were placed back in the manila envelope, regardless of whether they were completed, while extra surveys were placed in the white envelope (unused). The pretest was completed 0-3 days prior to the intervention, depending on school schedules and availability. The posttest was completed 14-27 days after the intervention, with most classrooms completing the posttest within 14 to 17 days, depending on school schedules and the ability to facilitate the posttest.

Quality Control

Data were collected using a customized form created with Scantron DesignExpert (Scantron) and scanned directly into a database with an Insight 700c scanner (Scantron) to avoid data entry errors. However, one of the survey matching elements required a handwritten response; these were typed manually into the database. To verify intervention fidelity, at least one individual who was not a member of the ACT Out! Ensemble attended every performance and documented the concordance between a prespecified checklist of elements for the intervention and the performance itself. These checklists were developed separately for each grade (since the scenarios vary) and are available in Multimedia Appendices 3-5. To establish coding reliability, a second individual attended performances for 6 clusters to conduct fidelity checks, and interrater reliability was computed (Multimedia Appendix 1).

Survey Matching Procedures

This study required an anonymous procedure to match students' surveys between pretest and posttest while remaining compliant with the requirements of the institutional review board. As described in the protocol [2], even recent meta-analyses had not identified a best-practice solution to such a dilemma [33]. Thus, the project team developed and used a novel anonymous matching procedure based on unique self-generated identification code elements and machine-assisted weighted matching. This approach was sufficiently complex that it required a separate full-length manuscript to articulate [34], and a complete description would extend well beyond the scope of this paper.

Analytic Methods

Missing Data

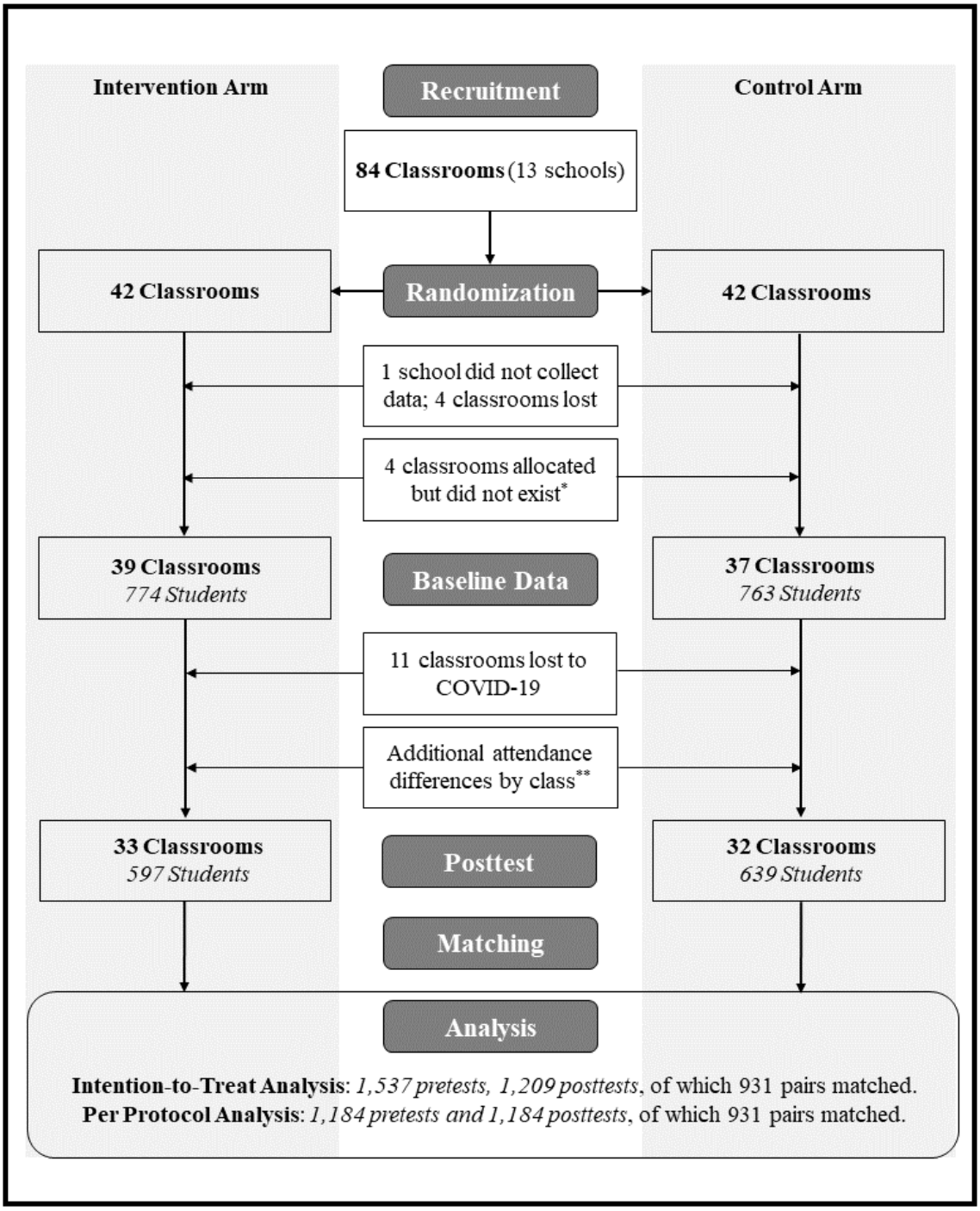
Multiple imputation (MI) using the Markov Chain Monte Carlo approach was completed using SAS (version 9.4; SAS Institute), utilizing PROC MI and MIANALYZE with the assumption that

data were missing at random. All variables that were collected were imputed for all analyses. Numbers of iterations were based on missingness in the per-protocol (PP) analysis, which had 1184 pretests and posttests, and thus 2368 surveys. Percent missingness ranged from a low of 1.22% to a high of 8.57%. SEC items not asked of fourth-grade students were present on 2078 surveys (removing 145 fourth-grade participants). Percent missingness within those variables ranged from 2.84% to 4.96%. Given this information, we selected 10 imputations for our analyses (integer greater than the missingness in the variable with the highest level of missingness, 10>8.57 [35]). Bias was also mitigated by presenting outcomes from 4 approaches.

Statistical Analyses

All outcomes were continuous, so linear mixed models using restricted maximum likelihood were fitted for each analysis (SAS PROC MIXED) with repeated measures for each participant. The time of survey administration (pretest or posttest), study arm, and time and study arm interaction were treated as fixed effects. The interaction of time by study arm was the hypothesis test for causal effects (eg, intervention group improved significantly more than the control group). All analyses allowed for clustering of students within schools and classrooms as random intercepts to alleviate the issue of inflated standard errors and used Kenward-Rogers degrees of freedom approximation to account for the cluster randomized trial design. *P* values were 2-sided and treated as significant at .05 or less; however, in keeping with recommendations from the American Statistical Society, we did not use *P* values as the sole determinant of outcome importance. Instead, we provided the full dataset and analytic code, and interpreted the output based on a combination of effect size, clinical significance, standard errors, and significance [36]. Similarly, we produced 4 sets of output, the ITT analysis in which all data were analyzed in the arm to which they were randomized (with and without MI; 1537 pretest and 1209 posttest), and the PP analysis in which only data resulting from a completed protocol were analyzed (with and without MI; 1184 pretest and posttest), in accordance with reporting recommendations [37] (Figure 1). Notably, the 931 cases that were matched do not represent the totality of students who complied with the protocol but rather are those who provided internally consistent information for the variables used to match anonymous surveys. The PP analyses included an additional 253 individuals (1184 in total) who were likely to have completed both surveys, even though their specific surveys could not be reliably matched between time points. The 931 individuals were included as repeated measures in the analysis, and the remaining 253 were included with surveys that were unmatched between time points.

Figure 1. Consort flow diagram. *Classroom count was provided by schools and used to randomize clusters. When arriving to deliver interventions, it was discovered that 4 classrooms that had been allocated did not exist (n=3 schools). **Attendance differences by cluster are provided in supplemental material for the matching procedure paper [34].



ITT has been suggested to more closely represent effectiveness while PP represents efficacy [38]. Thus, superiority randomized controlled trials typically emphasize ITT analyses with imputation. In this case, however, the preponderance of excluded data resulted predominantly from an unexpected global event (COVID-19) rather than intervention nonadherence. Being able to attribute attrition directly to an external factor unrelated to the study is rare in controlled studies. As a result, it is less clear to us that ITT better reflects the true findings than PP in this specific instance. Thus, we interpreted ITT and PP analyses in tandem, providing all data from each analysis. We felt that this approach, while more complex in terms of preparing written text, facilitated transparency in explicating the findings.

Results

Recruitment

The formal study start date was October 16, 2019, and interventions were delivered from November 6, 2019, to February 28, 2020. School recruitment was terminated in February once the anticipated numbers of clusters and participants reached the planned total. Initially, a total of 13

schools from across Indiana participated in the trial, comprising 84 classrooms for the eligible grade levels. Of those 84 classrooms, 42 were randomized to the intervention arm and 42 were randomized to the control arm. One school did not follow protocol and failed to correctly administer pretest surveys to either arm prior to intervention delivery, so it (4 classrooms) was summarily removed from the trial. In addition, 3 schools provided incorrect counts of classrooms to be randomized (3 control classrooms and 1 intervention classroom), so sequences were generated that included classrooms that did not exist. Upon discovery of this discrepancy, sequences and assignments were not altered because it would have affected allocation concealment. Thus, despite 1:1 allocation, the number of baseline classrooms was 76 (37 control and 39 intervention classrooms). Finally, an additional 11 classrooms (5 control and 6 intervention classrooms) at a single school were slightly delayed in completing posttests, and then schools were shut down for the academic year due to COVID-19 prior to data collection. Thus, the number of classrooms that completed posttests was 65 (32 control and 33 intervention). Table 1 shows the baseline characteristics of the 2 trial arms for all students who provided data, excluding blank surveys.

Table 1. Baseline sample characteristics of the study participants (n=1537).

Characteristic	Control group (n=763)	Intervention group (n=774)
Gender, n (%)		
Male	386 (51.8)	404 (52.9)
Female	359 (48.2)	360 (47.1)
Missing	18 (—[a])	10 (—)
Grade, n (%)		
Fourth	81 (10.6)	73 (9.4)
Seventh	307 (40.2)	293 (37.9)
Tenth	375 (49.2)	408 (52.7)
Race, n (%)		
White	526 (72.2)	548 (73.1)
African-American or Black	67 (9.2)	77 (10.3)
Asian	14 (1.9)	11 (1.5)
Native American or Alaskan Native	10 (1.4)	7 (0.9)
Hawaiian or Pacific Islander	0 (0.0)	2 (0.3)
Multiracial	74 (10.2)	61 (8.1)
Other	38 (5.2)	44 (5.9)
Missing	34 (—)	24 (—)
Hispanic/Latino, n (%)		
Yes	92 (12.7)	87 (11.8)
No	634 (87.3)	653 (88.2)
Missing	37 (—)	34 (—)
Bullying victimization[b], mean (SD)		
Traditional (physical)	0.57 (0.88)	0.57 (0.93)
Traditional (verbal)	1.13 (1.49)	1.20 (1.55)
Traditional (relational)	0.78 (1.20)	0.82 (1.23)
Cyber	0.48 (0.83)	0.56 (0.93)
Bullying perpetration[b], mean (SD)		
Traditional (physical)	0.25 (0.59)	0.24 (0.60)
Traditional (verbal)	0.56 (1.05)	0.61 (1.13)
Traditional (relational)	0.26 (0.74)	0.25 (0.71)
Cyber	0.25 (0.61)	0.24 (0.59)
Social-emotional competence[c], mean (SD)	3.20 (0.45)	3.18 (0.48)
Self-awareness[d], mean (SD)	2.94 (0.48)	2.90 (0.50)
Emotion regulation[d], mean (SD)	2.37 (0.61)	2.44 (0.62)
Relationship skills[d], mean (SD)	2.79 (0.52)	2.76 (0.55)
Responsible decision-making[d], mean (SD)	2.92 (0.54)	2.93 (0.55)

[a]—: not available.

[b]Count variable scored from 0 (no instances of any exemplars of bullying in the category) to 4 (4 or more instances of every exemplar of bullying in the category) [29].

[c]Scored from 1 to 4, where 4 is the optimal score [31].

[d]Seventh- and tenth-grade students only; scored from 0 to 4, where 4 is the optimal score [28].

Fidelity

Interrater reliability for fidelity coding was excellent (96.5% concordance). Fidelity to the intervention was high for all grades, though some seventh- and tenth-grade classrooms were not able to proceed through all 5 scenarios due to timing constraints. These instances were noted distinctly from fidelity because they resulted from longer-than-expected time completing the pretest survey immediately prior to the intervention, a factor that would not exist outside of the study. Fidelity was computed as the sum of all completed checkpoints for all clusters divided by the sum of all possible checkpoints for all clusters, within each grade. For the 5 fourth-grade classrooms, intervention fidelity was 100%. For the 15 seventh-grade classrooms, fidelity was 96.9%, but the fifth scenario was excluded for all clusters due to time constraints. For the 14 tenth-grade classrooms, fidelity was 98.4%, but 3 checkpoints for 1 classroom were excluded (fidelity checker was meeting with administrators), the third scenario was excluded for 2 clusters, the fourth scenario was excluded for 3 clusters, the fifth scenario was excluded for 3 clusters, and both the fourth and fifth scenarios were excluded for 1 cluster, all due to time constraints.

Outcomes

Sociodemographic Characteristics

All baseline data for the study are provided in Table 1, sorted by study arm. No significant sociodemographic differences were observed between the control and intervention arms based on chi-square tests with unadjusted alpha (.05) and pairwise exclusion of cases with missing sociodemographic values. The overall study sample was mostly male (790/1509, 52.4%), non-Hispanic/Latino (1287/1466, 87.8%), and White (1074/1479, 72.6%). More participants were in seventh (600/1537, 39.0%) and tenth (782/1537, 50.9%) grades than in fourth grade (154/1537, 10.0%).

Primary Objective 1

In our protocol [2], we hypothesized that ACT Out! Social Issue Theater was superior to treatment as usual for the development of overall SEC in students enrolled in elementary, middle, and high schools, measured approximately 2 weeks postintervention using the DSECS-S. The data did not support this hypothesis; no clinically or statistically significant interactions were observed (although this was not a “clinical” study, we use the term “clinical significance” to indicate findings where the magnitude, in our opinion, might reasonably be inferred to be of interest or value to potential stakeholders).

Primary Objective 2

In our protocol [2], we hypothesized that ACT Out! Social Issue Theater was superior to treatment as usual for reducing frequency (count) of perpetration of and victimization from traditional bullying (physical, verbal, and relational) and cyberbullying, measured approximately 2 weeks postintervention. These findings were complex. To interpret clinical significance, it is important to know that bullying scores are mean values based on count data of multiple bullying behaviors within a category, and so interpreting outcomes is different than for an attitudinal scale. For example, an individual who scored 1 for physical bullying victimization would need to have reported 1 instance of *each* of the 4 types of physical bullying victimization that compose that scale [2,29]. Similar interpretation applies to verbal (2 types), relational (2 types), and cyber (5 types) bullying. For example, a baseline bullying score of 0.568 (physical victimization) means that the average student reported experiencing more than 2 instances of physical bullying behaviors in the past 2 weeks (computed as .568*4). This should be taken into account when interpreting bullying outcomes.

There was limited causal, clinically significant evidence of small reductions (assessed via interaction effects of time by study arm) for cyberbullying victimization (favoring the intervention arm) and physical bullying victimization (favoring the control arm). For cyberbullying, reductions in the intervention arm victimization score ranged from -0.08 (P=.011, ITT with MI) to -0.13 (P<.001, PP without MI). This corresponded to mean cyberbullying victimization reductions of 0.40 to 0.65 instances/2 weeks, where the interaction term comparing the reduction in the intervention arm to the control arm was marginally significant in the PP analysis without MI (P=.067) but was increasingly nonsignificant in other models, ranging up to P=.301 for ITT with MI. For physical bullying, reductions in the control arm victimization score ranged from -0.13 (P<.001, ITT with MI; interaction P=.013) to -0.14 (P<.001, PP without MI; interaction P=.062). This corresponded to mean physical bullying victimization reductions of 0.52 to 0.56 instances/2 weeks. There was also limited evidence of a small effect of similar magnitude for increased physical bullying perpetration via the interaction effects. Increases in the intervention arm perpetration score ranged from 0.06 (P=.013, interaction P=0.060; ITT with MI) to 0.08 (P=.005, interaction P=0.032; ITT without MI), corresponding to increased perpetration of 0.24 to 0.32 instances/2 weeks, while the control arm did not have significant increases. However, only the ITT without MI model showed significance.

Finally, we observed an overall decrease in bullying victimization across pooled study participants (both arms). Findings were fairly uniform across models, so we provide only the most conservative (ITT with MI) outcomes in this paper. This included small-to-moderate, clinically significant overall reductions in physical (as above), verbal (control: -0.29, P<.001; intervention: -0.29, P<.001), and relational (control: -0.15, P=.001; intervention: -0.15, P=.003) bullying victimization. These corresponded to reductions of 0.58 (verbal) and 0.30 (relational) mean victimization instances/2 weeks. There was also some evidence of a small or moderate overall decrease in verbal bullying perpetration (control: -0.10, P=.023; intervention: -0.12, P=.005), corresponding to a reduction of 0.20-0.24 mean verbal bullying perpetration instances/2 weeks. These findings were not causal (ie, they were not observed differentially for the intervention clusters) and do not directly support the original hypothesis for this objective (except, potentially, for cyberbullying victimization); however, we believe that they do provide some favorable evidence for the program. Table 2 shows the ITT study outcomes, and Table 3 shows the PP study outcomes.

Table 2. Intention-to-treat study outcomes with standard errors.

Variable (# observations)	Control			Intervention			Interaction	
	Pretest, mean (SE), n=763	Posttest, mean (SE), n=614	*P* value of difference	Pretest, mean (SE), n=774	Posttest, mean (SE), n=595	*P* value of difference	Difference in differences (SE)	*P* value
Linear Mixed Models (no imputation)								
Bullying victimization								
Physical (2623)	0.60 (0.05)	0.46 (0.05)	<.001	0.58 (0.05)	0.56 (0.05)	.514	0.11 (.05)	.031
Verbal (2585)	1.16 (0.08)	0.85 (0.08)	<.001	1.24 (0.08)	0.94 (0.08)	<.001	0.02 (.08)	.852
Relational (2569)	0.82 (0.06)	0.65 (0.07)	<.001	0.83 (0.06)	0.68 (0.07)	.003	0.02 (.07)	.741
Cyber (2622)	0.49 (0.05)	0.45 (0.05)	.210	0.58 (0.05)	0.47 (0.05)	.001	-0.07 (.05)	.141
Bullying perpetration								
Physical (2604)	0.28 (0.04)	0.28 (0.04)	.860	0.26 (0.04)	0.34 (0.04)	.005	0.08 (.04)	.032
Verbal (2576)	0.59 (0.05)	0.50 (0.06)	.022	0.62 (0.05)	0.50 (0.06)	.004	-0.03 (.06)	.636
Relational (2570)	0.28 (0.04)	0.30 (0.04)	.516	0.28 (0.04)	0.30 (0.04)	.387	0.01 (.04)	.860
Cyber (2595)	0.27 (0.03)	0.28 (0.03)	.623	0.26 (0.03)	0.30 (0.03)	.108	0.03 (.04)	.412
Social-emotional competence (2699)	3.19 (0.02)	3.17 (0.03)	.182	3.17 (0.02)	3.15 (0.03)	.334	0.01 (.03)	.810
Social awareness (2384)	2.94 (0.02)	2.93 (0.03)	.847	2.91 (0.02)	2.92 (0.03)	.464	0.02 (.03)	.510
Emotion regulation (2374)	2.38 (0.03)	2.51 (0.03)	<.001	2.43 (0.03)	2.54 (0.03)	<.001	-0.02 (.04)	.559
Relationship skills (2366)	2.78 (0.03)	2.80 (0.03)	.315	2.75 (0.03)	2.79 (0.03)	.193	0.01 (.03)	.813
Responsible decision-making (2355)	2.91 (0.03)	2.95 (0.03)	.148	2.92 (0.03)	2.98 (0.03)	.006	0.02 (.03)	.460
Multiple imputation analyses (2746)								
Bullying victimization								
Physical	0.61 (.05)	0.48 (.05)	<.001	0.61 (.05)	0.60 (.05)	.830	0.13 (.05)	.013
Verbal	1.18 (.08)	0.89 (.08)	<.001	1.28 (.07)	0.99 (.08)	<.001	0.00 (.09)	.966
Relational	0.84 (.06)	0.69 (.06)	.001	0.89 (.06)	0.74 (.07)	.003	0.01 (.07)	.907
Cyber	0.51 (.05)	0.47 (.05)	.270	0.60 (.05)	0.52 (.05)	.011	-0.05 (.05)	.309
Bullying perpetration								
Physical	0.30 (.03)	0.29 (.04)	.928	0.30 (.03)	0.36 (.04)	.013	0.07 (.04)	.060
Verbal	0.61 (.05)	0.51 (.06)	.023	0.67 (.05)	0.55 (.06)	.005	-0.03 (.06)	.661
Relational	0.30 (.04)	0.33 (.04)	.353	0.31 (.04)	0.34 (.04)	.239	0.01 (.04)	.844
Cyber	0.28 (.03)	0.29 (.03)	.726	0.29 (.03)	0.32 (.03)	.148	0.03 (.04)	.430
Social-emotional competence	3.19 (.02)	3.17 (.03)	.209	3.17 (.02)	3.15 (.03)	.386	0.01 (.03)	.814
Social awareness	2.94 (.02)	2.93 (.02)	.732	2.91 (.02)	2.92 (.03)	.446	0.02 (.03)	.426
Emotion regulation	2.38 (.03)	2.52 (.03)	<.001	2.43 (.03)	2.55 (.03)	<.001	-0.02 (.04)	.672

Variable (# observations)		Control			Intervention			Interaction	
		Pretest, mean (SE), n=763	Posttest, mean (SE), n=614	*P* value of difference	Pretest, mean (SE), n=774	Posttest, mean (SE), n=595	*P* value of difference	Difference in differences (SE)	*P* value
	Relationship skills	2.78 (.03)	2.80 (.03)	.295	2.75 (.03)	2.78 (.03)	.182	0.01 (.03)	.815
	Responsible decision-making	2.91 (.03)	2.95 (.03)	.142	2.91 (.03)	2.98 (.03)	.005	0.03 (.03)	.327

Table 3. Per-protocol study outcomes with standard errors.

Variable (# observations)	Control			Intervention			Interaction	
	Pretest, mean (SE), n=603	Posttest, mean (SE), n=603	*P* value of difference	Pretest, mean (SE), n=581	Posttest, mean (SE), n=581	*P* value of difference	Difference in differences (SE)	*P* value
Linear Mixed Models (no imputation)								
Bullying victimization								
Physical (2285)	0.61 (.05)	0.47 (.05)	<.001	0.63 (.05)	0.59 (.06)	.312	0.10 (.05)	.062
Verbal (2252)	1.19 (.08)	0.87 (.08)	<.001	1.30 (.08)	0.98 (.08)	<.001	0.00 (.09)	.991
Relational (2239)	0.82 (.07)	0.65 (.07)	<.001	0.89 (.07)	0.72 (.07)	.001	0.00 (.07)	.953
Cyber (2285)	0.47 (.05)	0.44 (.05)	.292	0.63 (.05)	0.50 (.05)	<.001	-0.09 (.05)	.067
Bullying perpetration								
Physical (2272)	0.27 (.04)	0.27 (.04)	.954	0.27 (.04)	0.34 (.03)	.014	0.06 (.04)	.082
Verbal (2245)	0.57 (.06)	0.49 (.06)	.060	0.67 (.06)	0.52 (.06)	.001	-0.06 (.06)	.302
Relational (2244)	0.26 (.04)	0.29 (.04)	.314	0.30 (.04)	0.31 (.04)	.633	-0.02 (.04)	.725
Cyber (2263)	0.25 (.04)	0.27 (.04)	.388	0.27 (.04)	0.31(.04)	.210	0.01 (.04)	.757
Social-emotional competence (2336)	3.18 (.03)	3.15 (.03)	.198	3.16 (.03)	3.14 (.03)	.360	0.01 (.03)	.808
Social awareness (2043)	2.94 (.03)	2.93 (.03)	.640	2.92 (.03)	2.93 (.03)	.635	0.02 (.03)	.510
Emotion regulation (2034)	2.40 (.03)	2.52 (.03)	<.001	2.42 (.03)	2.54 (.03)	<.001	-0.00 (.04)	.944
Relationship skills (2029)	2.77 (.03)	2.79 (.03)	.348	2.73 (.03)	2.77 (.03)	.065	0.02 (.03)	.588
Responsible decision- making (2024)	2.91 (.04)	2.94 (.04)	.175	2.92 (.04)	2.98 (.04)	.007	0.03 (.03)	.400
Multiple imputation analyses (2368)								
Bullying victimization								
Physical	0.61 (.05)	0.48 (.05)	<.001	0.64 (.06)	0.62 (.05)	.568	0.11 (.05)	.036
Verbal	1.20 (.08)	0.91 (.08)	<.001	1.33 (.08)	1.01 (.08)	<.001	-0.02 (.09)	.817
Relational	0.83 (.07)	0.68 (.07)	.002	0.93 (.07)	0.76 (.07)	.001	-0.01 (.07)	.840
Cyber	0.48 (.05)	0.46 (.05)	.453	0.63 (.05)	0.54 (.05)	.007	-0.07 (.05)	.154
Bullying perpetration								
Physical	0.27 (.04)	0.28 (.04)	.856	0.29 (.04)	0.35 (.04)	.023	0.05 (.04)	.125
Verbal	0.57 (.06)	0.49 (.06)	.072	0.70 (.06)	0.55 (.06)	.002	-0.06 (.06)	.332
Relational	0.27 (.04)	0.31 (.04)	.180	0.32 (.04)	0.34 (.04)	.374	-0.01 (.04)	.767
Cyber	0.26 (.03)	0.28 (.03)	.400	0.29 (.04)	0.32 (.04)	.251	0.01 (.04)	.813
Social-emotional competence	3.18 (.03)	3.15 (.03)	.219	3.16 (.03)	3.15 (.03)	.500	0.01 (.03)	.732
Social awareness	2.94 (.03)	2.93 (.03)	.609	2.92 (.03)	2.93 (.03)	.591	0.02 (.03)	.459
Emotion regulation	2.40 (.03)	2.53 (.03)	<.001	2.41 (.03)	2.55 (.03)	<.001	0.01 (.04)	.881
Relationship skills	2.77 (.03)	2.79 (.03)	.354	2.72 (.03)	2.76 (.03)	.118	0.02 (.03)	.637
Responsible decision-making	2.91 (.03)	2.94 (.03)	.171	2.91 (.03)	2.98 (.03)	.006	0.04 (.03)	.296

Secondary Objective 1

Table 4 shows student perception of the ACT Out! intervention. Students were highly receptive to the ACT Out! performance. Merging affirmative responses (both "Yes" and "YES!," or, for negative questions, "No" and "NO!"), students found that the intervention was enjoyable (443/537, 82.5%), interesting (429/512, 83.8%), understandable (433/521, 83.1%), believable (433/517, 83.8%), important (417/506, 82.4%), and helpful (401/513, 78.2%). They also found that it was *not* a waste of time (424/518, 81.9%), boring (406/511, 79.5%), or difficult to understand (444/511, 86.9%).

Table 4. Perceptions of ACT Out! intervention. (Percentages may not add exactly to 100 due to rounding.)

Variable (# observations)	Values, n (%)
Enjoyable (537)	
NO!	46 (8.6)
No	48 (8.9)
Yes	235 (43.8)
YES!	208 (38.7)
Interesting (512)	
NO!	34 (6.6)
No	49 (9.6)
Yes	236 (46.1)
YES!	193 (37.7)
Waste of time (518)	
NO!	230 (44.4)
No	194 (37.5)
Yes	56 (10.8)
YES!	38 (7.3)
Boring (511)	
NO!	227 (44.4)
No	179 (35.0)
Yes	64 (12.5)
YES!	41 (8.0)
Understandable (521)	
NO!	36 (6.9)
No	52 (10.0)
Yes	241 (46.3)
YES!	192 (36.9)
Difficult to understand (511)	
NO!	245 (48.0)
No	199 (38.9)
Yes	43 (8.4)
YES!	24 (4.7)
Believable (517)	
NO!	45 (8.7)
No	39 (7.5)
Yes	234 (45.3)
YES!	199 (38.5)
Important (506)	
NO!	36 (7.1)
No	53 (10.5)
Yes	202 (39.9)
YES!	215 (42.5)
Helpful (513)	
NO!	47 (9.2)

Variable (# observations)	Values, n (%)
No	65 (12.7)
Yes	204 (39.8)
YES!	197 (38.4)

Secondary Objective 2

As planned, we conducted secondary analyses to see whether the intervention was superior to treatment as usual for specific subdomains of SEC measured for seventh- and tenth-grade students only (social awareness, emotion regulation, relationship skills, and responsible decision-making) using the WCSD-SECA. No notable or significant interaction effects were observed. However, all pooled students (across conditions) reported a small, statistically significant increase in emotion regulation. In the ITT model with MI, this was 0.14 (P<.001) for the control arm and 0.12 (P<.001) for the intervention arm. As above, such effects do not support causal attribution to the intervention.

Discussion

Brief Summary

The ACT Out! Social Issue Theater trial was a prespecified and preregistered cluster randomized controlled trial conducted by a research team external to the program developers and supported by additional analysts who both were independent of the research team and the developers. Study findings were mixed.

Implementation Fidelity

For school-based programs, implementation fidelity tends to be inconsistently documented and highly variable [39]. There is some evidence that achieving good fidelity may require intensive training of those delivering the intervention (eg, teachers, [40]) and may depend on school- and teacher-level variables [41]. Since the ACT Out! intervention was an improvisational and interactive intervention by actors, there was little precedent as to whether implementation fidelity would be achievable. We found that when provided with guidelines for core content elements, the professional actors in CMP were able to deliver nearly all (96.9% to 100%) prespecified content (Multimedia Appendices 3-5), even accounting for variance in student responses and different actors playing different roles, distinguishing this intervention from many school-based interventions. However, ACT Out! performances were short in duration and the actors had the delivery of the performance as their primary purpose; in contrast, teachers and schools must balance many different requirements simultaneously, involving the delivery of multiple sessions, and so high fidelity is conceptually reasonable to expect and may be a benefit of programs of this type.

Student Receptivity

The degree to which students report enjoying a program or finding it to be realistic and engaging can be interpreted as an indicator of program quality and is a common component of process evaluation [30]. The ACT Out! intervention was very positively received by students across all specified metrics. Although not an indicator of emotional *competence*, we infer that this may be interpreted as a partial measure of emotional *response* to the intervention.

Assessment of Effects on SEC

One of our primary hypotheses was that the ACT Out! intervention would improve students' SEC in the short-term; this was suspected to be the mechanism through which the proposed emotional catharsis of psychodrama [2] could be measured. This study did not support that hypothesis, with analyses demonstrating neither statistical nor clinical significance, except improvement in emotion regulation regardless of treatment condition for seventh- and tenth-grade students.

During the project kickoff meeting, individuals at CMP expressed concern about quantitatively measuring SEC, at one point asking the research team, "How do you measure the sunrise?" We collected SEC data using 2 different tools that approached SEC in complementary ways [28,31]; however, optimal measurement of SEC remains a topic of debate, even among the national SEL workgroup [42]. Thus, we note (as with all such measurement) that the trial did not definitively find that the ACT Out! intervention had not engendered SEC development; rather, it found that SEC, as measured by the DSECS-S and WCSD-SECA (2 validated tools), was not affected by the intervention. It does not necessarily follow that those tools are the optimal or correct ways to measure students' responses to the ACT Out! intervention (indeed, WCSD-SECA subscore reliability for this sample was suboptimal). It may also be the case that there was a partial ceiling effect [43] on overall SEC, as the baseline scores were relatively high: 3.202 and 3.176 for control and intervention groups, respectively, on a scale from 1-4, potentially making improvement from any source more difficult to achieve and measure. Given that all schools in the state already are required to offer SEL programming, this may also suggest that an intervention such as this would more appropriately be tested with subgroups of individuals who have lower baseline SEC (eg, not as a universal SEL program, but as an indicated program).

Assessment of Effects on Bullying

We hypothesized that the classrooms viewing the ACT Out! intervention would report reduced bullying victimization and perpetration [both traditional (physical, verbal, relational) bullying and cyberbullying] relative to the control classrooms. There was little evidence for an effect on perpetration, though 1 of the 4 models indicated the potential for slight increases for physical bullying in the intervention arm. There was also some evidence of a small reduction in cyberbullying victimization attributable to the intervention, though not for the traditional forms of bullying. That cyberbullying might be influenced

separately from traditional bullying is reasonable, as cyberbullying victimization is unique in several ways, such as where it occurs (in a digital space "outside" of school) and its ubiquity [44]. Further, some of the dramatic scenarios (2 of 5 for both seventh and tenth grades) explicitly focused on cyberbullying as opposed to traditional bullying.

There was also evidence that physical bullying victimization was lower among the control group than the intervention group at posttest, though this was not an iatrogenic effect since neither group reported increased victimization scores. This finding may have been related to the issue we discuss subsequently.

Interpretation of Pooled Victimization Effects

Students reported clinically and statistically significant reductions in physical, verbal, and relational bullying victimization at posttest relative to pretest in aggregate (pooled across both study arms). This does not directly address the study hypotheses, as improvements were seen in students who did not participate in the intervention. However, this study examined students across 3 grade levels (fourth, seventh, and tenth), with interventions offered at different times over the course of nearly 6 months, in 12 schools and 65 classrooms, with a relatively short timeframe between pretest and posttest (14 to 27 days). Thus, it was implausible (though not impossible) that an external factor outside of the study was responsible for this finding.

We therefore considered effects that may have resulted from the study procedures. It was possible that participants' responses at posttest were affected by completing the same items at pretest, either due to guessing and wanting to affect the study hypotheses or simple item-related biases introduced by familiarity with the questions [45]. However, some evidence suggests that questionnaire items do not affect student behavior [46]. Further, if this were the case, we would expect to have seen similar effects for cyberbullying victimization, bullying perpetration, and SEC, which we did not. We were also hesitant to ascribe these findings to regression to the mean [47]. The decrease was observed only for a specific subset of variables; as was already noted, bullying is common in school-based settings, so the likelihood that a large group of students from disparate settings and grades would significantly deviate from the population mean for bullying frequency is not conceptually strong. In addition, the impact of outlier cases on bullying frequency was minimized by the design, since the instance count in the questionnaire terminates at 4 ("4 or more times"). We also carefully avoided biases at the level of trial design by developing a protocol according to SPIRIT 2013 guidelines [48], preregistering the study, reporting even minor deviations, and attending to common sources of bias in clinical and prospective studies [49], though the possibility of unexplored confounding bias always must be considered [50]. Finally, 110 students in the control group indicated that they had seen a play or presentation by ACT Out! Ensemble before, though the degree of confounding influence, or the topic of prior performances, is unknown.

One such potential source of variance may have been the decision to randomize at the level of the classroom rather than at the level of the school. As has long been established, rigorous studies and evaluation of school-based programs is very methodologically difficult [51]. Prior research has indicated that randomizing at the school level can be problematic because schools often implement various SEL, SEC, and bullying programs, and so confounding variance can be introduced [23]. We were especially concerned about this when developing the protocol because SEL is written into expectations for Indiana schools, but not prescriptively (eg, schools can address it in different ways) [2]. By randomizing classrooms, we attempted to evade this problem by ensuring that a school's other activities outside of this study were relatively equally represented among intervention and control clusters. However, it is important to consider that bullying does not occur within pre-existing clusters; that is, one is not limited to bullying or being bullied by students in the same homeroom period or English class. Thus, it is possible that an intervention affecting a bullying-related behavior, delivered to a random half of clusters within a grade and school, would have an effect on all clusters.

If this were the core mechanism explaining our data, then both bullying perpetration and victimization would theoretically be reduced; however, only victimization was reported to have been lowered. Thus, after careful consideration of the findings, including lack of SEC effect, high student receptivity and intervention fidelity, and significant time effects for traditional bullying victimization only, we hypothesize that the ACT Out! intervention may engender a heightened, defensive bystander response in participants. Bystander intervention in bullying has been associated with self-efficacy (belief that an intervention can be successful) [52], perceived knowledge about how one might successfully intervene [53], and the degree to which a bullying event is interpreted as serious [54]. Many of the scenarios for each grade level emphasized the roles of individuals other than the bully and the victim within the vignette and illustrated ways that others could intervene in a situation. They also identified potentially serious consequences that could emerge from bullying, including self-harm, so we infer surface-level plausibility of this explanation.

It is important to emphasize that while the data from this study were consistent with this explanation, the study itself *does not* provide causal evidence that the intervention engenders an increased likelihood for bystanders to intervene in bullying, nor was this an initial study hypothesis. Rather, we only know definitively that reported victimization decreased over time, in aggregate, among all participants. Additional research will be needed to determine the mechanism(s) by which this occurred. However, it is important to interpret and acknowledge all study findings to promote transparent research literature, and we have attempted to do so here.

Limitations and Strengths

This study was truncated unexpectedly by the COVID-19 pandemic, which had the effect of preventing planned 3-month outcome data collection and moderately affecting the number of clusters available for analysis for short-term outcomes (loss of 11 clusters). There were also several unplanned deviations from the study protocol, each of which has been documented in Multimedia Appendix 1. Participating schools were from both urban and rural counties in Indiana, and student participants were generally more diverse than the population of Indiana as

a whole. However, some caution should be used when generalizing these findings outside of the participating schools, especially since participating schools were those that volunteered to participate in a randomized trial. Further, given sample proportions, the results can be generalized more readily to middle and high school students than elementary school students. The study also had several notable strengths, including prespecification of all analyses; use of multiple objective, external consultants to the research team; thorough documentation of all protocol deviations; use of validated measures; and provision of all student documents and data in an open-source format.

Conclusions and Next Steps

This study found no superiority for a 1-hour ACT Out! intervention compared to treatment as usual for SEC or offline bullying, but some evidence of a small effect for cyberbullying. As was already indicated, SEL and bullying interventions in schools tend to be lengthy and involved, and bullying interventions in particular may struggle to demonstrate effectiveness in randomized trials [24]. Since ACT Out! is much shorter and highly scalable, we interpreted the findings in this study, though few and small in magnitude, with interest.

We suggest several next steps for research in this area. First, a rigorous follow-up study with a new sample would be valuable, which addresses issues related to the interpretability of bullying victimization data, including measures of possible bystander effects and randomization at the school level while, if feasible, controlling for ongoing and recent bullying prevention programs. In doing so, scenario emphasis might also be reasonably shifted toward cyberbullying and away from physical bullying, for which potential iatrogenic effects in perpetration were computed in one of the models, though overall physical victimization declined. Second, additional data might also be collected on the sustainability of the effects beyond 2 weeks as well as on whether there is a dose-response relationship (eg, “Would 2 performances within a semester more strongly reduce victimization?”). This could also be extended by collecting measures related more broadly to student mental health, academic performance, and perceived school climate. Finally, on the practical side, given the high intervention fidelity, high student receptiveness, and preliminary evidence related to cyberbullying victimization, it would not be unreasonable for CMP to offer a performance of scenarios focused on cyberbullying prevention to supplement, rather than replace, extant bullying prevention programming. In practice (eg, outside of a trial), this intervention has comparatively low fiscal cost, only 1 hour of time is utilized, it requires no teacher time or preparation, and it may have some benefits.

Additional Resources

To facilitate replication and transparent research processes, we have included supplemental files that may be valuable to researchers. These include a table of intracluster correlations (Multimedia Appendix 6), as well as the analysis syntax and datasets for per-protocol and intention-to-treat analyses (Multimedia Appendices 7-9, respectively).

Acknowledgments

Funding for this study was provided by Lilly Endowment Inc, grant no. 2019 0543, to Claude McNeal Productions. Funding was provided to Prevention Insights via a subaward from that grant. Claude McNeal Productions and their representatives own the rights to the ACT Out! Social Issue Theater program. No one from that organization was involved in preparing the study protocol, interpreting findings, conducting analyses, or writing this manuscript, both as a matter of practice and per written agreement in the subaward to Prevention Insights.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Deviations from protocol.
[DOCX File , 14 KB - mental_v8i1e25860_app1.docx]

Multimedia Appendix 2
ACT Out! scenario guide.
[DOCX File , 24 KB - mental_v8i1e25860_app2.docx]

Multimedia Appendix 3
Fourth-grade fidelity instrument.
[DOCX File , 16 KB - mental_v8i1e25860_app3.docx]

Multimedia Appendix 4
Seventh-grade fidelity instrument.
[DOCX File , 16 KB - mental_v8i1e25860_app4.docx]

Multimedia Appendix 5
Tenth-grade fidelity instrument.
[DOCX File , 16 KB - mental_v8i1e25860_app5.docx]

Multimedia Appendix 6
Intracluster correlation table.
[DOCX File , 16 KB - mental_v8i1e25860_app6.docx]

Multimedia Appendix 7
Analysis syntax.
[ZIP File (Zip Archive), 3 KB - mental_v8i1e25860_app7.zip]

Multimedia Appendix 8
Dataset for per-protocol analysis.
[ZIP File (Zip Archive), 138 KB - mental_v8i1e25860_app8.zip]

Multimedia Appendix 9
Dataset for intent-to-treat analysis.
[ZIP File (Zip Archive), 144 KB - mental_v8i1e25860_app9.zip]

Multimedia Appendix 10
CONSORT E-HEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 680 KB - mental_v8i1e25860_app10.pdf]

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Abbreviations

BCS-A: Bullying and Cyberbullying Scale for Adolescents
CMP: Claude McNeal Productions
DSECS-S: Delaware Social-Emotional Competency Scale
ITT: intention to treat
MI: multiple imputation
PP: per-protocol
SEC: social-emotional competence
SEL: social-emotional learning
WCSD-SECA: Washoe County School District Social-Emotional Competency Assessment

Edited by G Eysenbach; submitted 19.11.20; peer-reviewed by S Kardes; comments to author 17.12.20; revised version received 18.12.20; accepted 18.12.20; published 06.01.21.

Please cite as:
Agley J, Jun M, Eldridge L, Agley DL, Xiao Y, Sussman S, Golzarri-Arroyo L, Dickinson SL, Jayawardene W, Gassman R
Effects of ACT Out! Social Issue Theater on Social-Emotional Competence and Bullying in Youth and Adolescents: Cluster Randomized Controlled Trial
JMIR Ment Health 2021;8(1):e25860
URL: http://mental.jmir.org/2021/1/e25860/
doi:10.2196/25860
PMID:33338986

Original Paper

Psychiatric Profiles of eHealth Users Evaluated Using Data Mining Techniques: Cohort Study

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Abstract

Background: New technologies are changing access to medical records and the relationship between physicians and patients. Professionals can now use e-mental health tools to provide prompt and personalized responses to patients with mental illness. However, there is a lack of knowledge about the digital phenotypes of patients who use e-mental health apps.

Objective: This study aimed to reveal the profiles of users of a mental health app through machine learning techniques.

Methods: We applied a nonparametric model, the Sparse Poisson Factorization Model, to discover latent features in the response patterns of 2254 psychiatric outpatients to a short self-assessment on general health. The assessment was completed through a mental health app after the first login.

Results: The results showed the following four different profiles of patients: (1) all patients had feelings of worthlessness, aggressiveness, and suicidal ideas; (2) one in four reported low energy and difficulties to cope with problems; (3) less than a quarter described depressive symptoms with extremely high scores in suicidal thoughts and aggressiveness; and (4) a small number, possibly with the most severe conditions, reported a combination of all these features.

Conclusions: User profiles did not overlap with clinician-made diagnoses. Since each profile seems to be associated with a different level of severity, the profiles could be useful for the prediction of behavioral risks among users of e-mental health apps.

(JMIR Ment Health 2021;8(1):e17116) doi:10.2196/17116

KEYWORDS

mental disorders; suicide prevention; suicidal ideation; data mining; digital phenotyping

Introduction

The development of new technologies shows promise for causing a revolution in the way chronic diseases are followed and treated [1]. In the past few decades, we have seen the following two major technological changes directly connected to the availability of medical information: (1) introduction of electronic health records in most health care facilities, and (2) accessibility to portable devices capable of acquiring information about their users. Both systems are already being used to enhance communication between health providers and final users and to improve the overall performance of health care. Indeed, public and private entities are massively investing in the development of web-based platforms or smartphone apps through which patients can organize their medical agenda, have access to all or part of their medical records, provide their input, and join their medical referents [2].

It seems reasonable to believe that the follow-up of persons with mental illness will be improved if eHealth systems lead to an increased interaction with health care providers. Our group and others have shown that electronic assessment is feasible with proper adaptation [3]. Efficient monitoring may prompt health responses in cases of emergency [4], inform accurately about real-life behaviors between medical appointments, reduce unnecessary visits, and sustain therapeutic decisions [5]. Other parameters, such as biomarkers and input from close relatives, can be added to the monitoring system. This kind of ecosystem already exists [6], and a growing body of evidence has shown that eHealth tools improve treatment outcomes in terms of engagement, symptom improvement, well-being, and self-care [7-13]. Their combination with machine learning techniques has also shown positive impacts on the diagnosis, prediction, and prevention of several diseases, such as cancer [14-16].

Despite these advances, the majority of potential users, such as elderly persons with low educational levels [17], seem to be unenthusiastic about e-mental health tools [18]. Utilization rates have been associated with the characteristics of health professionals [19], but there is little knowledge about the kinds of patients who use e-mental health, how they become users, and what are their patterns of use. Young age, high education, and dissatisfaction with the health care system might be common features among eHealth users [20]. We do not know if this profile also applies to patients with mental disorders, but their digital phenotype [21] is likely to contain valuable information for clinicians and providers alike [22,23]. Alterations in the patterns of use could help clinicians to detect pathological or risky behaviors and individual needs, and increase treatment efficiency.

In this article, a nonparametric latent feature model based on the Indian Buffet Process (IBP) explores the response patterns of 2254 psychiatric outpatients to a web-based questionnaire. We aimed to define specific profiles according to response patterns and then link profiles with psychiatric disorders. The study will thus specifically describe patients with psychiatric diagnoses who have used an eHealth application at least once. We hypothesize that data mining techniques, such as IBP, can be used to associate information from different questionnaires and assessments in a plausible model that could serve ultimately to plan health care delivery.

Methods

Sample

Participants were recruited from psychiatric outpatient facilities in the catchment area of Fundacion Jimenez Diaz, a University Hospital in Madrid, Spain. This hospital is part of the National Health Service and provides medical coverage to about 850,000 people. From May 2014 onwards, all clinicians working at the six mental health centers of the catchment area received specific training and were encouraged to use the MEmind Wellness Tracker systematically in their clinical activity. A total of 2254 patients signed up on the MEmind platform and completed the assessment, and they were subsequently included in the study. The assessment comprised the collection of information about sociodemographic features and diagnoses. Participants also filled up a short questionnaire. For this study, we used broad inclusion criteria. Every patient attending psychiatric consultations independent of diagnosis was considered. Thus, all clinicians in the catchment area were instructed to propose the use of the web application to every outpatient they saw with no restriction whatsoever regarding their diagnoses or their clinical statuses. The total number of outpatients who consulted during the study period was 30,808.

For the purpose of this study, we included only participants who voluntarily accessed the application and responded to an open-text field. We made this choice to select proactive participants who completed most of the questions at the user end. We noted a missing data rate of 12%, which resulted from the sum of clinical missing data and a lack of completeness of the questionnaires at the user end of the application.

This study was performed in agreement with the ethic requirements of the Declaration of Helsinki (World Medical Association, 2013) and was approved by the Institutional Review Board of the University Hospital Fundación Jiménez Díaz (Madrid, Spain). All participants provided written informed consent to participate in the study.

Assessment

Questionnaires

The data set consists of 23 questions from the following three different questionnaires: (1) a brief day assessment related to sleep quality, appetite, medication intake, aggressiveness, and suicidal behavior (six items); (2) the Who-5 Well-Being Index [24] (five items); and (3) the ninth version of the General Health Questionnaire [25] (12 items). All these questionnaires are short self-reported measures of current mental well-being. All items are yes-or-no questions, followed by the degree of agreement reported on a Likert scale (0 to 100 points). Although participants could repeat the assessment, only data from the first report were included in the model.

Clinical Diagnoses

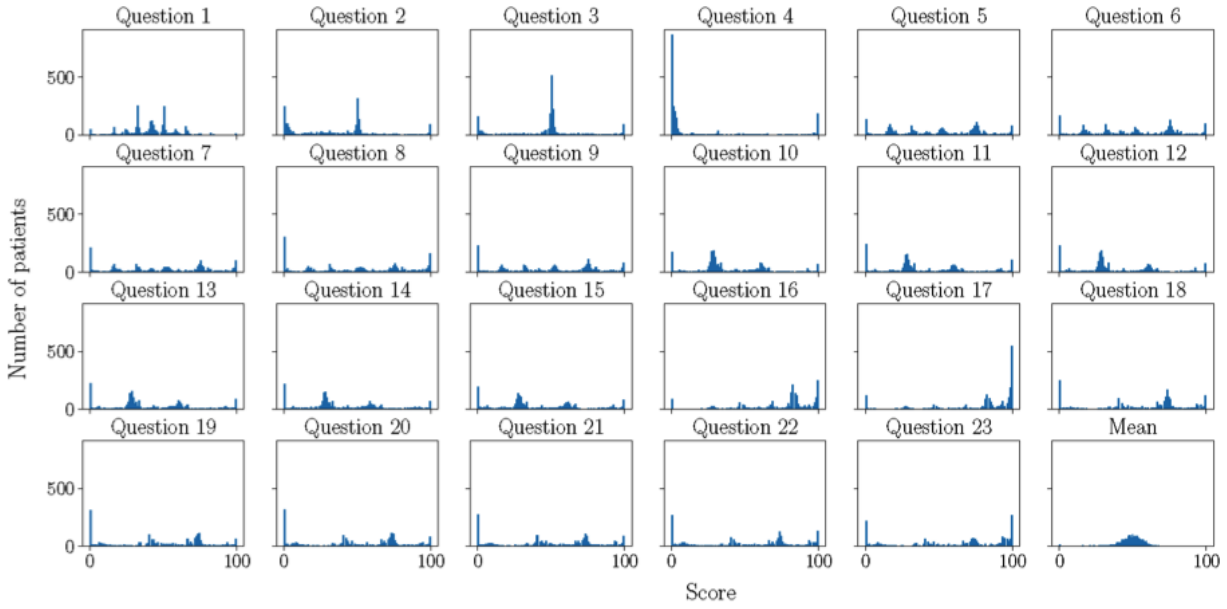
Diagnostic coding was based on the International Statistical Classification of Diseases and Related Health Problems (ICD-10) [26]. Thus, diagnoses of mental disorders were

classified into 10 groups (F0 to F9) according to ICD-10 (Multimedia Appendix 1). The corresponding physician coded the diagnosis for each patient and completed the clinical global impression (CGI) scale [27], which reflects the global functioning of a patient according to the view of the clinician on a scale (0 to 7 points). The CGI scale provides a summary measure accounting for patient history, psychosocial factors, behavior, and the impact of symptoms on the patient's ability to function (Multimedia Appendix 2).

Data Processing

First, the scores for the items with a positive valence in the questionnaire data set (items 1 to 15) were inversed. In this way, a higher score for any item of the questionnaire indicated poorer mental health. Second, we dichotomized every item score using a specific threshold in order to code the top 10% scores with the value "1" and the remaining 90% with the value "0" (Multimedia Appendix 3). The use of a centesimal scale increases the sensibility of the questionnaire. Responders tend to avoid extreme values unless they identify completely with them [28], but extreme responders do not seem to be affected by the length of the response scale [29]. By using the highest scores, we made sure that only the extreme responders were separated. The histograms of dichotomized scores for the items are shown in Figure 1.

Figure 1. Histograms of scores provided by eHealth users to each of the 23 questions of the mental well-being questionnaire. Scores range from 0 to 100. The last histogram presents the average score for all questions.



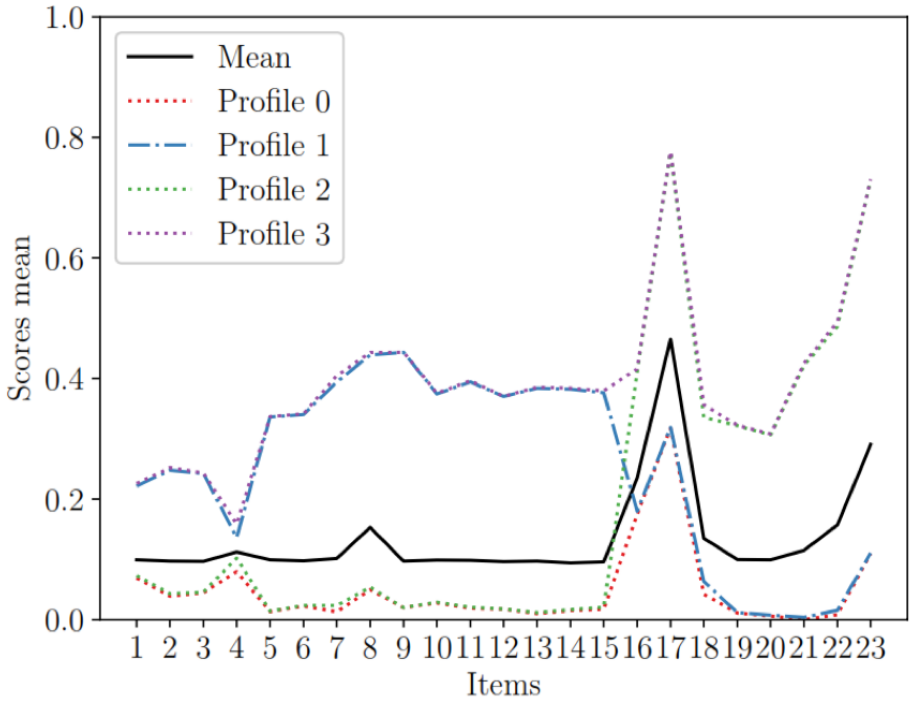
The clinical records of the participants provided a second source of data. These records included sex, age, clinical diagnoses, and CGI values. CGI values presented missing data, so subsequent analyses including this variable were carried out with a total sample of 2000 participants. For analyses involving clinical diagnoses, the total sample was 1787 participants. All patients with missing data were excluded from this part of the data modeling. Comorbid diagnoses were also examined when present.

Data Modeling

We applied the *Sparse Poisson Factorization Model* (SPFM) to model the data. The SPFM is based on the IBP [30], a nonparametric probabilistic method that proposes a sparse analysis of the variables. The input data for the model must be binary or categorical. The SPFM decomposes the input matrix into the following two nonnegative and disperse matrixes: matrix Z and matrix β. Latent factor sets can be calculated from them. The binary Z matrix represents the number of active factor sets for each patient (Multimedia Appendix 4). The β matrix weights the contribution of each factor set to each item of the questionnaire. Each factor set is characterized by precise values on the 23 questions. A higher weight (β) of a factor set for an item is associated with a greater probability to find a high score in that item when that particular factor set is active. The SPFM also estimates a *bias term*, a factor set that is present in all the patients of the sample [31]. The bias term is the "default" situation of an eHealth user and represents a profile shared by all patients that is independent of any additional feature. In that sense, the bias term allows the machine learning function to be shifted to better fit the data in a similar way as done by the y-intercept in an equation.

Different profiles have been obtained by applying the basic clustering method K-means [32]. The procedure classifies a given data set through a certain number of clusters fixed a priori. This method, applied on the Z matrix, associates data with similar characteristics into different clusters by using centroids. Thus, it allows clustering patients who show similar activation of their factor sets (Figure 2).

Figure 2. Item scores according to the four patient profiles and their averages for the whole sample.



Results

Sample Description

The sample involved 2254 patients, including 1184 (52.53%) women, 795 (35.27%) men, and 275 (12.20%) patients with missing data on sex. The mean age was 52.0 years (SD 15.1). Medical reports about the patients showed a CGI mean score of 2.95 (SD 1.95) (Multimedia Appendix 5) with a high percentage of participants scoring 3 (mildly ill; 844/2000, 42.20%) or 4 (moderately ill; 632/2000, 31.60%) and only a few scoring 6 or 7 (severely ill or extremely ill; 10/2000, 0.50%). According to the ICD-10 criteria, participants with mood disorders (F3; 347/1787, 19.43%), stress-related disorders (F4; 962/1787, 53.82%), and adult personality disorders (F6; 178/1787, 9.96%) represented most of the sample (Multimedia Appendix 6).

Data Classification

The SPFM latent model analysis found the following three components in the assessment: one *bias term* and two *factor sets*. Both the bias term and factor sets involved groups of items of the questionnaire that are particularly informative. The bias term is present for all patients and reflects a common behavioral pattern. On the other hand, factor sets 1 and 2 are based on subsets of answers with high informational value to discriminate patients. Factor sets 1 and 2 can be present or absent for a particular patient. They are present if the corresponding subset of responses has a high score (value “1”: highest 10% scores) and are absent if the corresponding subset of responses has a low score (value “0”: remaining 90% of the scores).

The K-means algorithm applied on the Z matrix established four different patient profiles according to the presence of none, one, or both factor sets. Profile 0 presents only the bias term, profile 1 presents the bias term plus factor set 1, profile 2 presents the bias term plus factor set 2, and profile 3 presents the bias term and each factor set. The number of patients in each profile is shown in Table 1. In Table 2 and Multimedia Appendix 7, we can appreciate how each profile responds differently to the questionnaire.

Table 1. Number of patients in each profile.

Profile	Number of patients	Factor set
0	1113	Bias term (0)
1	480	0+1
2	616	0+2
3	45	0+1+2

Table 2. Average score for each item in the self-reported questionnaire of current mental well-being according to the β matrix of factor sets.

Questions	Profile 0 Bias term (0)	Profile 1 Factor set 0+1	Profile 2 Factor set 0+2	Profile 3 Factor set 0+1+2
1. How many hours did you sleep today? (from 0 to 12)[a]	0.0689	0.1525	0.0041	0.1567
2. Quality of sleep[a]	0.0390	0.2089	0.0040	0.2129
3. Do you have appetite?[a]	0.0446	0.1980	0.0009	0.1990
4. Do you take your medication?[a]	0.0795	0.0566	0.0225	0.0791
5. I felt joyful and with good mood[a]	0.0133	0.3228	0.0006	0.3235
6. I felt peaceful and relaxed[a]	0.0223	0.3181	0.0012	0.3193
7. I felt active and robust[a]	0.0130	0.3811	0.0103	0.3915
8. I felt awake, fresh, and rested[a]	0.0496	0.3894	0.0041	0.3936
9. My daily life has many interesting things[a]	0.0199	0.4236	0.0000	0.4236
10. Have you been able to keep focus on the tasks you did?[a]	0.0276	0.3467	0.0013	0.3481
11. Have you felt that you have a useful role in life?[a]	0.0187	0.3756	0.0018	0.3774
12. Have you felt able to make decisions?[a]	0.0173	0.3529	0.0002	0.3531
13. Have you enjoyed regular activities from daily life?[a]	0.0100	0.3739	0.0016	0.3756
14. Have you felt able to cope with your issues?[a]	0.0149	0.3674	0.0016	0.3691
15. Do you feel reasonably happy taking into account the circumstances?[a]	0.0174	0.3591	0.0030	0.3622
16. Do you feel aggressiveness?	0.1745	0.0053	0.2362	0.2415
17. Do you have suicidal thoughts?	0.3177	0.0012	0.4573	0.4585
18. Have you had worries interfering with your sleep?	0.0422	0.0210	0.2931	0.3142
19. Have you felt constantly overwhelmed or tense?	0.0109	0.0006	0.3108	0.3115
20. Have you felt unable to overcome your troubles?	0.0060	0.0015	0.3005	0.3021
21. Have you felt unhappy or depressed?	0.0001	0.0037	0.4213	0.4251
22. Have you lost self-confidence?	0.0083	0.0071	0.4784	0.4855
23. Have you felt worthlessness?	0.1097	0.0010	0.6198	0.6208

[a]The scores from these items were inversed during data processing.

Patient Profiles

The bias term was associated with high scores in suicide thoughts and aggressiveness (items 5 and 6), as well as feelings of worthlessness (item 23). All patients in our sample shared the features of the bias term, but about half of them (n=1141) also presented one or two different factor sets. Those presenting factor set 1 were included in profile 1, which was characterized by the absence of positive mood, low sleep quality, low energy, and feelings of loss of control (items 1-3 and 5-15). Patients presenting factor set 2 were included in profile 2, which was characterized by intense suicidal thoughts, aggressiveness, intense feelings of depression and worthlessness, low self-confidence, and worries interfering with sleep (items 16-23). All these characteristics were simultaneously active in patients with profile 3, who presented simultaneously with both factors. No statistical differences were found between the profiles regarding the distribution of age or sex (F_3=1.391, P=.24 and χ^2_3=0.56, P=.90).

Association Between Patient Profile and Medical Evaluation

After modeling the data, we compared CGI scores and clinical diagnoses between profiles. The results showed that the CGI scores were higher than the mean in profile 1 (3.2, SD 1.27), with the largest percentage of participants evaluated with a score of 4 (192/453, 42.4%). For profile 2, the CGI scores were lower than the mean (2.78, SD 1.28), with a high percentage of participants evaluated with a score of 3 (256/557, 45.9%). Results in profile 3 were not compared given the low number of patients.

Most diagnoses fell within the F4, F3, and F6 categories in each profile and in the total sample, corresponding with affective disorders, neurotic and stress-related disorders, and disorders

of adult personality and behavior. The distribution of participants with profile 1 was similar for all the types of diagnoses. However, profile 2 seemed to be more frequent among patients with diagnoses of schizophrenia and psychological, behavioral, and emotional disorders with onset in childhood/adolescence (F2: 43/90, 48%; F8: 3/5, 60%; and F9: 14/38, 37%; Table 3).

Table 3. Distribution of patient profiles according to the main ICD-10 diagnostic categories for psychiatric disorders (F0-F9).

Category	Profile, n (%)			
	0	1	2	3
F0	7 (50.0)	3 (21.4)	2 (14.3)	2 (14.3)
F1	26 (45.6)	13 (22.8)	18 (31.6)	0 (0.0)
F2	37 (41.1)	10 (11.1)	43 (47.8)	0 (0.0)
F3	215 (49.6)	104 (24.0)	104 (24.0)	10 (2.3)
F4	614 (51.2)	269 (22.4)	290 (24.2)	26 (2.2)
F5	51 (48.1)	25 (23.6)	29 (27.4)	1 (0.9)
F6	109 (49.1)	58 (26.1)	51 (23.0)	4 (1.8)
F7	6 (66.6)	1 (11.1)	2 (22.2)	0 (0.0)
F8	2 (40.0)	0 (0.0)	3 (60.0)	0 (0.0)
F9	20 (52.6)	3 (7.9)	14 (36.8)	1 (2.6)

Discussion

The data modeling approach we applied was able to discriminate four different profiles of patients based on the answers to a brief electronic questionnaire. All profiles shared a component associated with feelings of aggressiveness, worthlessness, and suicidal thoughts (bias term or profile 0), which seemed to be common among patients who used e-mental health tools [33], such as the MEmind Wellness Tracker.

Sex and age distributions showed very little variability across the profiles, facilitating comparisons between them. In addition to profile 0 (bias term, default pattern), three profiles where found based on the scores of different sets of questions. It is important to bear in mind that a factor set was classified as active only when the scores were in the top 10% of the corresponding items. For example, even if the item of low sleep quality is absent from profile 2, a patient with that profile could still have high scores in that item compared with the general population and thus have relatively low sleep quality.

Patients in profile 1 reported a lack of positive mood, low quality of sleep, low energy, feelings of loss of control, and difficulties to face problems. These symptoms could be reactive to life difficulties and partly due to a lack of coping skills. Patients in profile 2 presented high scores in depressive feelings, worries interfering with their sleep, feelings of being overwhelmed and unable to overcome troubles, low self-confidence, and feelings of worthlessness. This pattern seems to be related with a greater inward focus and depressive-like symptomatology. Interestingly, patients in profile 2 also reported the highest scores for suicidal thoughts and feelings of aggressiveness. Indeed, patients in profile 2 reported five of the 10 ICD-10 diagnostic criteria for a depressive episode, including disturbed sleep, depressive feelings, reduced self-confidence, ideas of worthlessness, and ideas of suicide [26]. Surprisingly, those in profile 2 were evaluated by their physicians as having a higher level of functionality (CGI) than those in profile 1, despite higher levels of suicidal thoughts, aggressiveness, and depression in profile 2. This points to discordances between the medical assessment and the self-reported momentary assessment. Finally, profile 3 involved a small group of patients with high scores in all the items of the questionnaire. They shared the features of profile 1 and profile 2, and reported the most severely affected psychological state in our sample (the highest levels of distress).

Our study suggests that the analysis of data from electronic self-assessments can discriminate profiles or clusters of patients sharing similar clinical characteristics. These features do not seem to overlap with usual clinical diagnoses, since no differences were found in the prevalence of previous psychiatric diagnoses between profiles. Most patients in each profile received diagnoses in F4 (anxiety disorders) and F3 (mood disorders) ICD-10 categories, which were numerically the most common diagnoses in the sample. However, diagnoses of disorders with an onset during childhood and adolescence (eg, F8 and F9) and schizophrenia (F2) were overrepresented in profile 2. Profile 3 was particularly overrepresented among the small group of patients with organic mental disorders (F0) in the sample, which could implicate a more complex disease course. Interestingly, in a previous paper, we found that the assessments made by clinicians did not correlate well with patients' self-reports within 24 h of a clinical evaluation [34].

The presence of sporadic suicide thoughts can be relatively frequent in psychiatric patients, but eHealth apps could help to identify profiles with higher suicide risk, such as profile 2. Previous literature has suggested improvements in mood, well-being, anxiety, and self-awareness, as well as a higher adherence to treatments among users of eHealth apps [5,35-37]. Electronic assessment tools, such as the one used in our study, may support physicians to discriminate patients with high suicide risk in order to adjust their interventions.

Among the limitations of our study, we note the use of only baseline assessments and incomplete clinical information. The

described profiles might not be reflective of eHealth users who continue to use the app regularly. Besides, our intention was not to map the participants onto Diagnostic and Statistical Manual of Mental Disorders (DSM) or ICD categories but rather to identify symptomatic profiles that are not necessarily reflected in psychiatric diagnoses. This study was designed to explore the utility of a new method to classify e-mental health users, and it needs to be completed with follow-up data. Nonetheless, once the SPFM is trained, it will be possible to analyze changes in patient profiles during continuous assessment with several time points. It will also be possible to link the electronic assessment with medical records. Our results could help to select the most performing questions according to mental disorders or patient profiles, which, in turn, could be used to create shorter and more efficient questionnaires. We can see in our study that the question about medication intake had very low informative value.

There are still many concerns regarding e-mental health that need to be addressed. One of the main concerns reported by both professionals and users is related to the privacy, ownership, and responsible use of medical information [38,39]. This is one of the major challenges that eHealth needs to address by means of privacy-preserving technologies [40]. Accessibility and difficulties to find reliable sources of medical information are also important concerns in the population, especially among older adults [41]. Medical professionals also have doubts about the capacity of online information to improve the knowledge of patients and have reported concerns regarding the capacity of telemedicine to enhance physician-patient bond [39]. All these concerns must be addressed in order to improve the acceptability and use of eHealth tools. A recent study suggested that there is still a low preference for the use of eHealth tools among the adult general population [17]. However, those who have already used eHealth apps usually feel confident to continue using them. Some studies have reported a sense of security and the existence of a relational bond between eHealth apps and patients with psychiatric diseases [42,43]. Our analyses show that machine learning can help to classify e-mental health users and provide clues for their diagnoses and, importantly, their needs in terms of treatment. If machine learning helps physicians to take clinical treatment decisions based on data, the social perception about available eHealth tools will certainly improve.

Acknowledgments

This study received grant support from Instituto de Salud Carlos III (ISCIII PI13/02200; PI16/01852), Delegación del Gobierno para el Plan Nacional de Drogas (20151073), the American Foundation for Suicide Prevention (LSRG-1-005-16), the Ministerio de Ciencia, Innovación y Universidades (RTI2018-099655-B-I00; TEC2017-92552-EXP), and the Comunidad de Madrid (Y2018/TCS-4705, PRACTICO-CM).

Conflicts of Interest

EBG and AAR designed the MEmind application. The authors declare no other conflicts of interest.

Multimedia Appendix 1
List of categories from the ICD-10 Classification of Mental and Behavioral Disorders.
[DOCX File , 13 KB - mental_v8i1e17116_app1.docx]

Multimedia Appendix 2
Clinical global impression (CGI) scores: severity of illness.
[DOCX File , 12 KB - mental_v8i1e17116_app2.docx]

Multimedia Appendix 3
Dichotomized processing of data from the questionnaire scores.
[DOCX File , 14 KB - mental_v8i1e17116_app3.docx]

Multimedia Appendix 4
A binary Z matrix, presenting the number of active factor sets for each patient. Each line corresponds to a single patient. All patients present the bias term or factor set 0.
[DOCX File , 48 KB - mental_v8i1e17116_app4.docx]

Multimedia Appendix 5
Number of patients by clinical global impression (CGI) scores.
[DOCX File , 28 KB - mental_v8i1e17116_app5.docx]

Multimedia Appendix 6
Percentage of patients according to ICD-10 diagnoses.

[DOCX File , 26 KB - mental_v8i1e17116_app6.docx]

Multimedia Appendix 7
Average scores for each item of the self-reported questionnaire of current mental well-being according to the gamma distribution. The model is based on a β matrix. A higher weight (β) of a factor set for an item is associated with a greater probability to find a high score in that item when that particular factor set is active.
[PNG File , 30 KB - mental_v8i1e17116_app7.png]

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Abbreviations

CGI: clinical global impression
IBP: Indian Buffet Process
ICD: International Statistical Classification of Diseases and Related Health Problems
SPFM: Sparse Poisson Factorization Model

Edited by J Torous; submitted 20.11.19; peer-reviewed by S Goodday, A Daros; comments to author 10.01.20; revised version received 31.03.20; accepted 05.04.20; published 20.01.21.

Please cite as:
Lopez-Castroman J, Abad-Tortosa D, Cobo Aguilera A, Courtet P, Barrigón ML, Artés A, Baca-García E
Psychiatric Profiles of eHealth Users Evaluated Using Data Mining Techniques: Cohort Study
JMIR Ment Health 2021;8(1):e17116
URL: http://mental.jmir.org/2021/1/e17116/
doi:10.2196/17116
PMID:33470943

Original Paper

Mobile Phone Use and Acceptability for the Delivery of Mental Health Information Among Perinatal Adolescents in Nigeria: Survey Study

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Abstract

Background: There are several barriers that may hamper adolescent mothers' utilization of available health interventions for perinatal depression. Innovative treatment approaches are needed to increase adolescent mothers' access to mental health care for improved maternal and child health outcomes. Mobile phones have the potential to serve as important conduits to mental health care in Africa. However, mobile phone use patterns and needs among young mothers in Nigeria are not well documented.

Objective: This study sought to determine the prevalence of mobile phone use among perinatal adolescents and report patterns of use, as well as to assess the openness of young mothers to mobile health (mHealth) mental health interventions.

Methods: We surveyed 260 adolescent mothers (ages 16-19 years) in their perinatal or postnatal periods of pregnancies in 33 primary health care clinics in Ibadan, Oyo State, Nigeria in 2020. Respondents were included if they were pregnant with a gestation age of greater than or equal to 4 weeks, or had babies (which they had birthed) that were younger than 12 months.

Results: The total study sample consisted of 260 adolescent mothers with a mean age of 18.4 (SD 0.88) years. The majority of the respondents (233/260, 89.6%) owned mobile phones (eg, keypad, keypad and internet, smartphones); 22 (8.5%) of the 260 mothers had access to phones that belonged to relatives who lived in the same household, while 5 (1.9%) had access only to public paid phones. Only 23% (54/233) of phone owners (which is 20.5% of the total study population) had smartphones. On average, respondents reported first using mobile phones at 15.5 (SD 2.06) years old. The majority of respondents (222/260, 85.4%) reported using their phones for an average of 45 minutes daily for calls to family members. Facebook was the social media platform that was most often used among respondents who had phones with internet access (122/146 minutes per day, 83.4%). The majority of the sample responded as being "interested" and "very interested" in the use of mobile phones for preventive interventions (250/260, 96.2%) and treatment (243/260, 93.5%) information on mental illness such as depression and "hearing voices." Half of the respondents (126/233, 50.4%) preferred to receive such information in the form of text messages.

Conclusions: Findings from this study suggest that the vast majority of perinatal adolescents in Nigeria own and use mobile phones and that they are interested in leveraging these devices for prevention, treatment, and informational campaigns focused on mental health. The use of smartphones in this population is relatively low, and health intervention through text messages were favored by the women.

(JMIR Ment Health 2021;8(1):e20314) doi:10.2196/20314

KEYWORDS

mHealth; perinatal adolescent; perinatal depression; community; low income

Introduction

Sub-Saharan Africa has the world's highest level of adolescent childbearing [1]. In Nigeria, up to 31% of women have had a live birth before the age of 18 [1]. The challenges of pregnancy and childbirth increase the vulnerability of expectant mothers to common perinatal mental health problems such as anxiety and depression [2]. Pregnancy in adolescence occurs at a developmental period of intense psychological and physical change, thereby increasing the risk of mental illness [2].

Depression is the most common mental illness in childbearing women [3]. Perinatal depression (ie, depression occurring in pregnancy and up to one year into the postpartum period) is an important health issue affecting women and the emotional, cognitive, and physical development of their children [3]. Perinatal depression negatively impacts maternal-infant bonding, which is necessary for child brain development and growth [3]. In adolescent mothers, perinatal depression increases the risks associated with additional pregnancies, the use of aggressive parenting techniques, and levels of psychopathology in their children [4,5]. Psychosocial treatments delivered in primary care settings in developing countries have shown promise in combatting perinatal depression [6]. However, there are a host of barriers that may hamper young mothers' access to these interventions in clinical settings [7]. Innovative treatment approaches are needed to increase adolescent mothers' access to mental health care for improved maternal and child health outcomes. Mobile phones have the potential to serve as important conduits to mental health care in Africa.

There are reports that mobile phone subscriptions in low-to-middle-income countries exceed 95% of the population [8]. In Africa, mobile phone usage cuts across age groups and classes of different socioeconomic statuses [9]. The scale of usage among poor populations is particularly prominent in the sub-Saharan African region [10]. Mobile health (mHealth) approaches are increasingly being used to support mental health care [11] to overcome access related barriers such as cost of treatment, long waiting times at the clinics, and low human resources in health, even among youth populations [12]. However, to design usable and effective mobile interventions, it is important to understand the characteristics and needs of the interventions' intended users [13].

Available data on mobile phone ownership in Nigeria according to age groups are limited and do not capture the characteristics of vulnerable mothers in primary care [14,15]. To address this need, we surveyed 260 perinatal adolescent mothers receiving primary care services in clinics in Ibadan, Oyo State, Nigeria. The objectives of the study were to ascertain the 1) proportion of perinatal adolescents in this community that use mobile phones, 2) pattern of use of mobile phones in this population, and 3) openness of adolescent mothers to mHealth-supported mental health interventions. Data from this study will inform the design and development of a targeted mHealth intervention for the management of depression in this typically hard to reach population.

Methods

This project was approved by the University College Hospital/University of Ibadan ethics review board and carried out in 33 antenatal clinics in the 11 local government areas of Ibadan between the 24th of February and the 23rd of March 2020. Consecutive perinatal adolescent attendees in primary care who were between the ages of 16-19 years were approached to participate in the study. Under the Nigerian constitution, persons under 18 years are minors. Notwithstanding, the Child Rights Act makes the provision that a child who is 16 years old has the right to give consent for scientific investigation without parental consent [16]. Four experienced female research assistants fluent in Yoruba invited young perinatal women in the primary care clinics to participate in the survey. Survey questions were in Yoruba and were administered by our research assistants. At every clinic, the research assistants initially obtained information on the age of respondents from clinic records after which viable candidates were approached in the outpatient areas. All survey interviews were conducted on the different antenatal and immunization days of the 33 clinics. Only respondents who were pregnant (gestation age of >4 weeks) or who had babies younger than 12 months were invited to participate in the study. Of the 266 mothers who were approached, 260 agreed to participate in the survey. At the screening stage, before the consent process, 6 mothers refused to participate because they were too upset about being pregnant at young ages. All 260 willing participants were required to provide written, informed consent to participate in the study. Information obtained as part of the survey included basic demographic details of respondents, pattern of mobile phone use, and willingness to engage in the use of mobile phones for general health and mental health–related programs. Interview surveys were read out to participants because of the possible low literacy rate of respondents.

The interview process took an average of 15 minutes. Respondents were given detergent soap that cost an equivalent of 1$ as an incentive. Data entry, validation, cleaning, and analysis were done using SPSS version 15. Descriptive statistics were used to report findings.

Results

Demographic Characteristics of Respondents

The total study sample consisted of 260 adolescent mothers with a mean age of 18.4 (SD 0.88) years. The majority of the young women (141/260, 54.2%) were still pregnant, with a mean gestation age of 25.6 (SD 6.2) weeks, while others (119/260, 45.8%) had babies (children less than a year old) with a mean age of 36.2 (SD 26.6) weeks. The majority (204/260, 78.4%) had completed secondary school (12 years of schooling) education, while 17 of the 260 respondents (6.6%) had only a primary school education (6 years of schooling). Of the 260 respondents, 129 (49.5%) were artisans (tailors and hairdressers) and petty traders. Only 23 (8.8%) were married, whereas 157 (60.4%) were cohabiting and 80 (30.8%) were single.

Ownership, Usage, and Access to Mobile Phones

The majority of the respondents (233/260, 89.6%) owned mobile phones. The majority (54/233, 23.2%) of the owned phones were smartphones, whereas 92 of the 233 phones (39.5%) were keypad phones with internet functions (mostly with preloaded Facebook and gaming apps), and 87 (37.3%) were basic phones. The choice of mobile network was determined mostly by network coverage in the areas the respondents lived (133/233, 57.1%), and reduced cost of airtime and mobile data (89/233, 38.2%). More than three-quarters of the respondents (195/233, 83.7%) reported their phones as personally owned and not shared with others. On average, respondents reported 15.5 years as the age when they first started using a mobile phone. Out of the 260 total respondents, 27 (10.4%) did not owe a mobile phone, and 22 (8.5%) had access to phones that belonged mostly to relatives who lived in the same house with them for an average of 80 minutes per day. Phone ownership and use demographics are depicted in Table 1.

Table 1. Mobile phone ownership, privacy, and access among respondents (N=260).

Variable	Frequency (%)
Type of phone owned (n=233)	
Android	54 (23.2)
Keypad phones with internet access	92 (39.5)
Keypad phone	87 (37.3)
Type of network (n=255, multiple responses per respondent permitted)	
Airtel (free internet mode and bonus airtime)	138 (53.1)
MTN (bonus airtime)	53 (20.4)
Glo	61 (23.5)
9mobile/Etisalat	3 (1.2)
Why choose this network (n=233)	
Affordable (airtime and mobile data)	89 (38.2)
Convenient (network coverage in area lived)	133 (57.1)
No reasons	11 (4.7)
How often do you top up your mobile phone (n=233)	
Weekly	164 (70.3)
Bi weekly	27 (11.6)
>Monthly	42 (18.1)
Do others have access to the information on your phone (n=233)	
Yes	38 (16.3)
No	195 (83.7)
Age when you had your first phone, mean years (SD) (n=233)	15.5 (2.1)
Do you have access to a mobile phone that is not yours (n=27)	
Yes	22 (8.5)
No	5 (1.9)
If yes to the above, to whom does the phone belong (n=22)	
Relative living in the same house	16 (72.7)
Friends/neighbours not living in the same house	6 (27.3)
Time you have access to phones that is not yours per day, mean minutes (SD) (n=22)	80 (79)

Mobile Phone Usage

Table 2 shows the pattern of mobile phone use among respondents. The majority of respondents (222/260, 85.4%) used their phones for a daily average of 45 minutes, mostly to call family members. Texting (SMS) was the least prevalent activity (23/260, 8.8%) at an average of 12 minutes per day. Facebook was the most used social media site among respondents (122 average minutes per day, 83.4%), and only a minority of respondents reported using WhatsApp. Also, only 8 (3.1%) of the 260 respondents reported that they conducted Google searches; however, these respondents reported an average of 110 minutes of daily Google searches. The average times spent by respondents on different activities were 112 minutes using Facebook, 104 minutes using WhatsApp, 110

minutes Google searching, and 112 minutes watching movies online.

Table 2. Mobile phone patterns of use among perinatal adolescents (N=233).

Variable	Frequency, minutes/day (%)	Mean (SD)
Who do you call most	222 (85.4)	45 (40)
Husband/boyfriend	104 (46.8)	—[a]
Family members	100 (45.0)	—
Friends	13 (5.9)	—
In laws	5 (2.3)	—
Who do you text most	23 (8.8)	12 (11)
Husband/boyfriend	11 (47.8)	—
Family members	3 (13.0)	—
Friends	7 (30.4)	—
In law	2 (8.7)	—
Internet use		
Facebook	122 (83.6)	112 (92)
WhatsApp	23 (15.7)	104 (89)
Instagram	1 (0.7)	10 (10)
Other (Google)	8 (3.1)	110 (86)
Watching movies online	100 (38.5)	122 (80)
Playing games	27	75 (46)

[a]Not available.

Interest in mHealth

When asked if they would like general health information (how to take care of themselves during pregnancy) delivered to them via mobile phone, almost all of the respondents (253/260, 97%), even including those that did not own a mobile phone, responded affirmatively (Table 3). The majority also responded as being "interested" and "very interested" in the use of mobile phones for preventive information (250/260, 96.2%) and treatment information (243/260, 93.5%) on mental illness such as depression and "hearing voices." Half of the respondents (126/260, 50.4%) preferred to receive such information as text messages, while very few (26/260, 10.4%) preferred such information as videos on phone apps.

Table 3. Perinatal adolescents' interest in mHealth (N=260).

Variables	Frequency, n (%)
Would you like for mobile phones to be used to deliver health information to you	
Yes	253 (97.3)
No	7 (2.7)
Would you like it if the mobile phone is used to deliver health information on prevention of mental disorder such as depression or hearing voices to you	
Yes	250 (96.2)
No	10 (3.8)
Would you like it if the mobile phone is used to deliver health information on treatment of mental disorder such as depression or hearing voices to you	
Yes	243 (93.5)
No	17 (6.5)
How would you like such information to be delivered	
Phone calls	97 (38.8)
Text messaging	126 (50.4)
Short videos on an app	26 (10.4)
Named social networking platform (WhatsApp and Facebook)	1 (0.4)

Discussion

Principal Findings

To our knowledge, this is the first study that systematically summarizes the use of mobile phones among perinatal adolescents in primary care in Africa and the first to document the potential viability of mHealth use for mental health care delivery in this population. Primary care clinics in Nigeria are first-line public health facilities that serve the country's grassroots. A significant strength that increases the accuracy of our findings is its representation of community-dwelling, low-income perinatal adolescents from 33 antenatal clinics in Oyo state, southwest Nigeria. The research assistants were experienced in data collection among perinatal women in primary care and had no notable problem inviting and engaging perinatal adolescents to participate in the study.

There are several findings from this study that can inform mHealth innovations in maternal mental health care for young mothers in low-income settings. Our results showed that most adolescent mothers are adequately educated. This finding is contrary to previous findings that associates adolescent pregnancy with low literacy rates [17], limited educational attainment, and limited livelihood opportunities [18]. The level of education of adolescent mothers has implications for the viability of various mHealth interventions in this population. Considering their age group and level of education, text-based resources assisted with audio-visual tools would be a possible way to enhance user engagement of mHealth interventions [19]. Almost all of the young mothers interviewed owned or had access to a mobile phone, which they used every day [14]. Mobile phones owned included inexpensive smartphones that can host apps; keypad phones that can support internet searches, and other basic keypad phones with call, text, and radio functions. A minority of the respondents who did not have phones had access to their relatives' phones. This has implications for patient privacy in mHealth treatments. In such instances, it may be that young mothers would be required to type in passwords to access treatment information on a mobile phone app. There will also be a need for auto-lock functions immediately after use to prevent secondary users' access to what might be private health information.

Nine out of ten mobile phone users' choice of mobile network services was influenced by network coverage in the area they lived. Respondents also considered the availability of network facilities such as airtime credit, unlimited free data, airtime bonus, and night browsing modes [20]. This might also be useful in the choice of mobile networks in the planning of an mHealth intervention to allow incentives for the use of mobile phones. All respondents used a pay-as-you go method (ie, calling cards). More than two-thirds of the mobile phone owners topped up their network credit weekly at an average of approximately three-quarters of a US dollar to allow them to stay in contact with family members and friends.

Different competing data bundle plans by telephone network services in the country [21] allowed more than half of the respondents to use network data on the mobile phone. This is an important consideration when exploring potential mHealth approaches that require internet access for this population. This information suggests that if internet-based functions are required in an intervention model, it might be necessary to make provisions for network data because many of the respondents that use internet access rely on the free data bonus and free night browsing made possible by mobile network providers (a reason for the respondents' choice of networks). Only 23% (54/233) of phone owners (ie, 20.5% of the sampled population) had smartphones, which would mean smartphone apps for intervention in this population would lead to the exclusion of many adolescent perinatal women with depression. However,

smartphones are becoming more widely used in Nigeria [22], which may suggest greater potential for app-based interventions in this population in the future. Further research is needed to enquire about this population's willingness to engage in mHealth intervention models that are installed on the smartphone for offline use. Facebook was reported as the preferred social media tool among our respondents, a finding that is consistent with research conducted among low-income youth [23]. Also, although few social media sites were visited by adolescent mothers, as similarly reported among disadvantaged youth communities [24], patronage of a wider range of social media sites has been reported among university students in Nigeria [15]. More than half of the survey respondents who were mobile phone owners reported the use of social media on a daily basis for over an hour, a duration that is not dramatically different from previous reports in the country [15]. Nine out of ten respondents endorsed the use of the mobile phone for delivery of health information. When asked specifically about mobile phone use for information on prevention and treatment of mental disorders such as depression or mental disorders that cause auditory hallucinations, nine out of ten respondents were also interested in mHealth information delivery. These findings support a broad willingness to engage in mHealth initiatives for the delivery of care for mental illness among perinatal adolescents. Despite the pattern of mobile phone use among respondents, which indicated making calls as a prevalent activity and online videos as the second favorite internet activity, adolescents had a preference for mHealth messages in the form of text messages, perhaps because text messages would not require the use of their network credit or perhaps due to their desire for flexibility and convenience during mHealth interactions [25].

Limitations

As in all survey research, our findings are based on respondents' self-reports. Thus, our study is susceptible to inaccurate recall or unrepresentative reporting. Social desirability bias could have been a major limitation of this research. Data was self-reported, and respondents might have given what they viewed were socially acceptable responses. The majority of the questions were structured, and respondents might have chosen answers that did not totally reflect their views but instead reflected views of the researchers who constructed the survey.

Conclusions

The study suggests low-income perinatal adolescents are open to engaging in mHealth use for mental health service delivery. A variety of mobile phone-based interventions including those with audio-visuals can be considered as promising in this population because of the population's limited literacy rate. Smartphone access is currently limited in this population and equity issues will relate to use of the phone-based interventions with limited technology to maximize access. The majority of the young mothers we surveyed had access to mobile technology that would be necessary for the implementation of a successful mobile phone-based intervention.

Acknowledgments

Author LK's work is supported by a grant from the NIH (1 K43 TW011046-01).

Conflicts of Interest

DBZ has an intervention content licensing agreement with Pear Therapeutics and has a financial interest in FOCUS technology. He has consulted for eQuility, Trusst Health, and Otsuka Pharmaceuticals Ltd. The remaining authors declare no conflict of interest.

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Edited by J Torous; submitted 15.05.20; peer-reviewed by P Kawale, K Ronen; comments to author 25.07.20; revised version received 20.09.20; accepted 11.11.20; published 26.01.21.

Please cite as:
Kola L, Abiona D, Adefolarin AO, Ben-Zeev D
Mobile Phone Use and Acceptability for the Delivery of Mental Health Information Among Perinatal Adolescents in Nigeria: Survey Study
JMIR Ment Health 2021;8(1):e20314
URL: http://mental.jmir.org/2021/1/e20314/
doi:10.2196/20314
PMID:33496678

Original Paper

mPulse Mobile Sensing Model for Passive Detection of Impulsive Behavior: Exploratory Prediction Study

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Abstract

Background: Mobile health technology has demonstrated the ability of smartphone apps and sensors to collect data pertaining to patient activity, behavior, and cognition. It also offers the opportunity to understand how everyday passive mobile metrics such as battery life and screen time relate to mental health outcomes through continuous sensing. Impulsivity is an underlying factor in numerous physical and mental health problems. However, few studies have been designed to help us understand how mobile sensors and self-report data can improve our understanding of impulsive behavior.

Objective: The objective of this study was to explore the feasibility of using mobile sensor data to detect and monitor self-reported state impulsivity and impulsive behavior passively via a cross-platform mobile sensing application.

Methods: We enrolled 26 participants who were part of a larger study of impulsivity to take part in a real-world, continuous mobile sensing study over 21 days on both Apple operating system (iOS) and Android platforms. The mobile sensing system (mPulse) collected data from call logs, battery charging, and screen checking. To validate the model, we used mobile sensing features to predict common self-reported impulsivity traits, objective mobile behavioral and cognitive measures, and ecological momentary assessment (EMA) of state impulsivity and constructs related to impulsive behavior (ie, risk-taking, attention, and affect).

Results: Overall, the findings suggested that passive measures of mobile phone use such as call logs, battery charging, and screen checking can predict different facets of trait and state impulsivity and impulsive behavior. For impulsivity traits, the models significantly explained variance in sensation seeking, planning, and lack of perseverance traits but failed to explain motor, urgency, lack of premeditation, and attention traits. Passive sensing features from call logs, battery charging, and screen checking were particularly useful in explaining and predicting trait-based sensation seeking. On a daily level, the model successfully predicted objective behavioral measures such as present bias in delay discounting tasks, commission and omission errors in a cognitive attention task, and total gains in a risk-taking task. Our models also predicted daily EMA questions on positivity, stress, productivity, healthiness, and emotion and affect. Perhaps most intriguingly, the model failed to predict daily EMA designed to measure previous-day impulsivity using face-valid questions.

Conclusions: The study demonstrated the potential for developing trait and state impulsivity phenotypes and detecting impulsive behavior from everyday mobile phone sensors. Limitations of the current research and suggestions for building more precise passive sensing models are discussed.

Trial Registration: ClinicalTrials.gov NCT03006653; https://clinicaltrials.gov/ct2/show/NCT03006653

(JMIR Ment Health 2021;8(1):e25019) doi:10.2196/25019

KEYWORDS

mobile sensing; digital phenotyping; impulse control; impulsivity; self-regulation; self-control; mobile health; mHealth

Introduction

Mobile health (mHealth) technology has demonstrated the ability of smartphone apps and sensors to collect high-fidelity and high-frequency data pertaining to patient activity, behavior, symptoms, cognition, and context [1]. Mobile sensing, in particular, has the ability to collect data objectively and continuously during the lived experience of individuals. In behavioral and mental health, digital phenotyping [2-4] or personal sensing [5] has been proposed as an approach to quantify the "moment-by-moment and continuous individual-level human phenotype" using data from sensors on smartphones. Building on this potential, prior research using mobile sensing technology focused on specific psychological disorders [6-11] or general mental and physical well-being [12-14].

One construct that has not been rigorously examined is impulsivity and impulsive behavior. Impulsivity is a multidimensional construct primarily characterized by the inability to inhibit acting on short-term temptations despite long-term consequences or loss of potential gains. Consequently, it is the hallmark feature of self-regulation failures that lead to poor health decisions and outcomes, making understanding and treating impulsivity one of the most important constructs to tackle in building a culture of health [15-18]. Across studies and subtypes, highly impulsive individuals are significantly more likely to suffer from obesity, type II diabetes, substance use disorder, attention-deficit/hyperactivity disorder, gambling problems, bipolar disorder, borderline personality disorder, and suicidal behaviors, among others [17,19-21]. Prediction of impulsive behavior is nevertheless challenging due to the multidimensional and heterogeneous nature of the impulsivity construct and different manifestations of state impulsivity [20,22]. Such impulsive behavior includes the traits of urgency, lack of planning or premeditation, lack of perseverance, inattention, present and future discounting, response inhibition, and sensation seeking. Passive detection of impulsive behavior is a crucially important research goal given the widespread negative consequences of impulsivity.

Potential behavioral biomarkers of impulsive behavior are intuitively present in most interactions with digital technology. Mobile sensing may be especially useful for assessing impulsive behavior indicative of digital addiction, such as loss of control over mobile phone use, interference with other activities, and repeated phone checking. Objectively quantifying phone usage can further help inform the debate on the existence of digital addiction [23] and identify distinct problematic uses of smartphones. Preliminary evidence suggested a link between impulsivity traits and use of mobile devices. Studies of self-reported phone usage conducted by Billieux et al [24,25] revealed a direct relationship between the inability to delay gratification and different patterns of mobile phone use. In other studies, mobile analytics features, such as latency to respond to a text, were shown to predict personality traits associated with impulsivity, such as extraversion and neuroticism [26-29].

We developed a mobile sensing system—mPulse—to remotely monitor impulsivity on both Apple operating system (iOS) and Android platforms. Our system was designed based on data that are pervasive and available across both iOS and Android platforms and can be used to measure signals of daily activities, social interactions, and digital addiction. We selected call logs, battery charging, and screen checking as the mobile sensor data sources. We conducted a 3-week exploratory study with 26 participants as part of a larger mHealth study of impulsive behavior called the Digital Marshmallow Test (DMT) [30]. To validate the mobile sensing model, we used mobile sensing features to predict common self-reported impulsivity traits, objective behavioral and cognitive measures, and ecological momentary assessment (EMA) of impulsivity and constructs related to impulsive behavior (ie, risk-taking, attention, and affect).

Methods

Background

The DMT study by Sobolev et al [30] was designed to develop and test remote assessment of impulsivity using both iOS and Android applications for widespread dissemination to researchers, clinicians, and the general public. The DMT study included a baseline laboratory assessment and a 21-day study using the DMT mobile app [30,31]. Additional details can be found in the paper describing validation of the DMT app [30] and on the Open Science Framework [31].

Participants

Of the 116 participants enrolled in the DMT study, a subsample of 26 participants enrolled in this passive sensing study. The subsample included 14 females, 10 males, and 2 participants who refused to disclose, and the average age of the participants was 39.1 (SD 14.16) years. Twenty-two participants owned Apple (iOS) phones (ie, iPhones) and 4 owned Android phones. We compared the baseline subjective trait assessments of trait impulsivity and impulsive behavior between the current subsample of participants and the full sample and found no significant differences between the groups.

Data Sources

The DMT study included three main data sources, which we used as dependent variables in this study: (1) subjective, self-reported trait impulsivity assessments performed at baseline in the lab; (2) behavioral and cognitive active tasks performed daily on the DMT mobile app; and (3) self-reports, ecological momentary assessments (EMAs), and the Photographic Affect Meter (PAM) performed daily on the DMT mobile app.

Subjective, Self-Reported Trait Measures (Lab)

The DMT study included the two most popular self-report generalized impulsivity trait assessments collected in a lab setting: the 15-item short form of the Barratt Impulsiveness Scale (BIS-15) and the UPPS.

The BIS-15 [32] measures three aspects of impulsivity: attention (inability to focus attention or concentrate), motor (acting without thinking), and nonplanning (lack of future orientation or forethought).

The UPPS impulsive behavior scale [33] assesses impulsivity on subscales pertaining to urgency (acting rashly under conditions of negative affect), lack of premeditation (difficulty in thinking and reflecting on consequences of an act), lack of perseverance (inability to remain focused on a task), and sensation seeking (tendency and openness to try and enjoy exciting or dangerous activities).

Behavioral and Cognitive Active Tasks (DMT App)

The DMT app included an adaptation of three exploratory, lab-based behavioral and cognitive measures related to impulse control to mobile devices, called "active tasks": (1) a mobile Balloon Analogue Risk Task (mBART [34]), (2) a mobile go/no-go (mGNG [35]) task, and (3) a mobile delay discounting (mDD [36]) task. The mobile versions are exploratory and were partially validated as part of the DMT study (see the DMT study [30] for more details on each of these measures).

The mBART measures how individuals balance the potential for reward and loss via a simulated test where the participant can earn virtual money by pumping a balloon. It is based on the BART [34]. The mBART includes 15 trials and lasts approximately 2 minutes. We recorded the number of pumps, which indicates risk taking, and the total gains in the task for each trial.

The mGNG is a measure of attention and response control. It is based on the GNG task [35]. The mGNG included 75 trials, each of which had the following sequence: fixation cross (250 ms), blank screen (250 ms), vertical or horizontal cue (white rectangle) for 1 of 6 stimulus-onset asynchronies (100 ms, 200 ms, 300 ms, 400 ms, 500 ms, and 750 ms), go or no-go target (green or blue rectangle, respectively) until participant responds or 500 ms, and an intertrial interval (250 ms). Participants were instructed to respond by pressing the screen as fast as possible to green, but not to blue, targets. Cues signal a target at 70% probability (horizontal: go; vertical: no-go). We recorded the commission and omission errors and response latency before they reacted to the targets.

The mDD task is used to measure the ability to delay immediate, smaller, and shorter monetary and time-based rewards for longer, time-lapsed, but larger rewards. It is based on DD tasks that were used in research on addiction [36]. We used the algorithm as described by Frye and colleagues [37]. In the mDD task, participants were given five choices between a smaller, hypothetical monetary or time-based reward that varied from trial to trial based on the previous response and a larger, fixed reward that remained the same throughout all of the trials. We recorded the propensity of choosing an immediate, smaller reward in each trial.

Self-Report, EMA, and PAM (DMT App)

The DMT app included self-reports, EMAs, and PAM.

EMAs were based on a semantic differential scale and questions consisted of two opposite feelings, thoughts, or behaviors [38]. We measured five items from 0 (most positive) to 10 (most negative): (1) focused–distracted, (2) intentional–impulsive, (3) cautious–thrill-seeking, (4) engaged–bored, and (5) determined–aimless. These items were measured twice daily with respect to the feeling in the present moment in the morning (AM) and evening (PM).

Self-reported questions were also based on a semantic differential scale [38]. We measured five items from 0 (most positive) to 10 (most negative): (1) positive–negative, (2) intentional–impulsive, (3) productive–unproductive, (4) relaxed–stressed, and (5) healthy–unhealthy. These items were self-reported based on the general feeling in the previous day.

PAM was designed for momentary response where users choose an image that best represents their emotion at a given time [39]. We used the positive and negative affect scores from PAM that have been validated to correspond to the short version of the Positive and Negative Affect Schedule (PANAS) [40].

Descriptive Statistics of DMT Data

We analyzed the correlations between different self-reports (BIS-15 and UPPS) and behavioral measures (BAR and GNG) in the full sample of the DMT study (N=116) because it provides better estimates than the subsample of 26 participants in this study. Overall, our results corresponded to previous research on impulsivity by demonstrating high correlations between different self-reports but low correlations between behavioral measures and self-reports [22]. A full description of these results can be found in the paper describing the DMT study [30].

mPulse Sensing System and Data

AWARE Framework

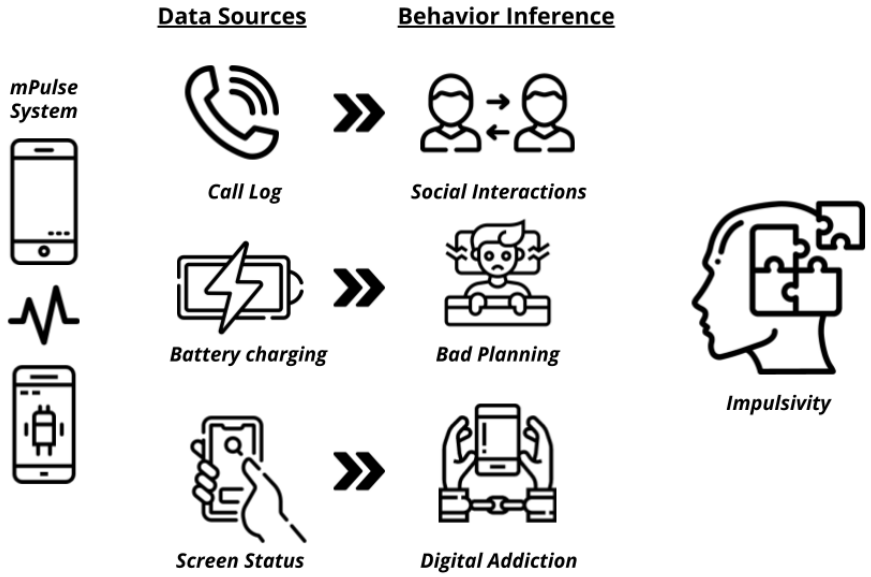
AWARE Framework is an open-source framework used to develop an extensible and reusable platform for capturing context on mobile devices [41]. It is available on both iOS and Android platforms as an installable app that collects phone sensor data (eg, activity and screen checking). In this study, we used the AWARE app to record call logs, battery charging, and screen checking locally on participants' phones.

Sensor Data

Our goal was to create sensing models that can effectively transform raw sensor data collected from mobile phones into measurable outcomes of clinical interest. We focused on data that are pervasively available across both iOS and Android platforms while minimizing battery consumption beyond the normal use of mobile devices and protecting user privacy. Therefore, despite the relevance of data sources such as accelerometers and location data for physical activity, mobility, and motor impulsivity, we elected not to include these data sources in the passive sensing model in this study. Eventually, three types of sensor data were identified and implemented in

the mPulse system (Figure 1) for these purposes: call logs, battery charging, and screen checking.

Figure 1. Conceptual framework of passive sensor data and inferred behavior.



Call Logs

Call logs are indicators of social interactions [42] and are frequently used in mobile sensing studies. Prior research, for example, identified negative correlations between frequency of incoming and outgoing calls and depressive symptoms in both clinical [43] and nonclinical [44] samples. In the mPulse system, we recorded time stamps of each call the participants sent or received and their durations. Any identifiable information, such as phone number or contact's name, were not recorded by the passive app.

Battery Charging

Battery logs are an indicator of daily activities [42]. We identified battery management as a potential indicator of self-regulation in the context of phone usage and planning. In the system, we recorded the time stamps and durations of battery charging events. We observed several instances of a charging event with a duration of 1 second followed by a longer charging event, which we suspected were caused by system error. Thus, we removed charging events that were shorter than 10 seconds. Using these criteria, 16.5% of the raw data were filtered out.

Screen Checking

Screen checking can serve as an indicator of digital and mobile addiction. For example, a previous study demonstrated that individuals with smartphone addiction presented with some symptoms common to substance- and addictive-related disorders such as compulsive behavior, tolerance, and withdrawal [45]. In the mPulse system, we measured screen checking by collecting the number of screen unlocks and the duration of each unlock session. Notification-induced screen-on events were intentionally excluded. We removed screen unlock sessions longer than 2 hours, which are triggered by unrelated usage, such as continuous use of the phone for navigation while driving. This resulted in the removal of only 0.4% of the data.

Feature Extraction

From the passive data, we extracted the same set of features for all sensor data, namely usage, frequency, entropy, mean, and standard deviation. This resulted in 15 passive features for the analysis:

- Use duration and frequency per hour: normalized duration and frequency for each hour—that is, the summation of sensor event durations and occurrences divided by total hours of data collected from each individual, respectively. For example, screen unlocks use duration per hour (denoted as screen_Use in Figure 2) refers to the average amount of time the screen was unlocked in each hour; battery_Freq refers to the number of battery charges triggered by a user in each hour.
- Use mean and standard deviation: used to measure individual usage baselines and variances. We calculated the means and standard deviations of the event durations (unit in hours) across the study for each participant. For example, screen_Mean=0.1 means that the average screen unlock duration was 0.1×60=6 minutes.
- Entropy: calculated from the possibility distribution of event occurrences over 24 hours. The intuition is that if the occurrences of the events distribute more uniformly across the day, the pattern is more random (higher entropy); otherwise, if the events occur more frequently at certain hours of the day, the pattern is more controlled (lower entropy). This was inspired by the use of the entropy feature in prior mobile sensing research to measure variability of time the participant spent at the location clusters [8].

Descriptive Statistics of Mobile Sensing

Means and standard deviations across individuals for the mobile sensing features are presented in Table 1. To predict assessment of trait impulsivity and impulsive behavior (BIS-15 and UPPS), we used averages across individuals as predictor variables. For predicting daily features, such as active tasks and EMA

questions, we used the 24-hour window before the morning assessment.

Table 1. Descriptive statistics of mobile sensor data and features.

Descriptive statistics	Battery charging, mean (SD)	Call logs, mean (SD)	Screen checking, mean (SD)
Usage (per hour)	0.30 (0.12)	0.02 (0.01)	0.17 (0.08)
Frequency (number per hour)	0.20 (0.15)	0.38 (0.28)	1.97 (1.22)
Mean (duration per activity in hours)	2.02 (1.33)	0.06 (0.04)	0.11 (0.05)
Deviations (duration per activity in hours)	2.81 (1.21)	0.15 (0.18)	0.17 (0.07)
Entropy	2.65 (0.24)	2.52 (0.25)	2.89 (0.10)

Results

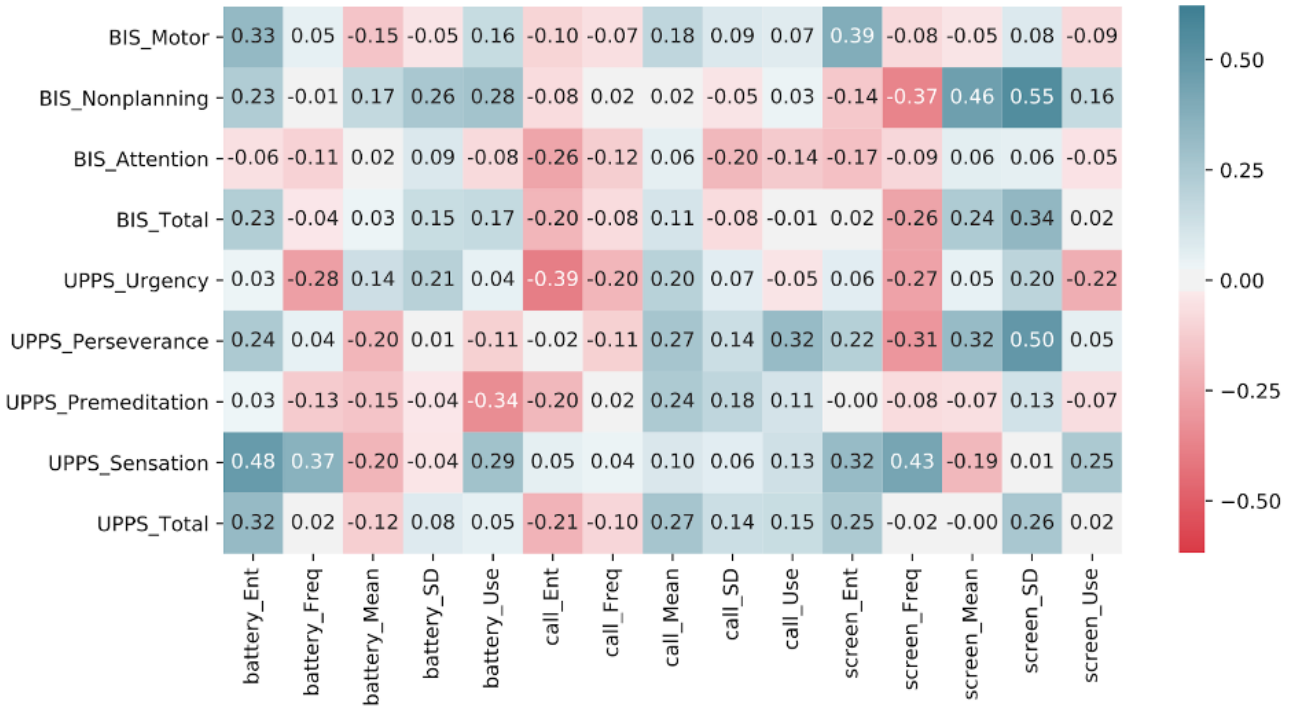
Predicting Clinical Assessments of Impulsivity Trait

In this section, we evaluate the value of mobile sensing in explaining and predicting trait impulsivity. We first examined the correlations between mobile sensing features and different components of trait impulsivity. Next, we compared the goodness of fit for regression models using mobile sensing features as predictors. Finally, we validated the predictive power of such models using leave-one-subject-out (LOSO) cross-validation.

Correlations Analysis

We found significant correlations between passive data and five of the components of trait impulsivity: (1) motor positively correlated with the entropy features extracted from screen checking (r=0.39, P=.05), suggesting that the temporal distribution of phone usage was associated with the trait of acting without thinking; (2) nonplanning correlated with several passive features, including the usage mean (r=0.46, P=.02) and usage deviations (r=0.55, P=.004) of screen-checking duration; (3) sensation seeking positively correlated with battery charging entropy (r=0.48, P=.01) and the screen-checking frequency (r=0.43, P=.03); (4) urgency negatively correlated with call entropy (r=–0.39, P=.04); and (5) perseverance positively correlated with the standard deviation of screen checking (r=0.50, P=.01). The full correlation table is shown as Figure 2.

Figure 2. Correlation between the 15 features of mobile sensor data and trait impulsivity scales (15-item short form of the Barratt Impulsiveness Scale [BIS-15] and UPPS) and subscales. Ent: entropy; Freq: frequency per hour; Mean: use mean; SD: use deviations; Use: use duration per hour.



Regression Analysis

We performed a multivariate regression analysis to examine the power of extracted mobile sensing features from day-to-day phone usage to explain components of trait impulsivity. Features were standardized across samples. Given our small sample size, we first used Lasso regularization to prevent overfitting by selecting the most important features. The same penalty threshold was used across all models (α=.05). We then used a linear regression model with ordinary least squares to estimate the trait impulsivity scores from the selected features. Model

performance was evaluated against adjusted R^2 and is summarized in Table 2.

Our analysis discovered four significant models: (1) sensation seeking ($F_{9,16}$=5.54; P=.002), with screen-checking frequency (β=.39; P=.01), call entropy (β=−.60; P=.001), and battery usage (β=.27; P=.01) as significant predictors; (2) perseverance ($F_{4,21}$=3.35; P=.03), with deviation of screen-checking duration as a significant predictor (β=.22; P=.006); (3) motor ($F_{6,19}$=2.42, P=.07), with screen entropy as a significant predictor (β=.24; P=.047); and (4) planning ($F_{4,21}$=3.76; P=.02), with deviation of screen-checking duration as a significant predictor (β=.33; P=.002).

Table 2. Descriptive statistics of laboratory subjective impulsivity and impulsive behavior trait, and regression analysis of mobile sensor data as predictors of impulsivity trait scales and subscales.

Scale and subscale	Descriptive statistics, mean (SD)	Regression summary	Significant features
BIS-15	1.77 (0.36)	$F_{4,21}$=1.36; P=.28; R^2=0.055	None
Motor	1.74 (0.45)	$F_{6,19}$=2.42; P=.07; R^2=0.254	Screen entropy (β=.24; P=.05)
Nonplanning	1.84 (0.54)	$F_{4,21}$=3.76; P=.02; R^2=0.307	Screen deviations (β=.33; P=.002)
Attention	1.66 (0.49)	$F_{2,23}$=1.19; P=.32; R^2=0.015	None
UPPS	2.04 (0.36)	$F_{4,21}$=3.48; P=.02; R^2=0.284	Call entropy (β=−.21; P=.01)
Urgency	2.07 (0.66)	$F_{7,18}$=1.16; P=.21; R^2=0.135	Call entropy (β=−.39; P=.04)
Lack of perseverance	1.57 (0.42)	$F_{4,21}$=3.35; P=.03; R^2=0.273	Screen deviations (β=.22; P=.006)
Lack of premeditation	1.73 (0.35)	$F_{4,21}$=1.27; P=.31; R^2=0.042	None
Sensation seeking	2.66 (0.64)	$F_{9,16}$=5.54; P=.002; R^2=0.621	Battery frequency (β=.27; P=.01); screen usage (β=.39; P=.01); call entropy (β=−.60; P=.001)

Prediction Analysis

LOSO cross-validation was performed to further examine the predictive power of the passive sensing features for out-of-sample data. We trained a separate linear support vector regression model for each set of passive features for 25 participants and tested it on the 1 remaining participant. We ran the same procedure 26 times to obtain predicted scores for all 26 participants. Model performance was evaluated against mean absolute error (MAE) and Pearson r. We found that the passive model predicted only the sensation-seeking trait with a MAE of 0.479. The correlation between predicted scores and true scores was significant (r=0.425; P=.03).

Predicting Daily Measures of State Impulsivity

Descriptive Statistics on Daily Variables

Descriptive statistics on daily variables used for prediction of state impulsivity are presented in Table 3.

Table 3. List of features from ecological momentary assessments and active tasks.

Features	Description	Descriptive statistics, mean (SD)
Present moment semantic differentials[a]		
Focused–distracted	Present moment distracted score	AM: 3.23 (2.45); PM: 3.71 (2.74)
Intentional–impulsive	Present moment impulsive score	AM: 3.86 (2.75); PM: 4.47 (2.93)
Cautious–thrill-seeking	Present moment thrill-seeking score	AM: 3.63 (2.20); PM: 3.63 (3.68)
Engaged–bored	Present moment bored score	AM: 3.24 (2.11); PM: 3.23 (2.33)
Determined–aimless	Present moment aimless score	AM: 2.74 (2.04); PM: 3.08 (2.19)
Previous day semantic differentials[a]		
Positive–negative	Previous day negativity score	2.59 (2.11)
Intentional–impulsive	Previous day impulsive score	3.95 (2.92)
Productive–unproductive	Previous day unproductive score	2.47 (1.99)
Relaxed–stressed	Previous day stressed score	4.64 (2.84)
Healthy–unhealthy	Previous day unhealthy score	3.92 (2.50)
PAM[b]		
Positive affect	Positive affect score from PAM	9.25 (3.50)
Negative affect	Negative affect score from PAM	5.79 (3.66)
mBART[c]		
Risk-taking	Average number of pumps across all trials	3.89 (1.09)
Total gains	Average total gain across all trials	10.31 (2.73)
mGNG[d]		
Response latency	Average response time across all trials	423.99 ms (67.70)
Commission error	Proportion of “go” errors across all “go” trials	0.02 (0.06)
Omission error	Proportion of “no-go” errors across all “no-go” trials	0.02 (0.03)
mDD[e]		
Present bias	Average propensity to choose immediate reward across all trials	0.34 (0.18)

[a]Measured on a scale from 0-10, with 0=most positive and 10=most negative.

[b]PAM: Photographic Affect Meter.

[c]mBART: mobile Balloon Analogue Risk Task.

[d]mGNG: mobile go/no-go task.

[e]mDD: mobile delay discounting task.

Predicting EMA

We used a generalized estimating equation (GEE) model to take into account the intraclass correlations for individual differences. We performed a multivariate regression analysis for five daily semantic differentials and positive and negative affect measures. We further performed a binary classification task by labeling samples with 1=higher than the median value and 0=lower than the median value for each daily measure. We used a logistic regression model and LOSO cross-validation. The full results are reported in Table 4.

Our analysis discovered three significant models for morning and evening semantic differentials: (1) focused–distracted (AM: r=0.276, P<.001, 83% accuracy; PM: r=0.194, P=.002, 74% accuracy); (2) cautious–thrill-seeking (AM: r=0.245, P<.001, 86% accuracy; PM: r=0.361, P<.001, 87% accuracy); and (3) determined–aimless (AM: r=0.360, P<.001, 94% accuracy; PM: r=0.217, P<.001, 91% accuracy). Our analysis also discovered four significant models for previous day semantic differentials: (1) positive–negative (r=0.316, P<.001, 84% accuracy); (2) relaxed–stressed (r=0.377, P<.001, 63% accuracy); (3) healthy–unhealthy (r=0.248, P<.001, 76% accuracy); and (4) productive–unproductive (r=0.271, P<.001, 92% accuracy). Models for positive affect (r=0.143, P<.001, 72% accuracy) and negative affect (r=0.171, P<.001, 72% accuracy) were also significant with similar effects. Notably, the models were not significant for predicting intentional–impulsive (r=0.057, P=.34, 68% accuracy).

Table 4. Regression analysis and classification of mobile sensor data as predictors of daily ecological momentary assessment questions for semantics differentials and the Photographic Affect Meter (PAM).

Features	Generalized estimating equation regression summary (Pearson *r*, within-group correlation)	Classification accuracy (SD) across individuals
Present moment semantic differentials (AM/PM)		
Focused–distracted	AM: *r*=0.276, *P*<.001, 0.388; PM: *r*=0.194, *P*=.002, 0.388	AM: 0.83 (0.21); PM: 0.74 (0.26)
Intentional–impulsive	AM: *r*=–0.04, *P*=.50, 0.743; PM: *r*=0.04, *P*=.51, 0.753	AM: 0.80 (0.28); PM: 0.64 (0.29)
Cautious–thrill-seeking	AM: *r*=0.245, *P*=<.001, 0.633; PM: *r*=0.361, *P*=<.001, 0.631	AM: 0.86 (0.17); PM: 0.87 (0.16)
Engaged–bored	AM: *r*=0.273, *P*=<.001, 0.329; PM: *r*=0.061, *P*=.322, 0.481	AM: 0.86 (0.14); PM: 0.84 (0.18)
Determined–aimless	AM: *r*=0.360, *P*<.001, 0.185; PM: *r*=0.217, *P*=<.001, 0.285	AM: 0.94 (0.12); PM: 0.91 (0.15)
Previous day semantic differentials		
Positive–negative	*r*=0.316, *P*<.001, 0.157	0.84 (0.17)
Intentional–impulsive	*r*=0.057, *P*=.34, 0.794	0.68 (0.28)
Productive–unproductive	*r*=0.271, *P*<.001, 0.161	0.92 (0.10)
Relaxed–stressed	*r*=0.377, *P*<.001, 0.134	0.63 (0.22)
Healthy–unhealthy	*r*=0.248, *P*<.001, 0.242	0.76 (0.21)
PAM		
Positive affect	*r*=0.143, *P*<.001, 0.112	0.72 (0.15)
Negative affect	*r*=0.171, *P*<.001, 0.114	0.72 (0.15)

Predicting Daily Active Tasks

We used a GEE model to take into account the intraclass correlations for individual differences. We performed an exploratory multivariate regression analysis for six features from the three behavioral and cognitive active tasks: mBART, mGNG, and mDD. We further performed a binary classification task by labeling samples with 1=higher than the median value and 0=lower than the median value for each daily measure. We used a logistic regression model and LOSO cross-validation. The full results are reported in Table 5.

Our analysis discovered five significant models that varied greatly in classification accuracy: (1) total gains from mBART (*r*=0.326, *P*<.001, 59% accuracy); (2) response latency (*r*=0.334, *P*<.001, 58% accuracy), commission error (*r*=0.155, *P*=.07, 89% accuracy), and omission error (*r*=0.361, *P*<.001, 87% accuracy) from mGNG; and (3) present bias from mDD (*r*=0.792, *P*<.001, 84% accuracy). Risk-taking from mBART was not statistically significant (*r*=0.067, *P*=.43, 48% accuracy).

Table 5. Regression analysis and classification of mobile sensor data as predictors of daily active behavioral and cognitive tasks.

Active tasks	Generalized estimating equation regression summary (Pearson *r*, within-group correlation)	Classification accuracy (SD) across individuals
mBART[a]		
Risk-taking	*r*=0.067, *P*=.43, 0.762	0.48 (0.23)
Total gains	*r*=0.326, *P*<.001, 0.505	0.59 (0.27)
mGNG[b]		
Response latency	*r*=0.334, *P*<.001, 0.765	0.58 (0.31)
Commision error	*r*=0.155, *P*=.07, 0.415	0.89 (0.16)
Omission error	*r*=0.361, *P*<.001, 0.121	0.87 (0.13)
mDD[c]		
Present bias	*r*=0.792, *P*<.001, –0.051	0.84 (0.33)

[a]mBART: mobile Balloon Analogue Risk Task.

[b]mGNG: mobile go/no-go task.

[c]mDD: mobile delay discounting task.

Discussion

This exploratory study examined the potential of detecting and monitoring state impulsivity and impulsive behavior in daily life using continuous and ubiquitous mobile sensing. We explored the predictive power of the mobile sensing system and model we developed (mPulse). We discovered relationships between passive mobile sensor data and self-reported impulsivity traits, EMA of impulsive behavior, and mobile behavioral and cognitive active tasks of risk-taking, attention, and time preference.

Principal Results

This is the first study to examine the relationship between passive mobile phone data, daily self-reports and self-report measures of trait impulsivity, and exploratory, objective, active mobile measures of impulsivity. Overall, our findings suggest that passive measures of mobile phone use such as call logs, battery usage, and screen on-off metrics can predict different facets of impulsivity and impulsive behavior in nonclinical samples. This study adds to the emerging literature on mobile phone phenotyping using ubiquitous sensor data as well as to the measurement of impulsive behavior in daily life [46-48]. Our results can further inform the development of digital interventions for individuals [49-51] by identifying and intervening with potential problematic behavioral patterns before they result in consequences.

First, we investigated the relationship between mobile sensing features and impulsivity traits on the individual level. Our regression models significantly explained variance in sensation-seeking, nonplanning, and lack of perseverance traits, but failed to explain motor, urgency, lack of premeditation, and attention traits. Passive sensing features from call logs, battery charging, and screen checking were particularly useful in explaining and predicting the sensation-seeking trait. The regression model indicated that overall battery charging frequency and screen-checking usage were significant positive predictors of sensation seeking, while call entropy was a significant negative predictor. Cross-validation further confirmed the validity of these mobile sensing features for predicting sensation seeking.

Sensation seeking in itself has multiple facets from thrill-seeking to boredom proneness to disinhibition. Therefore, due to the rewarding nature of interacting with mobile devices, one would expect to discover digital biomarkers of sensation seeking in mobile sensor data. Our results suggest that individuals high in sensation and thrill-seeking may be more prone to repeated phone checking and more intense interactions with their devices when they are using them (eg, less entropy). Previous studies have yielded mixed findings on the relationship between sensation seeking and psychopathology. For example, in a meta-analysis of the UPPS subscales, sensation seeking demonstrated the strongest associations with alcohol and substance use but an overall lower relationship with other clinical conditions than other UPPS traits [51]. It could be that these relationships represent not only maladaptive behaviors but also a desire to seek information, be conscientious at work or with family requests, and stay connected to others. Future studies should collect more information on the interaction between sensation and thrill-seeking and reasons for phone checking to parse out the positive and negative relationships between these passive metrics and outcomes.

Second, we explored the use of mobile sensing features to discover measures that assess state impulsivity and impulsive behavior in daily life. Our mobile sensing model successfully predicted objective behavioral measures, such as present bias in a delay discounting task, commission and omission errors in a cognitive attention task, and total gains in a risk-taking task. Our models also successfully predicted daily EMA questions on positivity, stress, health, and affect. Perhaps most intriguingly, our model failed to predict daily EMA questions designed to measure previous day and present moment impulsivity directly.

This finding indicates that it might be easier to predict constructs related to trait impulse control than self-reported state impulsivity itself in our sample. While studies have revealed that trait impulsivity is highly related to state impulsivity [47,48], there may be more powerful constructs that mediate the relationship between sensors and state impulsivity. For example, studies have revealed a close relationship between affect and impulsive behavior and, separately, between affect and phone sensor data [44], which may have more robust relationships than with state intentionality–impulsivity. It is also possible that because our sample skewed toward intentional versus impulsive responses, we were less able to detect differences. Despite this surprising finding, the data does suggest that combined mobile phone use features are associated with a range of important factors related to well-being, such as perceived productivity. This further highlights the need to personalize passive detection models of state impulsivity or impulsive behavior for the appropriate context, such as substance misuse, productivity, and gambling. It also suggests the need to compare this sample against clinical populations with potentially higher impulsivity scores. Taken together, the exploratory analysis between the passive mobile phone features and daily measures of impulsive behavior revealed that the range of combined mobile phone sensors can predict certain behaviors but that identifying the individual predictors of these components is more challenging.

Digital Addiction and Problematic Phone Usage

Passive mobile sensing can be particularly useful for detecting signs of digital addiction and problematic phone usage. Digital addiction and excessive phone usage are considered other negative consequences of impulsivity and self-regulation failures [24]. We considered this emerging theoretical relationship in the design of the mPulse sensing model, which provides ecologically valid features such as battery usage and screen checking. Our preliminary results confirmed this hypothesized relationship through the sensation-seeking trait, which can explain reward-based phone usage. The relationship between sensation seeking and screen checking was further evidenced by the significant associations between screen frequency and thrill-seeking EMA. It is also possible to use mobile sensing models to predict consequences of digital addiction, such as daily productivity. There is an opportunity to use our passive

sensing models to contribute to the debate on the existence and measurement of digital addiction and distinguish between actual and problematic phone usage [23]. Mobile sensing can help objectively detect signals of problematic phone usage and provide input into personalized interventions to reduce this impulsive behavior [52]. Future research should model and evaluate mobile sensing features as they relate to digital addiction and problematic use of smartphones.

Challenges of Detecting and Predicting Impulsive Behavior in Daily Life

Our inability to predict traits such as attention and urgency, which should theoretically correlate with mobile sensing features, indicates the challenge of predicting impulsivity using the sensors chosen for the current study. Similarly, our models struggled the most with predicting the EMA question that directly asked participants to self-report the general state impulsivity in the present moment and in the previous day. We suspect this finding might be due to the multidimensional nature of impulsivity and the complex interaction between trait and state impulsivity [20]. While studies showed promising results for measuring momentary impulsivity [46-48], the overall convergence between behavioral and self-report measures of the impulsivity construct remains low [22]. Future research should ideally include larger samples of clinical and nonclinical populations and different measures to discover and model these interactions. Mobile sensing and phenotyping can provide an additional objective method of assessing impulsive behavior. This method can provide further insight into a range of new, unexplored opportunities to understand human behavior and explain impulsive behavior.

Cross-Platform mHealth and Sensing

One of the primary goals of this study was to design a mobile sensing system and model, supporting both iOS and Android platforms. The majority of foundational research on mobile sensing was examined on a single platform, which limits the generalizability and real-life applicability of the findings. Cross-platform research services more diverse populations and offers different opportunities for passive and active assessment. Given differences between the two operating systems, compromises are required when considering passive sensor data sources to only collect the subset of sensor data that are available on all devices. Android devices in particular offer a wider range of passive sensing modalities, such as app usage and keyboard typing, compared with iOS devices. The mobile sensing capabilities of different platforms, however, continue to evolve and new restrictions might limit future research and replicability of our findings. Passive sensing can only be useful if the environments used to collect the data do not cause the user more burden than other methods of data collection.

Privacy and Ethical Concerns in Mobile Sensing

More comprehensive sensing suggests greater privacy concerns, as more data related to a person's life and behavior can be quantified, transmitted, and stored. The intention of collecting passive sensing active behavioral tasks and EMA data was to build and validate digital biomarkers that can assess impulsivity for future intervention and management, and the preliminary results show the promise of such data. Yet, there exist very real possibilities for such data to be used to exploit a user, for example through stimulated impulsive purchasing [53,54] or targeted advertising. These passive sensor data, including call logs, battery charging, and screen unlocks, were easy to collect and commonly used in other mHealth studies for monitoring sleep, mental health, and depression [7,8,55]. Researchers should be aware of possible exploitation and privacy concerns as we design similar health-related studies. At the same time, there is evidence that these data are already being collected by large companies. Developing individualized interventions directed at the person to increase awareness of vulnerability and potentially developing protective measures may be needed to combat the onslaught of socially engineered content.

Limitations and Future Work

There are several limitations to the study design that may have affected the performance of passive sensing models. One of these limitations is that the passive sensor data collection was noisy in the sense that user intentions were not fully captured by the current system. For example, it is potentially useful to distinguish screen checks in response to notifications from screen checks initiated by the users. Another limitation is that this study was based on a small sample size, as was the case with previous exploratory passive sensing studies. In addition, due to the cross-platform (iOS and Android) implementation of the mPulse system, the passive sensing and range of mobile sensing modalities were limited. Relevant data sources, such as keyboard and SMS logs, could potentially be used to examine behaviors but were not included in this study because they were only available on the Android platform. Another limitation is that our preference to protect user privacy and reduce battery drain led to the exclusion of relevant mobile sensor data sources, such as location and accelerometer data for motor impulsivity.

Future work should pursue replication of promising measures as well as explore novel sensing modalities with larger samples. Mobile sensor data sources, such as global positioning systems and accelerometers, can be explored to detect mobility and physical activity as predictors of motor impulsivity. Such future work should directly address technical limitations, including battery drain, privacy concerns with regard to location sharing, and the generalizability of mobile sensing models to both iOS and Android platforms. Similarly, physiological sensing modalities from wearable devices, such as heart rate variability, can provide multimodal sensing capabilities. These explorations can reveal more information and improve the prediction accuracy of state impulsivity and impulsive behavior.

Conclusions

We developed a mobile sensing system called mPulse for both iOS and Android smartphones to remotely detect and monitor state impulsivity and impulsive behavior as part of the DMT study. The design of our mPulse system was based on data that are pervasively available across both iOS and Android platforms: call logs, battery charging, and screen checking. In the exploratory study, we used mobile sensing features to predict trait-based, objective behavioral, and ecological momentary assessment (EMA) of impulsivity and related contacts (ie, risk-taking, attention, and affect).

Our findings suggest that passive sensing features of mobile phones can predict different facets of trait and state impulsivity. For trait impulsivity, the models significantly explained variance in sensation, planning, and lack of perseverance traits but failed to explain motor, urgency, lack of premeditation, and attention traits. On the daily level, the model successfully predicted objective behavioral measures such as present bias in a delay discounting task, commission and omission errors in a cognitive attention task, and total gains in a risk-taking task. Our models also successfully predicted daily EMA questions on positivity, stress, health, and affect. Overall, the study highlights the potential for continuously, passively, and remotely assessing impulsive behavior in daily life to advance the science of self-regulation and awareness.

Acknowledgments

HW, MS, and FM wrote the manuscript. FM, DE, and JPP designed the study. JK and HW implemented the mobile app for the study under the supervision of JPP and DE. HW, RPV, and MS conducted all statistical analyses. All authors reviewed the final manuscript.

This study was supported by a Robert Wood Johnson Pioneer Portfolio grant entitled The Digital Marshmallow Test: Multiple PI: FM and DE.

Conflicts of Interest

None declared.

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Abbreviations

BIS-15: 15-item short form of the Barratt Impulsiveness Scale
DMT: Digital Marshmallow Test
EMA: ecological momentary assessment
GEE: generalized estimating equation
LOSO: leave-one-subject-out
MAE: mean absolute error
mBART: mobile Balloon Analogue Risk Task
mDD: mobile delay discounting task
mGNG: mobile go/no-go task
mHealth: mobile health
PAM: Photographic Affect Meter
PANAS: Positive and Negative Affect Schedule

Edited by G Eysenbach; submitted 18.10.20; peer-reviewed by A Peckham; comments to author 09.11.20; revised version received 29.11.20; accepted 18.12.20; published 27.01.21.

Please cite as:
Wen H, Sobolev M, Vitale R, Kizer J, Pollak JP, Muench F, Estrin D
mPulse Mobile Sensing Model for Passive Detection of Impulsive Behavior: Exploratory Prediction Study
JMIR Ment Health 2021;8(1):e25019
URL: http://mental.jmir.org/2021/1/e25019/
doi:10.2196/25019
PMID:33502330

Review

Text Message Interventions in Adolescent Mental Health and Addiction Services: Scoping Review

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Abstract

Background: The vast majority of adolescent mental health and substance use disorders go undiagnosed and undertreated. SMS text messaging is increasingly used as a method to deliver adolescent health services that promote psychological well-being and aim to protect adolescents from adverse experiences and risk factors critical for their current and future mental health. To date, there has been no comprehensive synthesis of the existing literature on the extent, range, and implementation contexts of these SMS text message interventions.

Objective: The objective of this scoping review was to map and categorize gaps in the current body of peer-reviewed research around the use of SMS text messaging–based interventions for mental health and addiction services among adolescents.

Methods: A scoping review was conducted according to Levac's adaptation of Arksey and O'Malley's methodological framework for scoping reviews in six iterative stages. A search strategy was cocreated and adapted for five unique databases. Studies were screened using Covidence software. The PICO (patient, intervention, comparator, outcome) framework and input from multiple stakeholder groups were used to structure and pilot a data extraction codebook. Data were extracted on study methodology and measures, intervention design, and implementation characteristics, as well as policy, practice, and research implications.

Results: We screened 1142 abstracts. Of these, 31 articles published between 2013 and 2020 were eligible for inclusion. Intervention engagement was the most common type of outcome measured (18/31), followed by changes in cognitions (16/31; eg, disease knowledge, self-awareness) and acceptability (16/31). Interventions were typically delivered in less than 12 weeks, and adolescents received 1-3 messages per week. Bidirectional messaging was involved in 65% (20/31) of the studies. Limited descriptions of implementation features (eg, cost, policy implications, technology performance) were reported.

Conclusions: The use of SMS text messaging interventions is a rapidly expanding area of research. However, lack of large-scale controlled trials and theoretically driven intervention designs limits generalizability. Significant gaps in the literature were observed in relation to implementation considerations, cost, clinical workflow, bidirectionality of texting, and level of personalization and tailoring of the interventions. Given the growth of mobile phone–based interventions for this population, a rigorous program of large-scale, well-designed trials is urgently required.

(JMIR Ment Health 2021;8(1):e16508) doi:10.2196/16508

KEYWORDS

adolescent; mental health; eHealth; text messaging; SMS; information science; cell phone; implementation; review

Introduction

Limits of Face-to-face Mental Health and Addiction Care for Adolescents

Many mental health disorders emerge in adolescence, which contribute to the existing burden of disease among young people and later in life [1]. More than 50% of adult mental disorders have their onset before the mid-teen years [2,3]. Furthermore, adolescents experiencing depressive symptoms more than two-standard-deviations above the mean predicts a twofold to three-fold greater risk for an adult major depressive episode [4]. Notably, a survey of 10,123 adolescents aged 13 to 18 years in the continental United States showed that 40% of participants with one disorder also met criteria for another lifetime disorder [5]. Substance use and mental health disorders, for example, commonly co - occur [6] and are closely related to increased morbidity and mortality [7]. A recent meta-analysis of 41 studies conducted between 1985 and 2012 in 27 countries estimated a global point prevalence of mental disorders in children and adolescents of 13% [8]. From a global perspective, neuropsychiatric disorders are the leading cause of years lost due to disability among 10- to 24-year-olds [9].

The persistent lack of available services to identify and meet these needs is concerning. While several face-to-face psychological therapies have demonstrated effectiveness in the treatment of mental health and addictions, many children and adolescents do not receive or have access to these treatments [10,11]. Despite decades of effort to improve access, demand continues to outstrip provider capacity for face-to-face services [12,13]. In particular, children experiencing poverty [14], children in rural areas [15], and youth and families who experience self-stigma due to prejudice and stereotyping [16] consistently face unequal access or barriers to care. Even when face-to-face services are available, treatment engagement is challenging. For example, high levels of missed appointments and premature termination of therapy are significant for adolescents, with no-show and attrition rates of 40%–60% commonly reported for this population [17]. Given this global burden and the unsustainability of traditional intervention approaches to meet the rising demand, it is vital for new lines of research to generate innovative strategies and interventions for adolescent mental health and addictions.

Mental health systems facing these challenges increasingly look to advancements in information and communications technologies to augment provider capacity, promote healthy behavior and lifestyle changes, and overcome barriers that limit help-seeking [18,19]. However, the technology marketplace is continuously evolving into more dynamic, diverse, and sophisticated functionalities. As technologies are expected to increase in scope and impact, rapid updating and analysis of emerging evidence is needed to inform future research and signal new interventions to policy makers in order to accelerate implementation of high-quality services once effectiveness of these interventions has been established.

Leveraging Trends in Text Messaging for Adolescent Mental Health Research

One rapidly growing field of study is the use of SMS text messaging for delivering mental health and addiction interventions. Seven billion people, or 95% of the global population, live in an area covered by a mobile-cellular network [20], making SMS text messaging one of the most widely used information and communication technologies. Texting is used by most adolescent cell phone owners and has surpassed phone calls, instant messaging, social network messaging, and face-to-face talking as the preferred mode of communication for this age group [21]. Adolescents report convenience, discreetness, increased communication effectiveness, and reduced anxiety associated with texting or talking on the phone in comparison to in-person evaluations with a physician [22] as reasons for preferring this modality. The immediacy of reaching adolescents through texting is apparent, with 91% of texts read within the first 3 minutes of receipt [23]. Cell phone ownership among 12- to 17-year-olds has been steadily rising over the past several years and is consistent across race and gender groups [24]. Reports from 2019 indicated that among US teens, 69% have a smartphone by the age of 12 [25]; however, teens from lower-income families are slightly less likely to own cell phones than teens from higher-earning families [24]. Although smartphone ownership is rapidly growing, only about a third of the world's population (approximately 2.6 billion) used a smartphone in 2017 [26], compared to over 5 billion mobile phone subscribers. Even using conservative estimates, simple SMS text messaging that does not require smartphone capabilities will remain an important tool to reach adolescents for some time to come. Consequently, researchers and decision makers need strategic guidance on where new investments in SMS text messaging intervention development and testing are best positioned in the future.

Related Work and the Need for Mapping the Current Evidence Base

Texting is among the most frequently used technologies for low-intensity behavioral health interventions [27] and has demonstrated effectiveness in supporting a range of healthy behavior changes among adolescents with diabetes [28] and obesity [29] and for many other topics including sexual health [30] and contraception [31]. Interventions in these other health domains typically make use of multiple persuasive system design features (eg, personalization, reminders, feedback, branching/tailoring) [32], but there are significant gaps in the knowledge base about breadth of features used to deliver service through this modality and the contexts and populations in which SMS text messaging interventions focused on mental health or addictions have been tested.

The most recent synthesis of SMS text messaging intervention research for mental health or addictions present several limitations for addressing adolescent population needs. A 2016 review of SMS text messaging mental health interventions by Watson et al [33] excluded studies involving children and

adolescents, and reviews by Berrouiguet et al [34] and Rathbone and Prescott [35] did not provide information on the target age range of studies in their review, making it challenging to conduct any subanalysis of adolescent interventions specifically. Importantly, findings from these adult-focused reviews may not be generalizable to adolescent populations due to the unique developmental changes adolescents experience and their different technology preferences. A 2014 meta-analysis of 14 adolescent-focused intervention studies using SMS text messaging revealed a summary effect size of 0.25 on measures of substance use reduction [36]. However, 11 of the studies focused on tobacco use alone, making the generalization to the broader mental health and addictions continuum limited. A review by Badawy and Kuhns [37] of mobile phone interventions targeting adolescents published between 1995 and 2015 limited inclusion to studies where the primary or secondary outcome related to preventive behavior adherence, meaning that the review provides only a partial synthesis of SMS text messaging research across the full continuum of care. The most recently published relevant review was by Garrido et al in 2019 [38] and synthesized data on a broad range of mobile phone interventions for adolescent anxiety and depression, identifying only 4 text messaging interventions of any study design in their search strategy. Cursory scans of recently published literature suggest there are significantly more primary studies on mental health and addiction interventions for adolescents using text messages than have been previously reviewed. Further, limited discussion in previous reviews on the implementation characteristics of interventions under study (eg, costs, information and communications technology infrastructure required, provider training requirements) provide decision makers with few insights to inform real-world requirements of offering these interventions as sustainable services.

It is clear from the gaps identified that the foundational understanding of how these interventions have been implemented and designed, the measures used to evaluate impact, the contexts and mechanisms identified by researchers to explain intervention impacts, and recommendations being offered for policy, practice, and future research requires updating. The objective of this scoping review was to understand the current state of peer-reviewed research around the use of text message–based interventions for mental health and addiction services among adolescents.

Specifically, the review proposed to answer the following questions: What outcomes are measured to determine effectiveness and engagement? What are the technological and clinical design features of these interventions and services? What implementation contexts, mechanisms, barriers, and facilitators are described? What are the recommendations for practice, policy, and research reported by study authors?

Methods

Overview

A scoping review design is ideal for broad mapping and characterizing of existing research [39]. Scoping reviews share a similar process to systematic reviews, since they both are rigorous and transparent in identifying eligible literature but are divergent in purpose. Using a scoping review framework allows for broad exploration of the research to map key concepts, evidence types, and gaps in research in a defined field [40].

The Levac adaptation to Arksey and O'Malley's [41] methodological framework for scoping reviews was applied in six iterative stages: (1) identifying the research question, (2) identifying relevant studies, (3) selecting studies, (4) charting the data, (5) collating, summarizing, and reporting on the articles and (6) consulting with stakeholders. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guideline extension for minimum reporting standards in scoping reviews [42] and Joanna Briggs Institute recommendations for scoping reviews [43] were also followed.

Search Strategy

The search strategy was developed in collaboration with an evidence synthesis specialist at the Maritime SPOR SUPPORT Unit (MSSU), which is an organization that provides support to researchers and brings together key stakeholders to work on government priority projects. MEDLINE, Embase, PsycINFO, CINAHL, and Scopus databases were searched to identify a broad range of articles in October 2018. A search conducted in the Ovid MEDLINE "In-Process & Other Non-Indexed Citations" database was used to reduce the chance of omitting articles not included in PubMed and to capture the most recent literature possible. An example of the search terms and search strategy is available in Multimedia Appendix 1. Reference lists of related reviews were hand-searched for any additional citations. The search was updated by an evidence synthesis specialist at the MSSU on June 1, 2020.

Study Selection

After removing duplicates, titles and abstracts were uploaded into Covidence software (Covidence). The extensive time and effort requirements for conducting an unfunded review [44] and stakeholders on the overarching project team promoting rapid review approaches to inform decision making shaped the review protocol. To expedite the process while maintaining rigor, the primary author, with experience in eMental Health–related systematic reviews and text messaging intervention design (LW), completed screening at the title and abstract level, following defined eligibility criteria (see Multimedia Appendix 2). Any abstracts considered questionable were moved to the full-text review phase. For titles and abstracts identified in our updated search in June 2020, two reviewers (LW and SM) independently screened titles and abstracts. No test of agreement between reviewers was conducted; instead, all discrepancies were discussed until a decision on moving to full-text review was made.

Eligibility Criteria

The screener followed the "excluded terms" approach outlined by Carter [45] to improve accuracy and efficiency of single-screener processes without compromising the quality. To this end, several "exclude" terms were generated to quickly reject studies at the title/abstract level that had a high likelihood of being excluded. Exclude terms included HIV, neurodevelopmental, domestic violence, infant, pregnancy, cancer, sexual health, and contraception.

As several meta-analyses and systematic reviews of tobacco and smoking cessation interventions, including a 2016 smoking cessation Cochrane review [46], have already established high-quality evidence for SMS text messaging interventions in that area, intervention studies that focused only on smoking cessation were excluded in order to focus on mapping and characterizing the less well-established literature.

The inclusion criteria were as follows: the article was a primary study or abstract reporting outcome data; the study targeted children or adolescents (included in the age range ≤18 years) by design; text messages were one of the primary delivery mechanisms; the study was published in English; and the intervention was for mental health and addiction care (eg, symptom management, appointment reminders).

The exclusion criteria were as follows: the article was a systematic review, commentary, editorial, or protocol; the study targeted parents of children and adolescents receiving mental health care; the study targeted only smoking cessation or smoking prevention; SMS text messaging was only used for research data collection and had no therapeutic/educational purpose; or the intervention targeted a subgroup of patients with mental health as a secondary issue relative to an overarching medical condition (eg, cancer, HIV, pregnancy).

Full-text review was completed independently by one reviewer (Swati Rathore) at the outset. A validity check on a randomly selected set of 20 full texts was undertaken independently by a second reviewer (SM) to explore potential bias or inconsistency. Excellent interrater agreement (κ=0.90) was established. Questionable studies were discussed and resolved through consensus with a third reviewer (LW). In the case of a study that had a published protocol as well as a study outcome paper, only the outcome paper was included.

Data Extraction

Suggestions on synthesizing evidence from complex interventions were followed [47]. Briefly, such frameworks emphasize that decision makers are more interested in knowing when the intervention works (delivered by whom, how, how often, and in which setting) than in answering the simple question of “does it work?”. A codebook was drafted (LW and Swati Rathore) based on the PICO (patient, intervention, comparator, outcome) framework. Through consultation and discussion with a range of stakeholders (psychologists/clinicians, academic researchers, patient advisors, policy and planning experts, and mental health system administrators at the local and provincial level), the codebook was refined to highlight implementation and context features identified as “high value” information for decision makers. The data extraction form included the following 7 key sections: (1) *study identification* (ie, citation, year of publication, publication type); (2) *outcomes* (ie, purpose of the service or intervention, outcome types [health system, intervention acceptability, intervention engagement, clinical, physical, cognitive, emotional, functioning and coping, relationships, relaxation skills, compliance and adherence, behavioral], validity and reliability of outcome measure, name of measure, main findings, covariates); (3) *evaluation methods* (ie, sample size of the intervention group, study design, reporting of adverse events or safety issues, baseline data collection, follow-up schedule); (4) *intervention design* (ie, name of intervention, quantity of texts, frequency of texts, duration of intervention, framework or model used, access to service, bidirectionality, content of texts, co-design or patient-oriented); (5) *demographics* (ie, person responding to texts, training of intervention deliverer, community characteristics, sex, race, average age, age range for inclusion in study, cultural relevance, reasons for low uptake/nonadherence, country); (6) *implementation* (ie, oversight, honorarium or credit, technology quality and performance, cost reported, security and privacy, interoperability, communication); and (7) *recommendations* (ie, recommendations for practice, policy, and research made by the primary study authors).

The form was piloted independently by two reviewers (Swati Rathore and SM) for 3 articles to determine if both parties were in agreement and to see if any clarifications were needed. This enabled an early check on consistency and relevance. Data extraction was then split between the two coders, and discrepancies or questions were resolved by consensus with input from another reviewer (LW).

Analysis

All data for this scoping review were entered in Microsoft Excel (Microsoft Corporation). After data cleaning, a descriptive, analytical approach was used to generate summary statistics (counts, percentages, etc) of the data extracted for key sections 1-6. For section 7, key themes and issues from each study were identified by scrutinizing the results and discussion sections using thematic content analysis.

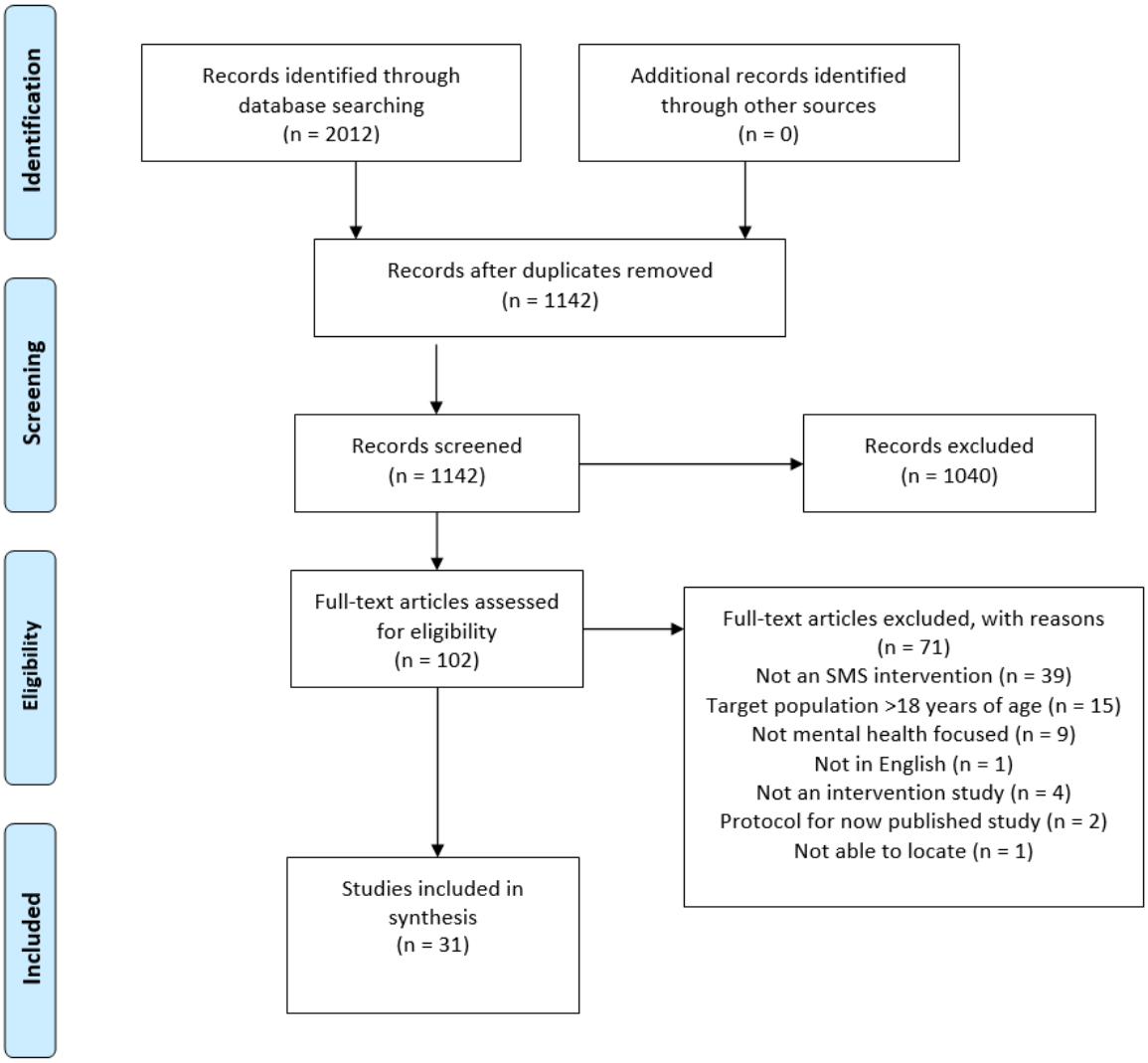
Results

Study Characteristics

We screened 1142 abstracts for possible inclusion (Figure 1). After title and abstract screening, 102 full-text articles were screened for eligibility, with 71 articles excluded at this stage. Thirty-one studies were included, with 28 published in peer-review journals, 2 dissertations, and 1 abstract that included outcome data [48-78].

Included articles were published between 2013 and 2020. Of the 31 included studies, 18 (58%) were conducted in the United States. With respect to study design, 29% (9/31) incorporated randomization, 19% (6/31) were qualitative designs, and 52% (16/31) were observational or cross-sectional. In 68% (21/31) of the studies, fewer than 100 study participants were exposed to the intervention or service (see Multimedia Appendix 2).

Figure 1. PRISMA flow diagram.



Measures and Outcomes

In additional to bespoke measures, over forty unique standardized outcome measures were used across the studies, measuring a wide range of symptom, global functioning, and therapeutic experience self-report scales and inventories. The measures categories with the widest use were intervention engagement (18/31; eg, number of texts sent, number of URL links clicked), cognitions (16/31; eg, disease knowledge, self-awareness), and acceptability (16/31; eg, satisfaction). Adherence to a predefined treatment protocol was measured in 7 studies, typically for substance use–related interventions (eg, reduction in number of drinks consumed). Fewer studies tracked social/relational outcomes (5/31; eg, quality of social relationships) or physical changes (2/31; eg, blood alcohol level). Forty-two percent of the studies (13/31) explicitly reported some evidence that the measures used were validated or reliable (eg, test-retest, internal consistency, and content validity checks). Twenty-six percent (8/31) reported outcomes that were measured immediately following exposure to the intervention. An additional 32% (10/31) measured outcomes within 3 months of intervention completion, but not immediately following, and 3 studies completed outcome tracking at 6 months postintervention or longer. Studies by Gonzales et al [59] and Whittaker et al [78] included a measure 12 months postintervention. Eighty-seven percent of studies (27/31) reported on at least one positive outcome including, for example, lowered stress [49], cost efficiency [52], less substance use [57], and treatment protocol adherence [51]. In the only randomized controlled trial of an intervention for adolescent depression that enrolled more than 500 participants, researchers found no evidence of benefit in depressive symptoms from a cognitive behavioral therapy–based SMS text message intervention compared to a control program [78]. However, youth reported finding the program helpful. One study reported not being able to complete outcome measurement due to major recruitment and retention issues during implementation [71]. Another study reported an adverse event/safety issue related to the intervention [71]. Across the 16 studies reporting on acceptability measures, the majority of adolescent participants (ie, >70%) in each case study reported being satisfied with the intervention.

Intervention Characteristics

Interventions ranged considerably in length/duration and intensity (see Multimedia Appendix 3). The models or frameworks most frequently cited for guiding intervention development were social cognitive theory (5/31) and cognitive behavioral therapy (3/31), with the health belief model (1/31) and normalization process theory (1/31) also explicitly identified. Nine studies reported that the intervention had been co-designed with adolescents. Texting frequency ranged from several times per day for one depression-focused study [56] to once every two weeks or month for another depression-focused study [54]. Most frequently, interventions were delivered in less than 12 weeks, and adolescents received 1-3 messages per week over that time. Thirty-five percent (11/31) of studies specifically indicated the intervention was for substance use or problem drinking, and 32% (10/31) focused on adolescents with depression. Almost two-thirds of studies (20/31) had bidirectional texting, either automated bounce-back prompts (eg, [57]) or person-driven (eg, [65]). The 2020 study by Haug et al [65] incorporated multiple uses of automated text messages where messages were used to push weblinks, video clips, and pictures in some instances but also used to help assess and deliver individualized feedback through quizzes (eg, "reply to this SMS with 'yes' or 'no'… are you meeting friends or going out today?"). Based on responses, a tailored but automated prompt would be sent (eg, "Hey Mike, great plan! Take a moment and imagine exactly how you could implement this plan…. Have a nice evening!"). Text messages across all studies were typically designed to convey empathy and encouragement (eg, "Stop… Breathe… And think about how you got through difficult times before. You got this!" [56]) and to support coping. The content and authenticity of the messages were cited by adolescent respondents as key elements of their engagement. As one respondent in the Duan et al study [58] reflected, "Don't include messages that make me feel like my parents are teaching me something, I need encouragement from a friend, not from a teacher or parent". Among studies utilizing bidirectional texting, 60% (12/20) required the researcher to respond to at least some of the texts. In 29% of studies (9/31), adolescents had the option to self-refer to the intervention. All other instances required provider or researcher referral or recruitment pathways. Two studies reported offering the intervention in more than one language.

Implementation Contexts and Features

Community characteristics of adolescents enrolled in the interventions were explicitly described in only 10 of 31 studies and included limited details on community socioeconomic status, urban/rural geographic location, or generic statements related to culturally diverse community samples. Demographic information on the adolescent study participants revealed that most of the interventions were designed to target 13- to 17-year-olds. In 5 studies, the intended age range of end users covered more than 10 years (eg, Antiss and Davies, 2015 [49], ranged from 12 to 24 years of age). Forty-eight percent of the studies (15/31) reported providing adolescents with an honorarium or compensation for study participation. At least some level of training for the provider was noted in 35% (11/31) of studies. Twenty-nine percent of studies (9/31) reported on the technical quality or performance (eg, all messages were received). Sustainability (plans for scale-up or long-term operational planning) was discussed in 2 studies. Eight studies (26%) provided details on privacy and security of electronic data, which included things like requiring password-protected phones [61], limiting collection and storage of personal identifying health information [53], and confidentiality approval [74]. None of the studies reported on the direct costs of delivering the intervention. In 32% (10/31) of studies, the technical infrastructure used to deliver the text messages required some level of interoperability between interfaces (eg, text redirecting to a survey tool housed on another platform). As retention of adolescents in the studies was quite high, overall there was limited discussion of barriers to uptake or nonadherence. One author noted that even though only 38% of texts (eg, asking a participant to rate their mood from 1-10) were responded to by adolescents in the study, participants still reported improved outcomes [69].

Practice, Policy, and Research Recommendations

Forty-two percent (13/31) of study authors reported that ease of use and broad accessibility were strengths of the services that made them feasible to roll out and resulted in high levels of uptake. Increased ability to tailor the scheduling of messages (eg, [67]; messages before or after school) or the content of messages (eg, [72]; including youth's name in the texts) was noted by 35% (11/31) of authors as a way to practically improve interventions further. Multiple study authors noted the importance of working with youth to co-design and shape the messages. The intensity of exposure to texts (ie, time of day, number sent, and frequency) was pointed to as an important practical consideration by 19% (6/31) of authors. No studies explicitly addressed or identified specific policy-related implications of their findings. For example, there were no explicit recommendations around ethics of sending youth text messages, electronic communication policies, risk, privacy, or safety monitoring guidelines that would need to be in place for the service to operate beyond the research. Two primary sub-themes were identified in future research directions proposed by primary authors: (1) opportunities for comparative component studies that look at whether and which features (eg, tailoring, different messaging schedules, and different media) improve adherence or outcomes (15/31; 48%) and (2) need for well-powered randomized controlled trials (13/31; 42%).

Discussion

Principal Findings

To our knowledge, this review provides the first comprehensive mapping of the current literature on use of SMS text messaging for delivery of mental health and addiction interventions to adolescents. The aim was to detail outcomes being measured, clinical and technical features of interventions, implementation contexts in which they have been studied, and the ensuing recommendations made by primary authors to support innovative research in the field moving forward. Findings suggest a growing evidence base regarding text message interventions for adolescent mental health and addictions. These interventions appear to be highly acceptable and accessible to adolescents,

easy to use, and have at least some positive impacts according to most studies. While these findings are consistent with the literature among adults receiving physical and mental health text message–delivered services [35], the research literature remains limited in several important ways. Overall, there are significant limitations in the trial designs. These include issues with small sample sizes (eg, pilot studies of less than 100 participants are typical), limited intervention duration, lack of randomized designs, nonstandard outcome measures and definitions, and few repeated measures in studies with longitudinal designs.

Limited grounding in, or at least reporting on, theoretical frameworks that drive intervention development was observed in this review. While most interventions tended to follow a basic architecture of less than 12 weeks and 2-3 messages per week, the content, levels of interactivity and personalization, use of media, and underpinning aims (eg, behavioral activation, acquisition of new knowledge, emotional regulation) were vastly different. Significant heterogeneity in intervention features was noted in our review, such as fixed message content or customized content; fixed-frequency or real-time support; standardized versus personalized messages; and unidirectional versus bidirectional communication. Without theoretical and therapeutic models to define and articulate how these intervention elements work to produce which outcomes (ie, satisfaction versus clinical change versus changes in thoughts and feelings), there is limited ability to generate and replicate rigorous hypothesis testing or clarify which mental health and addiction conditions at which level of illness severity might be best suited for SMS text messaging interventions. This finding further supports recommendations for standardized reporting of theories of change for behavioral interventions in academic research [79].

As this field emerges, high-quality studies will be required, despite rapidly evolving technical capabilities that can outdate services before they are able to be scaled up [80]. Preliminary usage data from primary studies in this review suggest adolescents will use and are satisfied with SMS text messaging services, but how satisfaction and engagement relate to direct health outcomes is unclear. In this review, over half of the included studies assessed some measure of acceptability or satisfaction. High scores on satisfaction outcomes across types of interventions, intensities, and countries of use point to possible ceiling effects of satisfaction measures [81]. Generating new knowledge about predictors of satisfaction and use (eg, treatment readiness, non–health-related texting use, degree of co-design [82]) could more usefully inform clinical practice guidelines for where these interventions are best matched to the needs of which adolescents, and under which circumstances. For example, adolescents across studies reported finding interventions helpful and acceptable and are satisfied with the experience even when they do not produce clinically significant changes (eg, [78]). The findings of this review have important implications for decision makers who are mandated to integrate services that show a return on investment. Mixed-effects studies that show interventions are "liked," but have little impact on quality of life or symptoms, may present challenges for scale-up. Unpacking the relationship between perceived acceptability and clinical change will be an important direction for future research on SMS text messaging interventions. Better understanding of unidirectional versus bidirectional messaging design and their impact on engagement and exposure to the "dose" of SMS text messaging interventions could add needed insights. Preliminary research in other health fields with this population has established that bidirectional texting increases intervention effectiveness [83] and is a valuable line of inquiry for mental health and addiction–focused interventions.

Frequency and duration of interventions in this review, even for the same presenting clinical condition, ranged considerably from multiple times a day to several texts over the course of months. Future studies should consider the impact of habituation, response fatigue, and perceived "intrusiveness" of texts among adolescents using these interventions. Generating new knowledge about intervention intensity might also inform decision makers about where interventions "sit" within clinical workflow and provider/client relationships. For example, two-thirds of the studies in the review included some form of bidirectional interaction. It is possible that just messaging back and forth with clinic or research staff sufficiently evokes a relationship dynamic that bolsters perceived social connectedness and sense of well-being. Future work is needed to determine if it is the *presence* of ongoing communication at all or the specific therapeutic *content* of SMS text messaging interventions that results in improved outcomes. Studies in our review generally lacked details about how theory or therapeutic principles guided the content, frequency, and duration decisions around texts being sent to youth. It is promising that a number of studies reported some level of adolescent engagement as co-designers to potentially explicate some of these mechanisms of change and decisions around frequency and intensity. Richer descriptions of co-design models and theoretical frameworks used to shape intervention development would be beneficial.

This review points to methodological decisions and implementation considerations (eg, study remuneration practices, self-referral versus provider referral, and researcher-led communication) that might impact adherence and outcomes once interventions are rolled out beyond the research cycle into full-service delivery. These will be important for future researchers to consider and suggest that hybrid implementation/effectiveness studies could be a valuable study design for this field. For example, nearly half of the studies in the review reported providing remuneration for study participants. Would engagement be as high if youth did not receive remuneration for participating, but the service was offered as standard of care? Over a third of the studies reported that human resources required specialized training in order to support the SMS text messaging intervention or that technical troubleshooting for youth was required. If those tasks were to be integrated into a clinician's existing workflow, how might that impact costs or sustainability? A significant gap identified in our review of implementation features was that none of the studies in the review provided costing information. The ability of this field to communicate cost-effectiveness data to policy makers that incorporate implementation costs is central to the likelihood of interventions being adopted by practitioners and would be in alignment with emerging standards for reporting

[84]. Future studies could look to advances in implementation science to incorporate methodologies and outcomes that address these issues. In addition, cross-disciplinary work with fields like human factors engineering and health systems engineering could be particularly valuable for understanding how the integration of SMS text messaging interventions relates to workflow [85].

A systematic review of the use of research evidence in public health decision-making processes recommended that more research target the needs of decision makers [86]. A strength of this review is that in adopting Levac's steps for scoping reviews, the research questions, data extraction and analysis, and reporting approaches were codeveloped with an interdisciplinary team of people with lived experience in mental health services and clinicians as well as local health system decision makers, through the MSSU. Their involvement was critical in identifying the diverse data of interest to be explored in this review. This scoping review, therefore, is set apart from other recent reviews by systematically highlighting persistent reporting gaps in the costing, sustainability planning, privacy and security, and technical infrastructure elements of SMS text messaging behavioral interventions for adolescents that are vital for translating research into real-world services. Knowing what has not been reported in the published literature is equally important for decision makers who are tasked with evaluating risks and return on investment. Recommendations for reporting on behavioral interventions have been around for over a decade [87,88] as well as new guidelines focused on mobile phone–based intervention reporting [89]. Gaps outlined in this review highlight knowledge-sharing opportunities on these important elements. Researchers in this rapidly advancing field can support decision makers to more quickly mobilize efforts to integrate effective, evidence-based SMS text messaging interventions by following these guidelines and integrating locally relevant information needs.

Limitations

There are several limitations to this review. Although inclusion criteria were kept as broad as possible while maintaining focus on the research question, only 31 studies met inclusion criteria. While this is a significantly larger number than any of the other related recent reviews, a search of the grey literature was not completed. The search strategy was also limited as a result of search terminology related to mental health and addictions, which has an extremely diffused and nuanced lexicon across different fields. This issue has been raised by other researchers [90] and reported as a significant obstacle to integrating mental health services within broader health care systems [91]. This relatively small and highly heterogeneous sample raises an issue of publication bias and increases the importance of assessing for bias within individual studies. Within currently recommended scoping review methods, quality appraisals are not typically undertaken. While this review did not conduct risk of bias appraisals, systematically broad mapping of basic study methods did identify discrete areas of methodological weakness, which have been detailed and summarized to inform future work. In the context of this burgeoning intervention literature, it was important to include a range of designs to fully scope what is currently known. Finally, this review combined results from trials with early pilot studies, program evaluations, and qualitative investigations, resulting in a wide range of interventions, follow-up durations, and study aims. A review of only high-quality studies may produce different summary conclusions.

Conclusion

Text message interventions are increasingly explored in adolescent mental health and addictions. However, the research to date has important limitations in terms of the heterogeneity of interventions and implementation characteristics of studies. There are significant gaps regarding the hypothesized theoretical and therapeutic mechanisms driving observed outcomes, which contributes to the lag in translating research into policy and practice. Impact on direct health outcomes, cost considerations, predictors of participant engagement, and ongoing sustainability or return on investment are underreported aspects of interventions studied to date. While studies broadly reported high levels of satisfaction with SMS text messaging interventions among adolescents, rigorous study designs are needed to parse out success features and how satisfaction related to engagement. Ideally, future research should formally compare characteristics (eg, number of texts, frequency, duration) in order to measure and adjust each of these parameters to meet the needs of adolescents as they change over time. Multiple lines of innovative inquiry in the use of SMS text messaging interventions for adolescent mental health and addictions are possible and promising.

Acknowledgments

We would like to thank Swati Rathore for her contributions to screening, data extraction, and codebook development. We want to acknowledge the support of all first-voice advisors, clinicians, administrators, and external partners who participated in the Maritime SPOR SUPPORT Unit "UniCity Team Priority Project" that guided this work. This work was supported by the Maritime SPOR SUPPORT Unit, which receives financial support from the Canadian Institutes of Health Research, the Nova Scotia Department of Health and Wellness, the New Brunswick Department of Health, the Nova Scotia Health Research Foundation, and the New Brunswick Health Research Foundation. The opinions, results, and conclusions reported in this paper are those of the authors and are independent from the funding sources. No endorsement by the MSSU or the named funding partners is intended or should be inferred.

Authors' Contributions

SM made substantial contributions to the design of the paper, conducted data screening and extraction, interpreted the results, drafted components of the paper, and approved the final version.
SJ made substantial contributions to the design of the work, contributed to the methodological plan, interpreted the results, critically revised drafts of the paper, and approved the final version.
SC made substantial contributions to the design of the work, interpreted the results, critically revised drafts of the paper, and approved the final version.
LAC made contributions to the design of the work, contributed to the methodological plan, interpreted the results, critically revised drafts of the paper, and approved the final version.
AM made substantial contributions to the design of the work, interpreted the results, critically revised drafts of the paper, and approved the final version.
LW made substantial contributions to the design of the paper, contributed to the statistical analysis, interpreted of the results, drafted the paper, and approved the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[DOCX File , 79 KB - mental_v8i1e16508_app1.docx]

Multimedia Appendix 2
Characteristics of included studies.
[DOCX File , 23 KB - mental_v8i1e16508_app2.docx]

Multimedia Appendix 3
Overview of intervention features and targeted population.
[DOCX File , 19 KB - mental_v8i1e16508_app3.docx]

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Abbreviations

MSSU: Maritime SPOR SUPPORT Unit
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Edited by G Eysenbach, J Torous; submitted 04.10.19; peer-reviewed by L Cilar, K L'engle; comments to author 06.04.20; revised version received 03.09.20; accepted 04.12.20; published 08.01.21.

Please cite as:
MacDougall S, Jerrott S, Clark S, Campbell LA, Murphy A, Wozney L
Text Message Interventions in Adolescent Mental Health and Addiction Services: Scoping Review
JMIR Ment Health 2021;8(1):e16508
URL: https://mental.jmir.org/2021/1/e16508
doi:10.2196/16508
PMID:33416504

Original Paper

A Mindfulness-Based Intervention for Student Depression, Anxiety, and Stress: Randomized Controlled Trial

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Related Article:

This is a corrected version. See correction statement: https://mental.jmir.org/2021/1/e27160

Abstract

Background: University students are experiencing higher levels of distress and mental health disorders than before. In addressing mental health needs, web-based interventions have shown increasing promise in overcoming geographic distances and high student-to-counselor ratios, leading to the potential for wider implementation. The Mindfulness Virtual Community (MVC) program, a web-based program, guided by mindfulness and cognitive behavioral therapy principles, is among efforts aimed at effectively and efficiently reducing symptoms of depression, anxiety, and perceived stress in students.

Objective: This study's aim was to evaluate the efficacy of an 8-week MVC program in reducing depression, anxiety, and perceived stress (primary outcomes), and improving mindfulness (secondary outcome) in undergraduate students at a large Canadian university. Guided by two prior randomized controlled trials (RCTs) that each demonstrated efficacy when conducted during regular university operations, this study coincided with a university-wide labor strike. Nonetheless, the students' response to an online mental health program on a disrupted campus can provide useful information for anticipating the impact of other disruptions, including those related to the COVID-19 pandemic as well as future disruptions.

Methods: In this parallel-arm RCT, 154 students were randomly allocated to an 8-week MVC intervention (n=76) or a wait-list control (WLC) condition (n=78). The MVC intervention included the following: (1) educational and mindfulness video modules, (2) anonymous peer-to-peer discussions, and (3) anonymous, group-based, professionally guided, 20-minute videoconferences. Study outcomes were evaluated at baseline and at 8-week follow-up using the following: Patient Health Questionnaire-9 (PHQ-9), the Beck Anxiety Inventory (BAI), the Perceived Stress Scale (PSS), and the Five Facets Mindfulness Questionnaire Short Form (FFMQ-SF). Generalized estimation equations with an AR (1) covariance structure were used to evaluate the impact of the intervention, with outcome evaluations performed on both an intention-to-treat (ITT) and per-protocol (PP) basis.

Results: Participants (n=154) included 35 males and 117 females with a mean age of 23.1 years. There were no statistically significant differences at baseline between the MVC and WLC groups on demographics and psychological characteristics, indicating similar demographic and psychological characteristics across the two groups. Results under both ITT and PP approaches indicated that there were no statistically significant between-group differences in PHQ-9 (ITT: β=–0.44, *P*=.64; PP: β=–0.62,

P=.053), BAI (ITT: β=–2.06, *P*=.31; PP: β=–2.32, *P*=.27), and FFMQ-SF (ITT: β=1.33, *P*=.43; PP: β=1.44, *P*=.41) compared to WLC. There was a significant difference for the PSS (ITT: β=–2.31, *P*=.03; PP: β=–2.38, *P*=.03).

Conclusions: During a university labor strike, the MVC program led to statistically significant reductions in PSS compared to the WLC group, but there were no other significant between-group differences. Comparisons with previous cycles of intervention testing, undertaken during nondisrupted university operations, when efficacy was demonstrated, are discussed.

Trial Registration: ISRCTN Registry ISRCTN92827275; https://www.isrctn.com/ISRCTN92827275

(JMIR Ment Health 2021;8(1):e23491) doi:10.2196/23491

KEYWORDS

online intervention; randomized controlled trial; university student; depression; anxiety; stress; mental health; efficacy; intervention

Introduction

The impact of COVID-19 and other disruptions on education, generally, and secondary education, specifically, can have major student mental health effects. COVID-19–related shutdowns of face-to-face high school education have been associated with significant student dropout rates in multiple cities in the United States, as high proportions of students, engaged face-to-face, failed to connect online (13%) [1]. With the escalating infection rates of both spring and fall 2020, many university courses that were initiated in face-to-face formats were completed online [2,3], with considerable uncertainties about the fall 2020 semester and the impact of COVID-19 outbreaks on campus life generally.

However, the response of students to other campus crises can provide useful data in anticipating the effects of other disruptions. In 2018, during a 4-year project assessing the effects of mindfulness-based cognitive behavioral therapy (M-CBT), York University was impacted by a faculty and teaching assistant strike. Most students respected picket lines and did not attend classes until the strike resolved, which occurred after the end of the usual calendar-defined semester. Despite the strike, study recruitment and intervention testing proceeded. Here, we report the results of that randomized controlled trial (RCT).

The RCT undertaken was identical to two prior studies [4,5] on the same campus site under noncrisis conditions. As the studies were undertaken months apart, there were minimal environmental differences, other than seasonal change. In the initial study [4], 113 students (mean age 24.8 years) participated in an 8-week online M-CBT program and significant between-group benefits were found on measures of depression (Patient Health Questionnaire-9 [PHQ-9]), anxiety (Beck Anxiety Inventory [BAI]), quality of life (Quality of Life Scale [QOLS]), and mindfulness (Five Facet Mindfulness Questionnaire - Short Form [FFMQ-SF]), favoring the intervention group (MVC) compared to wait-list controls (WLC). In the follow-up study [5], 159 students (mean age 22.5 years) participated in the same 8-week online M-CBT program and significant between-group differences were again found on identical measures of depression (PHQ-9), anxiety (BAI), mindfulness (FFMQ-SF), and quality of life in intervention participants, compared to wait-list controls. These two demonstrations of intervention efficacy prepared us to investigate how the campus crisis may have affected student responses.

All three studies were motivated by the rising prevalence of mental health disorders, including depression and anxiety, among college students worldwide, prior to the COVID-19 pandemic [6]. In the United States, for example, analyses of college data show that mental health disorders are among the top 5 diagnostic categories seen at college health services and are responsible for the highest number of visits (4.93) per student [7]. Multiple US studies have suggested there is an increasing prevalence of mental health disorders, especially depression and anxiety, among undergraduate college and university students [7-14].

Additionally, of concern for online researchers, there are possible links between decreased youth mental health and increased online activity (ie, “screen time”) [15-17]. Strong arguments and reliable data support the perspective that online activities, particularly social media engagement, have unhealthy impacts for some youth populations [15-17]. Disruptions of regular face-to-face classes at universities and high schools may have elevated levels of unhealthy “screen time” for select populations. Accordingly, it is worthwhile to ascertain what changes might have occurred when university students experiencing a disruption that likely increased time spent online used an online mental health intervention.

A student survey of 32 Canadian postsecondary institutions indicated a high prevalence of high anxiety (56.5%), hopelessness (54%), seriously depressed mood (37.5%), and overwhelming anger (42%) [18]. The mental health problems seen among North American students are also apparent worldwide, as the World Health Organization (2018) reported increasing mental disorders in college and university students [6].

Despite student distress, the face-to-face counseling offered in colleges and universities has not kept pace with demand. For example, from 2007 to 2012, full-time enrollment in the Ontario (Canada) college system increased by 26% while the number of counselors employed in the college system increased by only 4.6% [19]. This discrepancy has resulted in observations of underserved students and overwhelmed counselors amid the increasing distress among students.

Mindfulness-based interventions have been demonstrated to positively impact psychological and physical health [20-22], with several meta-analyses demonstrating impacts across clinical

and nonclinical populations [22-27]. However, with large numbers of students (50,000-60,000 on some campuses), there may not be sufficient numbers of trained personnel to convey helpful mindfulness-based practices directly.

Accordingly, we developed a web-delivered M-CBT program (aimed at creating a Mindfulness Virtual Community, or MVC) to reduce depression, anxiety, and stress in university students and, as mentioned above, previously reported on two RCTs targeting Canadian university students that indicated efficacy [4,5].

Methods

Trial Design and Ethical Approval

This study was a two-arm parallel-design RCT comparing the web-based Mindfulness Virtual Community program to a wait-list control group. The Human Participant Research Committee at York University provided research ethics approval for the RCT (Certificate number: e2016 - 345).

Participants and Recruitment

Eligibility criteria were applied to recruit actively enrolled undergraduates aged ≥18 years, with English-language fluency and self-reported confidence in completing the study. Students were excluded if they reported substance abuse or episodes of psychosis during the month prior to the trial.

The study was advertised using study posters, class announcements, and email invitations via listservs of student associations in the Faculties of Health and Liberal Arts. Interested students contacted the research staff via email or phone and were screened for student registration, substance abuse, and indications of psychoses. If abuse or psychotic behaviors "interfered in routine life within the last month," students were excluded and provided with a list of accessible mental health resources. In addition, a registered clinical psychologist could be contacted directly if there was a perceived need for interim mental health counseling.

Eligible and willing students received detailed in-person information about the study and provided informed written consent. Participants had the option to receive an honorarium of Can $50 (US $39) or 2% in course grade (for professors who gave permission for this option) or three credits (equivalent to 2% course grade) in the Undergraduate Research Participation Pool (URPP) of the Department of Psychology. Each participant also received a resource list that included information about health and social services on campus and in the community (eg, the 24/7 "Good to Talk" helpline for postsecondary students in Ontario). Our protocol included a safety mechanism whereby participants were asked verbally and on the consent form to contact the research staff if they felt distress during the trial period so that "limited counselling with a clinical psychologist could be arranged, if needed." No such requests arose during the reported study period.

A sample of 480 students (160 students per group) was recruited over 3 semesters (Fall 2017, Winter 2018, and Fall 2018). The 3 samples were not combined due to the campus environment differences related to the 3-month strike in Winter 2018. Here, we report on a sample of n=154 students in a two-arm RCT.

Randomization

Participating students were randomized to the MVC intervention or the wait-list (control) using 1:1 block randomization. The randomized allocation sequence was computer-generated by an off-site research team member and allocations were concealed in sequentially numbered opaque envelopes [28]. The envelopes were only opened after written consent was obtained, ensuring participants and staff were blind prior to the allocation. Each participant in the MVC group received a unique ID and a temporary password; participants changed passwords after their first login, while IDs remained the same to reduce the potential of multiple accounts or identities. Participants in all groups completed online questionnaires at baseline (T1) and 8 weeks (T2).

Intervention

The MVC intervention was 8 weeks in duration and featured the following: (1) 12 student-specific mental health modules conveyed by online video, (2) 3 anonymous discussion boards dedicated to depression, anxiety, and stress, and (3) an anonymous 20-minute group-based live videoconference led by a moderator (with a master's degree in psychology), during which students raised and discussed topics covered in the modules (Figure 1).

Figure 1. The Mindfulness Virtual Community design.

Each mental health module consisted of 1 educational content video and 1 mindfulness practice video recorded with male and female voices and offered in high- and low-resolution formats (12 videos per module); participants could choose the type of video preferred. The videos were made available for participants 24 hours/day to watch or listen to on internet-linked computers, smartphones, or tablets. The module scripts and resulting audio recordings were created by an investigator with extensive experience as a clinical research psychologist and mindfulness researcher (PR) [29-34]. They drew on mindfulness and CBT principles, with the topics informed by prior focus group study [35,36]. The choice of moving and still images used in the videos involved collaborative work (PR, CE, and FA). The module topics and video durations are presented in Table 1. The role played by the online mindfulness moderator was informed by a pilot study [4].

This study can be characterized as being at stage 2 of the National Institute of Health stage model [37], progressing from a pilot study during which the entire platform was tested. In this study, we continued to test the MVC intervention in a research context with research therapists/providers.

Table 1. Topics and duration of modules.

Topics	Education videos (duration in minutes and seconds)	Mindfulness videos (duration in minutes and seconds)
Overcoming stress, anxiety, and depression	7:09	9:00
Mindfulness and being a student	5:18	9:14
Mindfulness for better sleep	4:40	8:13
Thriving in a fast-changing world	7:23	8:23
Healthy intimacy	7:32	9:33
Destigmatization	6:13	9:12
No more procrastination	3:42	10:48
Pain reduction and mindfulness	3:48	9:48
Healthy body image	5:44	9:54
Healthier eating	10:10	9:26
Overcoming trauma	6:01	9:43
Relationships with family and friends	7:49	8:09

New modules were regularly released during the 8-week intervention period. Following release, they were accessible to students for the remaining intervention period. The videoconferences were offered biweekly in three 20-minute evening sessions. The students in the intervention group received email reminders from project staff prior to the release of each module and prior to the live videoconferences. Access to the internet was assumed to be a minor obstacle as the prior focus group study revealed that 94.4% of the students had access to a smartphone and 93.1% had access to laptops or personal home computers. All participants had free internet access on campus and nearly all reported internet access through smartphones and/or laptop computers [38].

The MVC was constructed in partnership with an industry partner (ForaHealthyme Inc) and designed to be a virtual environment supportive of personal mindfulness practice and related CBT self-help. It facilitated mutual help interactions between participants, and between participants and the moderator. The two categories of users were students and health professionals (who moderated the discussion board dialogues and led the live videoconferences). All users used a login and a password to gain access.

Once logged in, each student could do the following: (1) access the educational and mindfulness video modules, (2) access 3 peer-to-peer discussion boards, 1 for each of the 3 mental health conditions targeted by the RCT (anxiety, stress, and depression), (3) notify the moderator about any message posting that represented a problem to the student (eg, online bullying), (4) access a calendar to book an upcoming videoconference, (5) access a virtual "room" that allowed videoconferencing (camera and microphone being off as default) and private text-based chatting with the moderator, and (6) a resource page with contact information for various social and health services.

Once the moderator logged in, they had access to the same options as the students, as well as several additional features: the ability to delete any message on the discussion boards deemed potentially distressing to other users, the ability to populate the calendar with dates and times for upcoming videoconference sessions, the ability to start a videoconference session (camera turned on by default), and the ability to respond privately to incoming text messages in the videoconferencing virtual "room."

The moderator had weekly supervision sessions with the team psychologist (PR) to optimize responses to the videoconferences and submitted weekly written reports (without individual names) about topics raised by students and responses to them. The content of the modules and the platform structure remained unchanged during the 8-week intervention; the name of the university that received the research grant and the name of the partnering information technology company appeared on the main page of the platform.

Study Outcomes and Measures Used

The primary outcomes were depression, anxiety, and perceived symptoms of stress. Depression symptoms were assessed with the PHQ-9 [38], where each item is rated on a 0-3 scale and total scores range from 0 to 27 (0-4 indicates minimal/subclinical depression, 5-9 indicates mild depression, 10-14 moderate, 15-19 moderately severe, and ≥20 indicates severe depression). Anxiety was measured using the 21-item BAI [39], where each item is rated on a 0-3 scale and the total score range is 0 to 63 (0-7 indicates a minimal anxiety level, 8-15 a mild anxiety level, 16-25 a moderate anxiety level, and 26-63 a severe anxiety level). For the measurement of stress, we used the 10-item PSS [40], where each item is rated on a 0-4 scale, and the total score range is 0 to 40 (scores of 0-13 indicate mild levels of stress, 14-26 moderate, and 27-40 high). The secondary outcomes were quality of life, life satisfaction, and mindfulness. We used the 16-item Quality of Life Scale (QOLS) [41]; each item is rated on a scale from 1 to 7 and the total score ranges from 16 to 112. Student life satisfaction was measured using the 6-item Brief Multidimensional Students' Life Satisfaction Scale-Peabody Treatment Progress Battery (BMSLSS-PTPB) [42]; each item is rated on a scale from 1 to 5, and item scores are averaged together to give a total score that ranges from 1 to 5. The level of mindfulness was measured by the 24-item FFMQ-SF [43]; each item is rated on a scale from 1 to 5, and the total score range is 24 to 120. The subscales in the FFMQ-SF are nonreactivity to inner experience (5 items), observing (4 items), acting with awareness (5 items), describing (5 items), and nonjudging of inner experience (5 items). We assessed each of the scales for internal consistency within the T1 and T2 data sets, and Cronbach α ranged from .87 and .90 for PHQ-9; .94 and .94 for BAI; .88 and .90 for PSS; and .85 and .84 for FFMQ-SF" at T1 and T2 respectively. Participants also completed a sociodemographic questionnaire at T1 that inquired about age, gender, birth country, years lived in Canada, first language, relationship status, and ethnic heritage.

All outcomes and other variables were measured by the self-report questionnaires at T1 and T2. The primary RCT outcomes were depression, anxiety, and perceived stress, while mindfulness was measured as a secondary outcome. It was hypothesized that symptom scores for depression, anxiety, and stress at T2 would be significantly lower in the MVC group compared with the WLC group, and that mindfulness scores at T2 would be significantly higher in the MVC group (compared with WLC). The outcomes were measured with the following validated scales: PHQ-9 [40]; BAI [41], PSS [42], and FFMQ-SF [43]. Participants also completed a sociodemographic questionnaire at T1.

Sample Size and Statistical Analysis

The sample size was calculated for 80% power and 5% type I error to detect a standardized effect size of 0.5 or larger. The required sample size was 63 students per arm. Our recruitment goal was 80 participants per arm, assuming an attrition rate of ~20%.

Descriptive statistics for demographic and psychological characteristics were calculated at baseline, and potential between-group differences were assessed using chi-square tests of independence for categorical variables, and *t* tests for numeric variables. To evaluate the impact of the intervention on study outcomes (ie, depression, anxiety, perceived stress, and mindfulness), generalized estimating equations with an AR (1) covariance structure were employed. Outcome evaluations were performed on both an intention-to-treat (ITT) and per-protocol (PP) basis, with the group × time interaction indicating a between-group change in study outcomes. As the missing data were minimal (<10% overall) and considered to be missing at random, multiple imputations were used to estimate missing observations. For all outcomes, effect sizes are presented for between-group comparisons at follow-up, evaluated by Cohen *d* and calculated as difference between MVC and WLC means divided by their pooled standard deviations. Cohen d effect size for between-group and within-group (repeated measures) comparisons are calculated according to procedures outlined in Lakens [44].

Results

Participants

Study participants were 154 undergraduate university students randomized to MVC (n=76) or WLC (n=78) conditions. Of the 154 participants with complete baseline assessments, 7 participants (9.2%) within the MVC and 1 (1.3%) WLC participant dropped out of the study without completing follow-up assessments. As indicated in Table 2, there were no statistically significant between-group differences at baseline in age, gender, country of birth, first language, relationship status, and ethnicity, indicating similar proportions of demographic characteristics across the MVC and WLC groups. Similarly, there were no statistically significant between-group differences in health status and access to private mental health services, with 74.7% of participants across both groups indicating good/very good/excellent health, and 60.4% of participants (across both groups) indicating no access to private mental health services. In addition, there were no significant between-group differences in hours spent at work (paid and unpaid) and in physical activity. In relation to psychological characteristics, no statistically significant between-group differences were detected at baseline between MVC and WLC scores on PHQ-9 (*P*=.88), BAI (*P*=.86), PSS (*P*=.60), and FFMQ-SF (*P*=.44), and in the following subscales: nonreactivity (*P*=.87), observing (*P*=.63), acting with awareness (*P*=.56), describing (*P*=.40), and nonjudgment (*P*=.44).

Table 2. Participants' demographic characteristics at baseline.

Demographic characteristics	All (n=154)	Mindfulness Virtual Community (n=76)	Wait-list control (n=78)	*P* value
Age (years), mean (SD)[a]	23.10 (8.09)	22.02 (5.52)	24.18 (9.95)	.10
Gender, n (%)				
Male	35 (22.7)	18 (23.7)	17 (21.8)	.96
Female	117 (76.0)	57 (75.0)	60 (76.9)	
Other	2 (1.3)	1 (1.3)	1 (1.3)	
Country of birth, n (%)				
Canada	91 (59.1)	46 (60.5)	45 (57.7)	.72
Other	63 (40.9)	30 (39.5)	33 (42.3)	
Years in Canada, mean (SD)[b]	10.73 (7.05)	11.05 (6.21)	10.42 (7.82)	.73
First language, n (%)				
English	103 (66.9)	50 (65.8)	53 (67.9)	.78
Other	51 (33.1)	26 (34.2)	25 (32.1)	
Relationship status, n (%)				
Single, not in a relationship	79 (51.3)	40 (52.6)	39 (50.0)	.70
Single, in a relationship	56 (36.4)	27 (35.5)	29 (37.2)	
Married or common law	13 (8.4)	5 (6.6)	8 (10.3)	
Divorced, separated, widowed, or other	6 (3.9)	4 (5.3)	2 (2.6)	
Ethnicity, n (%)				
White	40 (26.0)	17 (22.4)	23 (29.5)	.69
Black	25 (16.2)	11 (14.5)	14 (17.9)	
South Asian	37 (24.0)	21 (27.6)	16 (20.5)	
Other	35 (22.7)	19 (25.0)	16 (20.5)	
Multiple ethnicities	17 (11.0)	8 (10.5)	9 (11.5)	
Self-rated health, n (%)				
Poor or fair	39 (25.3)	23 (30.3)	16 (20.5)	.38
Good	60 (39.0)	28 (36.8)	32 (41.0)	
Very good or excellent	55 (35.7)	25 (32.9)	30 (38.5)	
Access to private mental health care, n (%)				
Yes	61 (39.6)	31 (40.8)	30 (38.5)	.77
No	93 (60.4)	45 (59.2)	48 (61.5)	
Weekly hours of activities, mean (SD)				
Paid work	7.78 (10.60)	7.76 (9.22)	7.81 (11.84)	.98
Unpaid work (including volunteer work)	2.87 (5.42)	2.89 (5.81)	2.85 (5.04)	.96
Vigorous physical activities[c]	1.68 (1.87)	1.75 (1.76)	1.62 (1.97)	.66
Patient Health Questionnaire score, mean (SD)	9.60 (6.14)	9.53 (5.83)	9.67 (6.50)	.88
0-9	77 (50.0)	39 (51.3)	38 (48.7)	.74
≥10	77 (50.0)	37 (48.7)	40 (51.3)	
Beck Anxiety Inventory score, mean (SD)	16.88 (13.32)	16.68 (13.56)	17.06 (13.17)	.86
0-21 (low)	100 (65.0)	49 (64.5)	51 (65.4)	.69
22-35 (moderate)	35 (22.7)	16 (21.0)	19 (24.4)	
≥36 (high)	19 (12.3)	11 (14.5)	8 (10.2)	

Demographic characteristics	All (n=154)	Mindfulness Virtual Community (n=76)	Wait-list control (n=78)	*P* value
Perceived Stress Scale score, mean (SD)	21.30 (7.66)	21.63 (7.72)	20.99 (7.63)	.60
0-13 (low)	25 (16.2)	11 (14.5)	14 (17.9)	.74
14-26 (moderate)	90 (58.4)	44 (57.9)	46 (59.0)	
27-40 (high)	39 (25.3)	21 (27.6)	18 (23.1)	
Five-Facet Mindfulness Questionnaire score, mean (SD)	74.15 (12.42)	73.36 (11.22)	74.92 (13.52)	.44

[a]Based on n=152 participants (missing data on n=2).

[b]Based on n=63 participants born outside of Canada.

[c]Based on n=151 participants (missing data on n=3).

Outcome Evaluations

Table 3 shows the means and standard deviations for study outcomes at baseline and at 8-week follow-up for the MVC and WLC groups. Table 3 further includes effect sizes for the mean difference between MVC and WLC at 8-week follow up. The PHQ-9 and the FFMQ-SF exhibited negligible between-group differences at 8 weeks, while the between-group effect sizes for the BAI, PSS, and FFMQ-SF nonjudgment subscale were in the small range (d=0.20-0.24).

Table 3. Descriptive statistics for depression, anxiety, stress, and mindfulness scores.

Outcomes	Intention to treat			Per protocol		
	Mindfulness Virtual Community, mean (SD)	Wait-list control, mean (SD)	Cohen *d*	Mindfulness Virtual Community, mean (SD)	Wait-list control, mean (SD)	Cohen *d*
	n=76	n=78		n=69	n=77	
Patient Health Questionnaire-9						
Baseline	9.67 (6.50)	9.53 (5.83)	N/A[a]	9.80 (6.63)	9.42 (5.78)	N/A
8 weeks	7.76 (6.12)	8.05 (6.25)	0.05	7.81 (6.41)	8.05 (6.30)	0.04
Beck Anxiety Inventory						
Baseline	16.68 (13.56)	17.06 (13.17)	N/A	16.91 (13.56)	16.91 (13.19)	N/A
8 weeks	12.15 (10.50)	14.58 (12.29)	0.21	12.29 (10.84)	14.61 (12.37)	0.20
Perceived Stress Scale						
Baseline	21.63 (7.72)	20.99 (7.63)	N/A	21.52 (7.74)	20.99 (7.68)	N/A
8 weeks	18.44 (7.51)	20.11 (7.83)	0.22	18.28 (7.82)	20.12 (7.88)	0.24
Five Facets Mindfulness Questionnaire-Short Form						
Baseline	73.35 (11.22)	74.92 (13.52)	N/A	73.22 (11.10)	74.92 (13.61)	N/A
8 weeks	75.65 (10.08)	75.89 (12.49)	0.02	75.62 (10.58)	75.89 (12.57)	0.02
Five Facets Mindfulness Questionnaire-Short Form, Nonreactivity subscale						
Baseline	14.33 (3.79)	14.22 (4.31)	N/A	14.20 (3.77)	14.20 (4.34)	N/A
8 weeks	14.65 (3.26)	14.69 (3.58)	0.01	14.67 (3.39)	14.68 (3.60)	0.003
Five Facets Mindfulness Questionnaire-Short Form, Observing subscale						
Baseline	13.38 (3.31)	13.65 (3.64)	N/A	13.38 (3.33)	13.69 (3.65)	N/A
8 weeks	13.46 (3.18)	13.90 (3.43)	0.13	13.45 (3.33)	13.90 (3.45)	0.13
Five Facets Mindfulness Questionnaire-Short Form, Acting with Awareness subscale						
Baseline	15.54 (4.12)	15.92 (4.08)	N/A	15.72 (4.10)	15.92 (4.11)	N/A
8 weeks	16.10 (3.87)	16.39 (4.08)	0.07	16.09 (4.05)	16.40 (4.11)	0.08
Five Facets Mindfulness Questionnaire-Short Form, Describing subscale						
Baseline	16.32 (4.16)	16.89 (4.15)	N/A	16.22 (4.30)	16.90 (4.17)	N/A
8 weeks	16.92 (3.51)	17.19 (4.26)	0.07	16.90 (3.68)	17.18 (4.29)	0.07
Five Facets Mindfulness Questionnaire-Short Form, Nonjudgement subscale						
Baseline	13.79 (3.28)	14.24 (3.99)	N/A	13.69 (3.28)	14.22 (4.01)	N/A
8 weeks	14.52 (3.48)	13.72 (3.69)	0.22	14.52 (3.65)	13.73 (3.71)	0.22

[a]N/A: not applicable.

Table 4 presents the results for ITT and PP models on the impact of the intervention on PHQ-9, BAI, PSS, and FFMQ-SF scores, including FFMQ-SF subscale scores. Except for PSS, there were no statistically significant reductions compared to WLC. For PSS, compared to the WLC group, the MVC group had a statistically significant reduction with both ITT and PP analytic approaches (ITT: β=–2.31, *P*=.03; PP: β=–2.38, *P*=.03). When compared to the WLC group, the MVC group also exhibited a slight increase in the FFMQ-SF nonjudgment subscale (ITT: β=1.25, *P*=.06; PP: β=1.31, *P*=.06).

Table 4. Generalized estimating equations for depression, anxiety, stress, and mindfulness outcomes from baseline to 8 weeks.

Outcomes	Intention to treat	*P* value	Per protocol	*P* value
	Mean (SE), 95% CI		Mean (SE), 95% CI	
Patient Health Questionnaire-9				
Intercept	9.53 (0.66), 8.24 to 10.81	<.001	9.42 (0.65), 8.13 to 10.70	<.001
Time	–1.47 (0.63), –2.70 to –0.25	.02	–1.37 (0.63), –2.59 to –0.14	.03
Group	0.14 (0.99), –1.79 to 2.08	.88	0.38 (1.03), –1.63 to 2.40	.71
Group × Time	–0.44 (0.95), –2.31 to 1.43	.64	–0.62 (0.99), –2.57 to 1.32	.53
Beck Anxiety Inventory				
Intercept	17.06 (1.48), 14.16 to 19.97	<.001	16.91 (1.49), 13.98 to 19.84	<.001
Time	–2.48 (1.51), –5.44 to 0.49	.10	–2.30 (1.52), –5.28 to 0.68	.13
Group	–0.38 (2.14), –4.58 to 3.82	.86	0.004 (2.20), –4.31 to 4.32	.99
Group × Time	–2.06 (2.02), –6.03 to 1.92	.31	–2.32 (2.09), –6.42 to 1.77	.27
Perceived Stress Scale				
Intercept	20.99 (0.86), 19.31 to 22.67	<.001	20.99 (0.87), 19.28 to 22.69	<.001
Time	–0.88 (0.69), –2.24 to 0.48	.20	–0.87 (0.70), –2.24 to 0.50	.22
Group	0.64 (1.23), –1.77 to 3.05	.60	0.53 (1.27), –1.95 to 3.02	.67
Group × Time	–2.31 (1.06), –4.39 to –0.24	.03	–2.38 (1.10), –4.54 to –0.22	.03
Five Facets Mindfulness Questionnaire-Short Form				
Intercept	74.92 (1.52), 71.94 to 77.90	<.001	74.92 (1.54), 71.90 to 77.94	<.001
Time	0.97 (0.99), –0.97 to 2.90	.33	0.97 (1.00), –0.99 to 2.93	.33
Group	–1.57 (1.99), –5.46 to 2.33	.43	–1.70 (2.03), –5.69 to 2.28	.40
Group × Time	1.33 (1.69), –1.99 to 4.64	.43	1.44 (1.75), –1.99 to 4.87	.41
Five Facets Mindfulness Questionnaire-Short Form, Nonreactivity subscale				
Intercept	14.22 (0.49), 13.27 to 15.17	<.001	14.20 (0.49), 13.23 to 15.16	<.001
Time	0.47 (0.38), –0.28 to 1.22	.22	0.48 (0.39), –0.28 to 1.24	.21
Group	0.11 (0.65), –1.16 to 1.39	.86	0.008 (0.66), –1.30 to 1.32	.99
Group × Time	–0.15 (0.64), –1.40 to 1.10	.81	–0.02 (0.67), –1.32 to 1.29	.98
Five Facets Mindfulness Questionnaire-Short Form, Observing subscale				
Intercept	13.65 (0.41), 12.85 to 14.46	<.001	13.69 (0.41), 12.88 to 14.50	<.001
Time	0.25 (0.32), –0.39 to 0.88	.45	0.21 (0.32), –0.43 to 0.85	.52
Group	–0.27 (0.56), –1.36 to 0.82	.63	–0.31 (0.57), –1.44 to 0.81	.59
Group × Time	–0.16 (0.53), –1.20 to 0.88	.76	–0.14 (0.56), –1.23 to 0.95	.80
Five Facets Mindfulness Questionnaire-Short Form, Acting with Awareness subscale				
Intercept	15.92 (0.46), 15.02 to 16.82	<.001	15.92 (0.46), 15.01 to 16.83	<.001
Time	0.47 (0.43), –0.38 to 1.31	.28	0.48 (0.44), –0.38 to 1.33	.27
Group	–0.38 (0.66), –1.67 to 0.91	.56	–0.20 (0.68), –1.52 to 1.13	.77
Group × Time	0.09 (0.66), –1.21 to 1.39	.89	–0.11 (0.68), –1.46 to 1.23)	.87
Five Facets Mindfulness Questionnaire-Short Form, Describing subscale				
Intercept	16.89 (0.47), 15.97 to 17.80	<.001	16.90 (0.47), 15.97 to 17.82	<.001
Time	0.30 (0.34), –0.36 to 0.97	.37	0.28 (0.34), –0.39 to 0.95	.41
Group	–0.57 (0.66), –1.87 to 0.73	.39	–0.68 (0.70), –2.05 to 0.69	.33
Group × Time	0.31 (0.50), –0.68 to 1.29	.54	0.40 (0.52), –0.63 to 1.43	.45
Five Facets Mindfulness Questionnaire-Short Form, Nonjudgement subscale				

Outcomes	Intention to treat	*P* value	Per protocol	*P* value
	Mean (SE), 95% CI		Mean (SE), 95% CI	
Intercept	14.24 (0.45), 13.36 to 15.12	<.001	14.22 (0.45), 13.33 to 15.11	<.001
Time	–0.52 (0.40), –1.29 to 0.26	.18	–0.49 (0.40), –1.27 to 0.30	.22
Group	–0.45 (0.58), –1.60 to 0.69	.44	–0.53 (0.60), –1.70 to 0.65	.38
Group × Time	1.25 (0.65), –0.03 to 2.53	.06	1.31 (0.69), –0.04 to 2.66	.06

Tables 5 and 6 show additional analyses that focused on discerning which subgroups were affected more or less by the intervention (given varying baseline depression, anxiety, and perceived stress levels). Across 3 levels of depressive symptoms per PHQ-9 categories (ie, mild, moderate, and severe symptom levels), intervention group reductions were greater than those of the control group. An exception was the moderately severe category, where the greater effect size observed was in the controls. We have highlighted the Cohen *d* effect sizes to facilitate comparisons. The moderately severe category has modest effect size differences.

When similar analyses involved female-male comparisons, the effect sizes and mean reductions were greater in females across mild, moderate, moderately severe, and severe categories. Reductions in cell size are noted, particularly for the male data, as the female study sample far exceeded the male sample (Tables 7 and 8).

Table 5. Analysis of Patient Health Questionnaire-9 subgroups: intervention.

Patient Health Questionnaire-9, intervention	Minimal (0-4)	Mild (5-9)	Moderate (10-14)	Moderately severe (15-19)	Severe (20-27)
	N=20	N=19	N=20	N=11	N=6
Mean (T1/T2)	2.20/4.86	6.84/5.41	11.95/8.79	16.54/12.70	23.33/12.33
Mean difference, Cohen *d*	2.66, 0.64	–1.43, 0.50	–3.16, 0.67	–3.84, 0.55	–11.0, 2.18

Table 6. Analysis of Patient Health Questionnaire-9 subgroups: control.

Patient Health Questionnaire-9, wait-list control	Minimal (0-4)	Mild (5-9)	Moderate (10-14)	Moderately severe (15-19)	Severe (20-27)
	N=17	N=21	N=26	N=10	N=4
Mean (T1/T2)	1.82/2.17	7.19/6.52	11.61/10.53	16.90/12.41	22.50/14.00
Mean difference, Cohen *d*	0.35, 0.20	–0.67, 0.19	–1.08, 0.29	–4.49, 0.68	–8.5, 1.52

Table 7. Analysis of Patient Health Questionnaire-9 subgroups: male.

Patient Health Questionnaire-9, intervention, females	Minimal (0-4)	Mild (5-9)	Moderate (10-14)	Moderately severe (15-19)	Severe (20-27)
	N=14	N=16	N=13	N=9	N=5
Mean (T1/T2)	2.36/3.37	7.00/5.31	11.92/7.82	16.44/12.19	22.60/11.00
Mean difference, Cohen *d*	1.01, 0.44	–1.69, 0.56	–4.1, 1.24	–4.25, 0.58	–11.6, 3.07

Table 8. Analysis of Patient Health Questionnaire-9 subgroups: female.

Patient Health Questionnaire-9, intervention, males	Minimal (0-4)	Mild (5-9)	Moderate (10-14)	Moderately severe (15-19)	Severe (20-27)
	N=5	N=3	N=7	N=2	N=1
Mean (T1/T2)	2.00/5.00	6.00/5.93	12.00/10.57	17.00/15.00	27.00/19.00
Mean difference, Cohen *d*	3.00, 0.97	–0.07, 0.33	–1.43, 0.18	–2.00, 0.37	–8.00, N/A

In established BAI categories (ie, low, moderate, and severe symptoms) intervention group reductions were less than control reductions in both low and high symptom categories, while in the moderate symptom category, intervention reductions were greater (Tables 9 and 10). When analyses focused on comparing females with males, the effect sizes and mean reductions were greater in females across moderate and high categories, while the low category results can be characterized as equal. There were reductions in cell size due to the female-male comparisons (Tables 11 and 12).

Table 9. Analysis of Beck Anxiety Inventory categories: intervention.

Beck Anxiety Inventory, intervention	Low (0-21)	Moderate (22-35)	High (≥36)
	N=49	N=16	N=11
Mean (T1/T2)	8.06/8.41	26.00/17.29	41.54/21.34
Mean difference, Cohen *d*	0.35, 0.05	–8.71, 1.27	–20.21, 1.72

Table 10. Analysis of Beck Anxiety Inventory categories: control.

Beck Anxiety Inventory, wait-list controls	Low (0-21)	Moderate (22-35)	High (≥36)
	N=51	N=19	N=8
Mean (T1/T2)	8.90/11.02	28.05/20.77	43.00/22.62
Mean difference, Cohen *d*	2.12, 0.22	–7.28, 0.93	–20.38, 2.31

Table 11. Analysis of Beck Anxiety Inventory categories: female.

Beck Anxiety Inventory, intervention, females	Low (0-21)	Moderate (22-35)	High (≥36)
	N=36	N=14	N=7
Mean (T1/T2)	8.42/8.32	26.14/16.54	43.14/21.53
Mean difference, Cohen *d*	–0.10, 0.01	–9.60, 1.38	–21.61, 1.84

Table 12. Analysis of Beck Anxiety Inventory categories: male.

Beck Anxiety Inventory, intervention, males	Low (0-21)	Moderate (22-35)	High (≥36)
	N=12	N=2	N=4
Mean (T1/T2)	7.50/8.05	25.0/22.5	38.75/21.00
Mean difference, Cohen *d*	0.55, 0.07	–2.50, 0.16	–17.75, 0.77

In perceived stress, intervention and control comparisons demonstrated, at the moderate and high stress levels, greater reductions in the intervention group with approximately equal reductions observed at the low level (Tables 13 and 14). When analyses focused on female-male comparisons, in the moderate and high levels, females demonstrated more change than males, while in the low group females had a negative intervention effect (their stress increased) while males had no intervention effects (ie, neither positive or negative; Tables 15 and 16).

Table 13. Analysis of Perceived Stress Scale categories: intervention.

Perceived Stress Scale, intervention	Low (0-13)	Moderate (14-26)	High (27-40)
	N=11	N=44	N=21
Mean (T1/T2)	9.55/11.09	20.25/17.93	30.86/23.36
Mean difference, Cohen *d*	1.54, 0.26	–2.32, 0.40	–7.5, 1.59

Table 14. Analysis of Perceived Stress Scale categories: control.

Perceived Stress Scale, wait-list controls	Low (0-13)	Moderate (14-26)	High (27-40)
	N=14	N=46	N=18
Mean (T1/T2)	9.14/10.64	20.78/20.57	30.72/26.28
Mean difference, Cohen *d*	1.5, 0.28	–0.21, 0.04	–4.44, 0.88

Table 15. Analysis of Perceived Stress Scale categories: female.

Perceived Stress Scale, intervention, female	Low (0-13)	Moderate (14-26)	High (27-40)
	N=8	N=33	N=16
Mean (T1/T2)	8.87/11.0	19.97/17.55	31.25/23.41
Mean difference, Cohen *d*	2.13, 0.50	–2.42, 0.42	–7.84, 1.77

Table 16. Analysis of Perceived Stress Scale categories: male.

Perceived Stress Scale, intervention, males	Low (0-13)	Moderate (14-26)	High (27-40)
	N=3	N=11	N=4
Mean (T1/T2)	11.33/11.33	21.09/19.06	30.0/21.25
Mean difference, Cohen *d*	0.00, 0	–2.03, 0.33	–8.75, 1.33

Altogether, females gained more benefit than males and intervention subjects benefitted more than controls. Gains were most evident in depression and perceived stress reductions. Anxiety results (BAI outcomes) were more variable, likely reflecting the immediate anxiety reduction effects in controls with the suspension of expected exams and assignments.

Discussion

Principal Findings

This study was undertaken at a labor strike–affected university, following identical procedures described in two prior studies at the same site, conducted when no crises existed [4,5]. Accordingly, participant responses to the previous RCTs are usefully compared to responses in this study (referred to as "Study 3" below).

In the previously reported RCTs [4,5], significant between-group differences were observed in depression (PHQ-9), anxiety (BAI), quality of life (QOLS), and mindfulness (FFMQ-SF). In the first RCT, significant between-group differences were additionally found in perceived stress (PSS). In this study, a significant between-group difference was only found in the PSS (P=.03), while a marginal (P=.06) difference was observed in the Nonjudgment subscale of FFMQ-SF.

Despite the limited between-group differences in this disrupted-campus study, significant group × time effects suggested that the MVC intervention had a positive impact on students. However, while in Study 1 and 2 the WLC depression scores (PHQ-9) [4,5] increased over time (Time 2>Time 1; perhaps due to anticipating increasingly demanding academic tasks), in Study 3, the WLC subjects had substantially reduced depression scores (Time 1<Time 2, by –1.4 in mean raw score). As the intervention within-group reductions were nearly equivalent across studies 1, 2, and 3, the significant between-group differences absent in Study 3 appeared related to the self-reported depression reductions (between Time 1 and Time 2) in WLC subjects.

Cross-study differences were also observable in the BAI indices, where in Study 1 and 2, WLC scores increased over time (Time 2>Time 1), whereas in Study 3 the WLC scores decreased over time (Time 2<Time 1) by a mean (raw) scale score of –2.38. Once again, the within-group reductions were nearly equivalent across studies 1, 2, and 3 (–4.2, –4.8, and –4.5, respectively) indicating that reductions in the between-group differences in Study 3 were related to anxiety reductions in the WLC group.

Other interesting cross-study differences were observable in PSS indices where significant between-group differences were found in Study 1 and Study 3, but not in Study 2. In Study 1 and 3, the WLC group scores were nearly equivalent (Time 1 and Time 2) as were the reductions achieved in the intervention group (Study 1: –3.10, Study 2: –3.19, in raw scores).

One interpretation of such study comparisons is that students experienced the crisis as reducing academic pressure, with the result of them experiencing less distress (represented in lower mean WLC group depression and anxiety scores). While the lowered distress was likely temporary (outcomes were assessed 8 weeks after baseline, and prior to resumed course activity), the pattern might have also affected motivations regarding participation in the intervention. If so, this would have contributed to the lack of significant between-group differences in depression and anxiety in this study.

It is notable that while there were no significant between-group differences previously observed in Study 2 for the PSS, there was a significant difference observed in this study (Study 3) and Study 1. It seems that while the burdens of depression and anxiety in the WLC group were reduced in Study 3, there was not an equivalent reduction of the immediate stress represented in PSS items. Several PSS items refer to "unexpected happenings beyond control, anger and irritation due to loss of control," and positive control (a reversed item) over "important things." Such items reflect the lost control that can occur during a campus strike. Thus, significant between-group differences favoring the intervention could have occurred because intervention participants felt positive intervention effects related to the disruption caused by the strike. Why PSS differences were found in Study 1 is an interesting question for speculation. Notably, tense, publicized negotiations preceded the strike, during the period when Study 1 was undertaken. Students might have been aware of the increasing strike probability, with that awareness represented on the PSS intervention-attributable differences.

If the academic disruption was experienced as a temporary reduction in distressing academic pressures, the "strike" reaction is congruent with focus group findings preceding the 3 RCTs,

which helped prioritize intervention topics [37,38]. Specifically, from focus group findings, "procrastination" was reported as a prevalent student problem. Their transcript responses referred to seeking and finding internet distraction while ignoring difficult academic tasks. A frequently described experience was that initially brief divergences consumed more time than planned and resulted in delays in "getting down to work," causing schoolwork to suffer and anxieties to increase.

These descriptions appear similar to the internet-based problems described in interviews with members of the I-Gen (generation) cohort [42]. For example, given normative engagement in more internet-based interactions, only a few keystrokes separate tasks of high consequence from stress-reducing "escapes" (using computers and smartphones).

While few motivational obstacles accompany the transition from "work" to entertainment, the return to committed work is more difficult. This contrasts with the differences experienced when one physically goes to a library or classroom and has peer interaction. While distracting temptations exist, social reinforcements counteract tendencies to surrender to distractions. The face-to-face shutdown that largely happened around the York University strike led to reduced academic pressures and normative social academic reinforcements.

Approximately 30%-60% of undergraduate students report regular procrastination in studying for exams, writing term papers, and doing weekly readings to the point where performance is compromised [45-49]. The increased stress due to procrastination can manifest as anxiety, irritation, regret, despair, and/or self-blame [45-53].

Procrastination in students can be associated with maladaptive perfectionism [31,32], where students develop perfectionistic attitudes and project the likely disapproval of others. Under these conditions, procrastination serves to control and reduce the anxieties stemming from such dysfunctional attitudes. These perspectives were demonstrated to have validity in previous intervention trials [31,32] and were applied in the MVC intervention content.

In closing, student participants in an 8-week RCT demonstrated behavior changes, although the study site was a strike-affected and disrupted campus. In two previously published RCTs at the same site under normal conditions, with the same intervention, significant between-group differences in depression, anxiety, quality of life, and mindfulness were observed, with significant between-group differences in perceived stress in one RCT (Study 1) but not in the other (Study 2). In the current strike-affected RCT, there was a significant between-group difference in perceived stress but an absence of significant findings regarding depression, anxiety, quality of life, and mindfulness. Further examinations indicated the between-study differences were, to some degree, the result of lower (when compared to the previous trials) depression/anxiety self-report observed in the WLC group rather than positive intervention group changes. One interpretation of these differences was that students experienced the disruption that occurred during the 8-week trial as a reprieve or pressure easing. The RCT participants self-reported being less anxious and depressed within the 8 weeks. On the other hand, the presence of significant between-group differences in perceived stress demonstrated the assistance received from the intervention following the more immediate loss of control due to life disruptions (ie, strikes).

Several study limitations must be taken into account. This was not a single- or double-blinded trial. The study duration of 8 weeks did not allow us to test for longer-term effects (eg, 6 or 12 months), which would have resulted in a more fully assessed crisis effect. A further limitation is the high female preponderance in the control and intervention groups, as more precise future research projects would address gender differences through stratification with larger participant samples from multiple research sites (involving multiple universities and colleges). Missing data was also a limitation, somewhat mitigated by the use of a multiple imputation method. Lastly and importantly, given the marginal between-group differences found in this study in mindfulness self-report (FFMQ-SF), there was no measure of the participants' mindfulness practice external to platform participation.

Conclusion

Our results suggest that an 8-week online M-CBT video-based program is an effective intervention for reducing perceived stress among undergraduate university students on a disrupted campus. To some degree, the online M-CBT interventions offer an opportunity to address mental health conditions in postsecondary populations under disrupted campus conditions that might have similarities to COVID-19–related disruptions, which may have resulted in face-to-face academic interactions being suspended.

Acknowledgments

The authors acknowledge the contribution of all students who gave their valuable time to participate in the study. We thank ForaHealthyMe.com Inc. as an industry partner in this project who provided great support. The work reported in this paper was funded by the Canadian Institutes for Health Research (CIHR) eHealth Innovations Partnership Program Grant (eHIPP; Grant No. EH1-143553). The project's principal investigators are CE (nominated), FA, and PR.

Authors' Contributions

CE, FA, and PR designed the study and questionnaire, received the funds, and contributed equally. PR led module development, providing written content and voice. MP analyzed the data. PR verified the analysis and prepared the first draft, and all authors provided critical feedback and revised it. The MVC Team members are (alphabetically): Sahir Abbas, BSc; Yvonne Bohr, PhD;

Manuela Ferrari, PhD; Wai Lun Alan Fung MD, ScD, FRCPC; Louise Hartley, PhD; Amin Mawani, PhD; Kwame McKenzie, MD, FRCPC; and Jan E. Odai, BA. These team members made contributions to several aspects of the project and results development. They all approve the final version and agree to be accountable for all aspects of the submitted paper. The trial protocol could be accessed on reasonable request to corresponding authors.

Conflicts of Interest

It is the understanding of the university and researchers that the Project Intellectual Property belongs to CEM, FA, and PR. The industry partner ForaHealthyMe.com owns all rights and title to the copyrights of any computer source code software that was developed out of this research project.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1362 KB - mental_v8i1e23491_app1.pdf]

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Abbreviations

BAI: Beck Anxiety Inventory
BMSLSS-PTPB: Brief Multidimensional Students' Life Satisfaction Scale-Peabody Treatment Progress Battery
FFMQ-SF: Five Facets Mindfulness Questionnaire Short Form
ITT: intention to treat
M-CBT: mindfulness-based cognitive behavioral therapy
MVC: Mindfulness Virtual Community
PHQ-9: Patient Health Questionnaire-9
PP: per protocol
PSS: Perceived Stress Scale
QOLS: Quality of Life Scale
RCT: randomized controlled trial
WLC: wait-list control

Edited by J Torous, G Eysenbach; submitted 13.09.20; peer-reviewed by C Benjet, J Melcher; comments to author 24.09.20; revised version received 19.11.20; accepted 02.12.20; published 11.01.21.

Please cite as:
Ritvo P, Ahmad F, El Morr C, Pirbaglou M, Moineddin R, MVC Team
A Mindfulness-Based Intervention for Student Depression, Anxiety, and Stress: Randomized Controlled Trial
JMIR Ment Health 2021;8(1):e23491
URL: https://mental.jmir.org/2021/1/e23491
doi:10.2196/23491
PMID:33264098

Original Paper

Comparing Effectiveness Between a Mobile App Program and Traditional Cognitive Behavior Therapy in Obsessive-Compulsive Disorder: Evaluation Study

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Abstract

Background: This study proposes a digital program for the treatment of mental illness that could increase motivation and improve learning outcomes for patients. Several studies have already applied this method by using an exposure and response prevention–inspired serious game to treat patients with obsessive-compulsive disorder (OCD).

Objective: We hypothesized that a mobile cognitive behavior therapy (CBT) program would be as effective in treating OCD as traditional offline CBT. In addition, the treatment efficacy in response to mobile CBT for OCD might be associated with increased brain activity within the cortico-striato-thalamo-cortical (CSTC) tract.

Methods: The digital CBT treatment program for OCD, OCfree, consists of 6 education sessions, 10 quests, and 7 casual games. Information was gathered from 27 patients with OCD (15 offline CBT and 12 OCfree CBT). During the 6-week intervention period, changes in clinical symptoms and brain function activity were analyzed.

Results: There was no significant difference in the change in OCD symptoms and depressive symptoms between the two groups. However, the OCfree group showed greater improvement in anxiety symptoms compared to the offline CBT group. Both offline CBT and OCfree CBT increased the functional connectivity within the CSTC tract in all patients with OCD. However, CBT using OCfree showed greater changes in brain connectivity within the thalamus and insula, compared to offline CBT.

Conclusions: OCfree, an OCD treatment app program, was effective in the treatment of drug-naïve patients with OCD. The treatment effects of OCfree are associated with increased brain connectivity within the CSTC tract. Multisensory stimulation by education, quests, and games in OCfree increases the activity within the thalamus and insula in patients with OCD.

(JMIR Ment Health 2021;8(1):e23778) doi:10.2196/23778

KEYWORDS

obsessive-compulsive disorder; exposure and response prevention; cognitive behavior therapy; cortico-striato-thalamo-cortical tract; functional connectivity; prevention; cognitive; mental illness; behavior therapy

Introduction

Overview

Obsessive-compulsive disorder (OCD) is a debilitating mental disorder associated with significant social and occupational impairments [1], affecting 2%-3% of the population worldwide [2]. It is diagnosed by the presence of obsessions, compulsions, or both [2]. Obsessions are characterized as intrusive thoughts or images that are often unwanted and repeat constantly. Compulsions, on the other hand, are defined as repetitive behaviors or mental thinking that people feel they need to do, often to counter the obsessions.

Along with obsession and compulsion, functional brain changes in patients with OCD have also been noted. Many studies have

found the cortico-striato-thalamo-cortical (CSTC) tract to be one of the crucial brain circuits involved in OCD [3,4]. Within the CSTC tract, patients with OCD showed different brain activity in response to various stimuli [5,6]. In response to emotion-related tasks, patients with OCD showed overactivation within the anterior cingulate cortex, insula, caudate head, and putamen, which are thought to play a part in salience, arousal, and habit responding [5]. In addition, underactivation was shown in the medial prefrontal cortex and posterior caudate, which are associated with cognitive and behavioral control [5]. Regions outside the CSTC tract are also of interest, as Zhang et al showed altered functional connectivity (FC) in resting-state functional magnetic resonance imaging (Rs-fMRI) between the cerebellum and CSTC circuit in OCD patients [6].

Of several treatment options for OCD, cognitive behavior therapy (CBT) with exposure and response prevention (ERP) is regarded as one of the first choices in many clinical guidelines [7,8]. The National Institute for Health and Care Excellence recommends intensive CBT (over 10 therapist hours including ERP) or a selective serotonin reuptake inhibitor (SSRI) as initial treatment [7]. The American Psychiatric Association also recommends CBT with ERP, SSRIs, or both as first-line treatments [8]. Recent reviews on the literature have found that CBT with ERP has larger effect sizes than pharmacotherapy, although interpreting this as CBT with ERP being better than medication must be avoided as there are many factors to consider [9].

However, CBT with ERP is not without its flaws. One of the main disadvantages of CBT is that it is time consuming, and efficacy is tied to the participant's engagement with the therapy [10]. Moreover, Barnes et al found that homework, one of the key elements of CBT, was one of the main reasons for low adherence because it is linked to negative school homework experiences [10].

Many methods have been devised to overcome this disadvantage. The delivery of mental health services through the internet is one method being considered [11,12]. This method has the potential to increase patient engagement and availability [11]. In a randomized controlled trial of family-based treatment for OCD, internet delivered cases showed higher response rates than clinic cases, and this difference persisted after treatment, although the difference was not statistically significant [12]. Another method used is serious games. Eichenberg and Schott argued that serious games could increase motivation and improve learning outcomes, thereby supplementing some of the weaknesses of the conventional internet-mediated health program [13].

Serious games are defined as games developed with a purpose other than entertainment [14]. Notable examples of these are games designed to improve aircrew training [15] or education [16]. Serious games are also used in the medical field to help patients. A meta-analysis and systematic review showed that serious games for mental health were effective in reducing symptoms related to depression, autism spectrum disorder, post-traumatic stress disorder, attention-deficit/hyperactivity disorder, and alcohol use disorder [14]. Serious games have also been shown to lower anxiety and related symptoms. Kim et al reported that a serious game helped lower depression and anxiety in breast cancer patients [17]. A pilot study also showed that a serious game helped reduce anxiety and pain in children before day-care surgery [18]. More recently, Hong et al used an ERP-inspired serious game to treat OCD patients; the patients showed improved OCD symptoms, which correlated with increased brain connectivity between the dorsal anterior cingulate cortex and the prefrontal cortex, after 3 weeks of game play [19].

Hypothesis

To our knowledge, a mobile app using serious games with both ERP and CBT for OCD has not yet been developed. Therefore, we designed a mobile app based on these theories and conducted a randomized controlled trial comparing the developed program directly with traditional CBT with ERP in OCD patients. We hypothesized that the mobile CBT program would be as effective in the treatment of OCD as traditional offline CBT. In addition, the treatment efficacy in response to mobile CBT for OCD might be associated with increased brain activity within the CSTC tract.

Methods

Participants

Through advertisements for treatment of OCD, 32 patients with OCD were recruited from the Department of Psychiatry at Chung-Ang University Hospital. All patients with obsession or compulsion symptoms were screened using the structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), and diagnosed by a psychiatrist (DHH). Inclusion criteria were as follows: (1) age>18 years, (2) diagnosed with OCD based on DSM-5, (3) drug naïve, and (4) right-handedness. Exclusion criteria were as follows: (1) IQ<80; (2) history of medical or other psychiatric disorders; (3) history of substance use disorders; (4) contraindications to MRI scanning, including claustrophobia or metal implant; and (5) current psychotherapy or medication treatment.

Of the 32 patients with OCD, 1 patient was excluded due to psychotic symptoms of hallucinations. The remaining 31 patients were randomly classified into two groups: an offline CBT group (n=16) and a web-based CBT using OCfree group (n=15). One patient in the offline CBT group and 1 patient in the OCfree group were excluded due to taking medication for anxiety reduction, and another patient in the OCfree group was excluded due to a brain infarction finding in the baseline fMRI. In the OCfree group, 1 patient did not complete the study protocol because they did not want to visit the hospital during the COVID-19 pandemic. Finally, the information of 27 patients with OCD (15 offline CBT and 12 OCfree CBT) was analyzed. Participants who entered the trial received a maximum of 100,000 won (around US $89) during the whole trial to compensate for travel fees. The institutional review board of Chung-Ang University Hospital approved this study, and all participants provided written informed consent.

Study Design

A randomized and treatment-as-usual controlled design was applied for this study. Individual in-person CBT was selected as treatment-as-usual with reference to the American Psychiatric Association practice guidelines [20]. The guideline recommends CBT or medication (SSRI) as the first-line treatment for OCD, states that individual and group CBT seem equally effective, and mentions that internet-delivered CBT is promising and deserving of further research [20]. After screening, all patients with OCD were randomly assigned to receive offline CBT once per week or web-based CBT using OCfree daily for 6 weeks, according to the randomization sequence generated using SPSS version 24.0 (IBM Corp, Armonk, NY, USA), with a 1:1 allocation (offline CBT:CBT using OCfree). At baseline and after intervention, all patients with OCD were assessed with the Korean version of the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) for OCD symptoms [21,22], the Korean version of the Beck Depression Inventory-II (BDI) for depressive symptoms [23,24], and the Korean version of the Beck Anxiety Inventory (BAI) for anxiety symptoms [25,26].

After baseline psychological scales and fMRI data were acquired, the offline CBT group had an hour-long individual session per week with a psychiatrist for 6 weeks. The CBT sessions were designed similarly to the traditional 10-session CBTs but shortened to match the online CBT session numbers. Homework was given and checked for each session.

The OCfree CBT group also had an individual psychiatrist assigned to meet the participant each week and oversee the CBT for 6 weeks. The psychiatrist in the OCfree group used the OCfree program to conduct CBT, and each session lasted approximately 40 minutes. The program has a scheduler system that assigns participants different programs within OCfree for their daily use, and the participant can use different parts of the program as many times as they wish. The psychiatrist would check the program each week for compliance.

OCfree Program

The mobile app (OCfree) for obsessive-compulsive disorder treatment consists of three categories: education, quests, and serious games. The education category consisted of 6 sessions: (1) learning about OCD: learn about symptoms, causes, and treatments; (2) analyzing obsessions: trigger factors for obsession and compulsive behaviors, compulsive infiltration, fearful ending; (3) understanding strategies with OCD; (4) customized treatment plan; (5) factors for change: a firm resolution; and (6) explanation of cognitive therapy. The learning time of each education session was 20-30 minutes. The quest category consists of 10 subcategories. Those are paired with each education session and supplied to patients as homework: (1) assessment of obsession and compulsion using 65 questions for obsession and 65 questions for compulsion, (2) analyzing the symptoms of obsession and compulsion with 8 panels, (3) understanding false beliefs related to obsession, (4) creating a customized treatment plan for you, (5) preparing for change by yourself, (6) working book for cognitive therapy and 4 adjuvant categories, (7) practice postponing anxiety, (8) ERP using imagination via voice recording, (9) identifying emotions, and (10) practicing choosing. The game category consists of 7 casual games: (1) shooting game, (2) break block game, (3) germ-removing game, (4) doubting and checking game, (5) symmetry and ordering game, (6) numbering and counting game, and (7) mental ritual game (Figure 1).

The shooting game is similar to the fixed shooter arcade game, Galaga. By controlling a spaceship, the players can destroy aliens while avoiding enemies' projectiles. The spaceship is displaced with the object that OCD patients dislike (want to avoid) such as a needle, knife, death, germ, or airplane. The break block game is a modified version of the classic Breakout block game. The players use the paddle to bounce the ball and destroy the bricks. Behind the brick, there is a "word" that is associated with the obsession. When the bricks are completely destroyed, the "word" disappears. Before starting the block game, the OCD patients type the "word" that is associated with the obsession. In the germ-removing game, players can remove pictorial germs represented on the palm of a hand until only one germ remains. The OCD patient should wait 5 seconds before removing the last one. The number of germs increases when the stage is cleared. In the doubting and checking game, players can touch a pictorial faucet on a screen until the number "1" is represented. Like the germ-removing game, OCD patients should wait 5 seconds before the last touch (Figure 1). The objects of the checking can change in accordance with the patients' obsessions, including a doorknob and gas valve. In the symmetry and ordering game, players can place books on a bookshelf in accordance with size and color. OCD patients should wait 5 seconds before arranging the last one. More books of various sizes and colors are presented after each stage is cleared. In the numbering and counting game, players type a number that they are preoccupied with. This number is the same as the number of eggs on the screen. The players touch the eggs to hatch them until the last egg remains. The OCD patients should wait 5 seconds before touching the last egg to hatch. In the mental ritual game, players type a word that they are preoccupied with. The word then multiplies and spreads on the screen. Of the multiplied words, 10% are modified in a different or wrong spelling (one or two characteristics are different), compared to the original spelling. OCD patients should only touch words written in the original spelling.

Figure 1. OCfree program: (1) learning about OCD: learn about symptoms, causes, and treatments, (2) analyzing obsessions: trigger factors for obsession and compulsive behaviors, compulsive infiltration, fearful ending, (3) understanding strategies with OCD, (4) understanding false beliefs related to obsession, (5) analyzing the symptoms of obsessions and compulsions with 8 panels, (6) creating a customized treatment plan for you, (7) shooting game, (8) break block game, (9) germ-removing game.

Brain Imaging Data Acquisition and Processing

A 3.0 Tesla Philips Achieva scanner was used to acquire Rs-MRIs. Only right-handed participants entered the trial due to reports showing functional and anatomical differences in the brain between right- and left-handedness [27]. A total of 230 volumes for 720 seconds were gathered using the following parameters: repetition time/echo time=3000/40 milliseconds, 40 slices, 64×64 matrix, 90° flip angle, 230-mm field of view, and 3-mm section thickness, without a gap. Using the programs of the Data Processing Assistant for Rs-fMRI [28] and the Rs-fMRI Data Analysis Toolkit (REST) [29], all acquired imaging data were prepared for preprocessing and processing. Brain activity within regions of interest (ROIs) was derived

from the fractional amplitude of low-frequency fluctuations (fALFF), extracted using REST software. Seed-based FC analysis was performed using the seed ROI extracted from the previous step of correlation comparison between Y-BOCS and fALFF. More details of the fMRI data preprocessing and processing were described in our previous study [30].

Statistical Analysis

Demographic and clinical characteristics of the offline and OCfree groups were analyzed using the Mann-Whitney U test. The differences in sex ratio and symptom improvement between the two groups were analyzed using a chi-square test. Symptom improvement was defined as a decrease of 2.85 in 25% of Y-BOCS scores based on a reliable change index of symptoms (standard error of measure=1.03, effect size=0.91) [31]. Statistical significance was set at $P<.05$.

The correlation between the fALFF and Y-BOCS scales was calculated using multiple regression analysis in Statistical Parametric Mapping 12 (SPM12; Wellcome Centre for Human Neuroimaging). The changes in fALFF from baseline to 4 weeks in all patients were estimated using a paired *t* test in SPM12. The differences in the change of fALFF and FC from the thalamus to other brain areas between the offline and OCfree groups were estimated using repeated-measures analysis of variance in SPM12. The ROIs were extracted based on the cluster in the t-map with a defined threshold (uncorrected $P<.001$, voxels>20).

Results

Demographic Characteristics and Clinical Scales

There were no significant differences in age, years of education, Y-BOCS scores, BDI scores, and BAI scores between the offline CBT and OCfree groups at baseline (Table 1).

Table 1. Demographic data and clinical scales.

Characteristic	OCfree group (n=12)	Offline CBT[a] group (n=15)
Age (years), mean (SD)	25.7 (7.7)	24.7 (10.7)
Sex, n		
Male	5	6
Female	7	9
Education (years), mean (SD)	13.3 (1.8)	13.8 (2.1)
Economic status (income)[b], n		
Low	2	3
Middle	7	9
High	3	3
Y-BOCS[c], mean (SD)		
Pretreatment	21.9 (5.7)	19.5 (4.1)
Posttreatment	16.7 (5.4)	15.9 (4.7)
BDI[d], mean (SD)		
Pretreatment	19.3 (4.9)	16.5 (11.2)
Posttreatment	9.3 (5.3)	10.3 (9.5)
BAI[e], mean (SD)		
Pretreatment	19.8 (10.7)	16.2 (11.7)
Posttreatment	9.4 (8.6)	11.0 (9.4)

[a]CBT: cognitive behavior therapy.

[b]Economic status (income): low, <US $20,000/year; middle, US $20,000-40,000/year; high, >US $40,000/year.

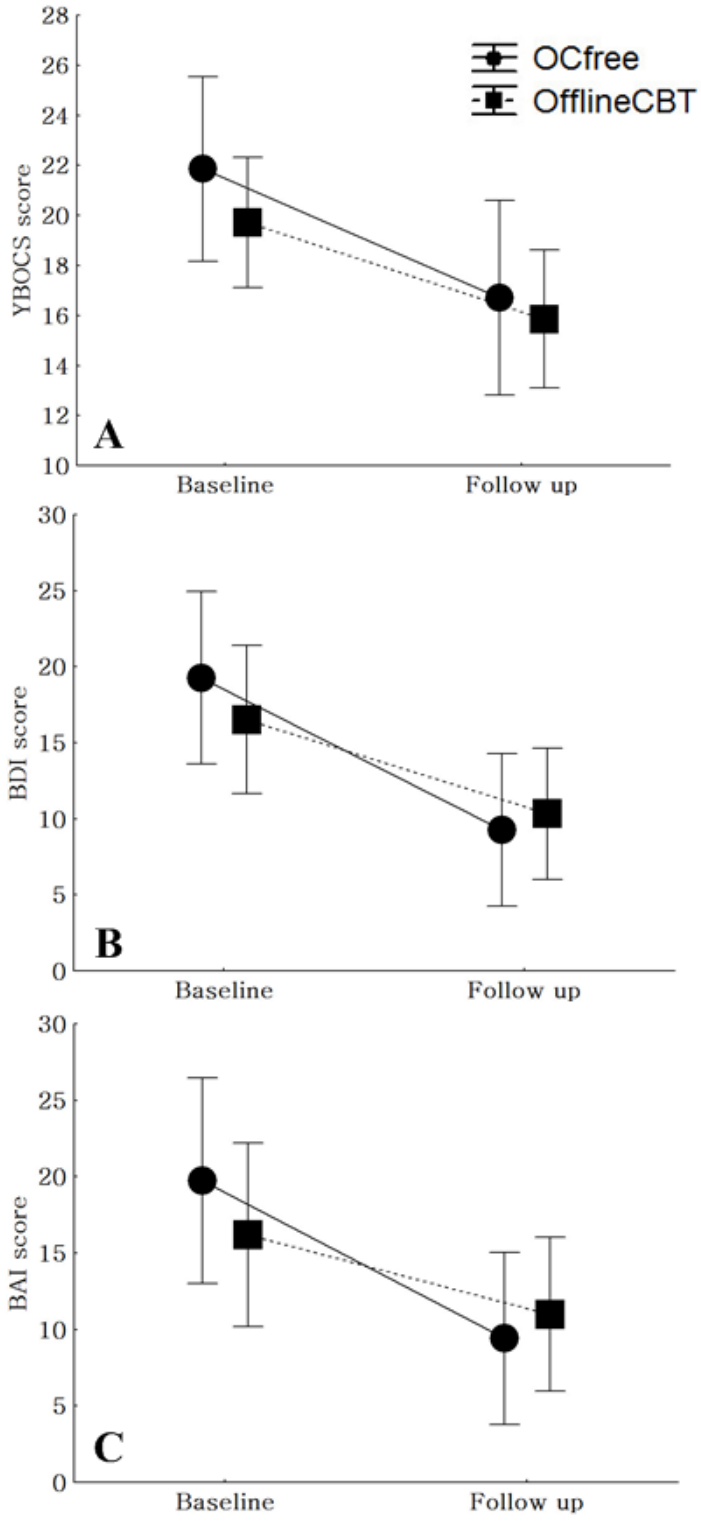
[c]Y-BOCS: Yale-Brown Obsessive Compulsive Scale.

[d]BDI: Beck Depression Inventory.

[e]BAI: Beck Anxiety Inventory.

The number of improved OCD patients in the OCfree group (improvement vs nonimprovement: 8/12, 67% vs 4/12, 33%) was greater than that observed in the offline group (8/15, 53% vs 7/15, 47%), but the difference was not statistically significant ($\chi^2=0.5$; $P=.69$). There were also no significant differences in the change of Y-BOCS scores ($F=0.50$; $P=.48$) and BDI scores ($F=2.16$; $P=.16$) between the two groups. Compared to the offline CBT group, the OCfree group showed greater improvement in BAI scores ($F=5.74$; $P=.02$) (Figure 2).

Figure 2. Comparisons of the changes of (A) Y-BOCS, (B) BDI, and (C) BAI scores between the offline CBT group and OCfree group. BAI: Beck Anxiety Inventory. BDI: Beck Depression Inventory. CBT: cognitive behavior therapy. Y-BOCS: Yale-Brown Obsessive Compulsive Scale.



Results of the Program Usage and Satisfaction Survey

On average, program compliance was 91.4%. The 6 education modules were used 6.0 times each, and the 10 quest modules were used 10.8 times each during the 6 weeks of program usage. The 7 game modules were used, on average, 12.1 times each.

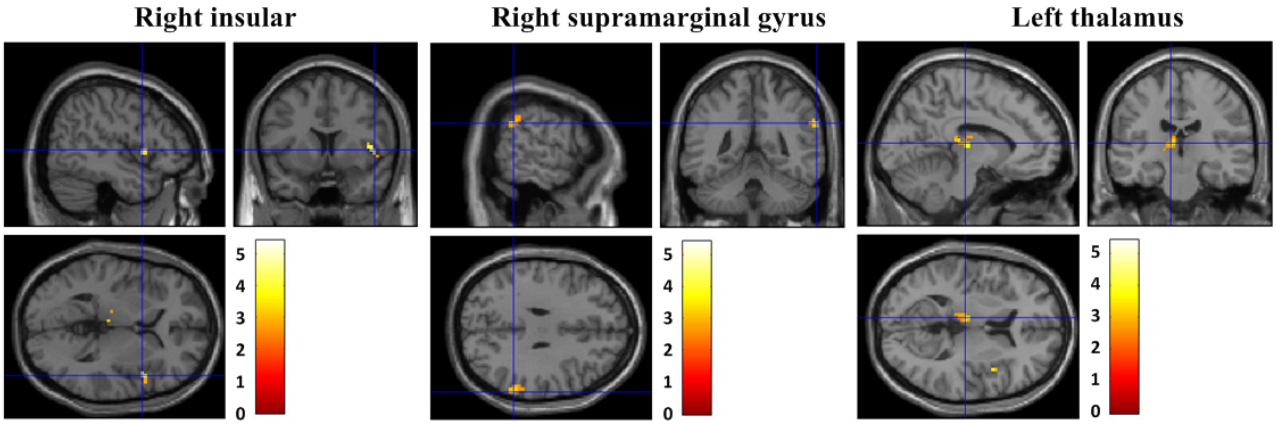
An anonymous survey was taken at the end of the program, and 10 out of 12 participants completed it. The participants were given, among other things, a choice of 1 to 5 stars to measure overall satisfaction, 1 being the lowest and 5 being the highest. The overall satisfaction was 3.4 stars out of 5. The majority of 2- or 3-star ratings were due to minor errors in the program, giving it a somewhat crude feeling. The 4- and 5-star reviews stated that the program helped them get to know their obsessions and compulsions better. Of the 10 completed surveys, 5 (50%) said that they would like to continue using the program even

after the trial, and 7 (70%) wished to recommend it to other people with similar symptoms. There have been no reports of adverse effects of the program. Adverse effects were checked by the psychiatrist conducting the CBT sessions each week and not asked about in the anonymous survey.

Correlation Between the Y-BOCS Scale and Brain Activity (fALFF)

In all patients with OCD, Y-BOCS scale scores were negatively correlated with fALFF within the right insular (Talairach code x, y, z: 48, 9, 3; T=5.41; $P_{uncorrected}$<0.001; k_E=20, Brodmann area [BA] 13), right parietal supramarginal gyrus (x, y, z: 63, −45, 30; T=4.42; $P_{uncorrected}$<0.001; k_E=26, BA 40), and left thalamus (x, y, z: −9, −21, 9; T=4.23; $P_{uncorrected}$<0.001; k_E=29) (Figure 3).

Figure 3. Correlation between the Yale-Brown Obsessive Compulsive Scale and brain activity.

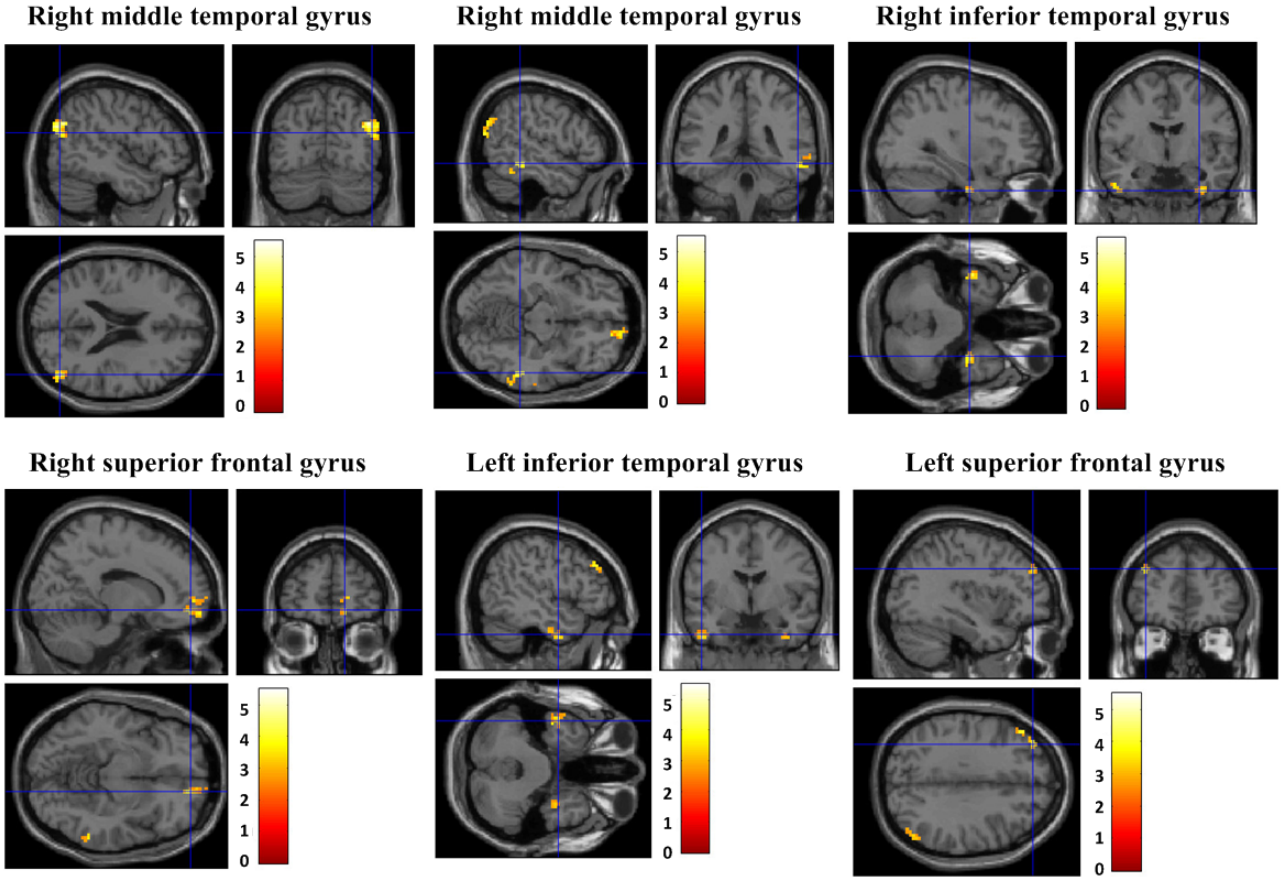


Comparison of the Changes in fALFF Between the OCfree Group and Offline CBT Group

During the intervention period, the fALFF within the right middle temporal gyrus (x, y, z: 48, −72, 21; T=5.50; $P_{uncorrected}$<0.001; k_E=101, BA 39), right middle temporal gyrus (x, y, z: 54, −39, −12; T=4.41; $P_{uncorrected}$<0.001; k_E=73, BA 20), right inferior temporal gyrus (x, y, z: 33, −6, −39; T=4.30; $P_{uncorrected}$<0.001; k_E=216, BA 20), right superior frontal gyrus (x, y, z: 15, 54, −9; T=4.24; $P_{uncorrected}$<0.001; k_E=34, BA 10), left inferior temporal gyrus (x, y, z: −48, −3, −36; T=4.22; $P_{uncorrected}$<0.001; k_E=39, BA 20), and left superior frontal gyrus (x, y, z: −36, 45, 33; T=4.02; $P_{uncorrected}$<0.001; k_E=31, BA 9) had increased in all patients with OCD (Figure 4).

During the intervention period, the OCfree group showed increased fALFF within the right parahippocampal gyrus (x, y, z: 39, −42, −6; T=4.60; $P_{uncorrected}$<0.001; k_E=35, BA 19), compared to the offline CBT group.

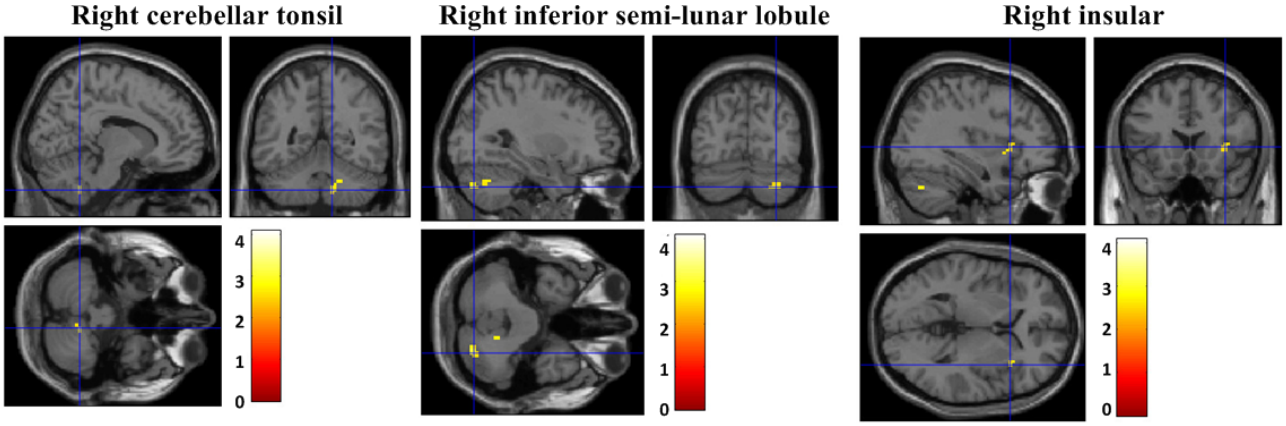
Figure 4. Comparison of the changes in fractional amplitude of low-frequency fluctuations between the OCfree and offline cognitive behavior therapy groups.



Comparison of the Changes in FC Between the OCfree Group and Offline CBT Group

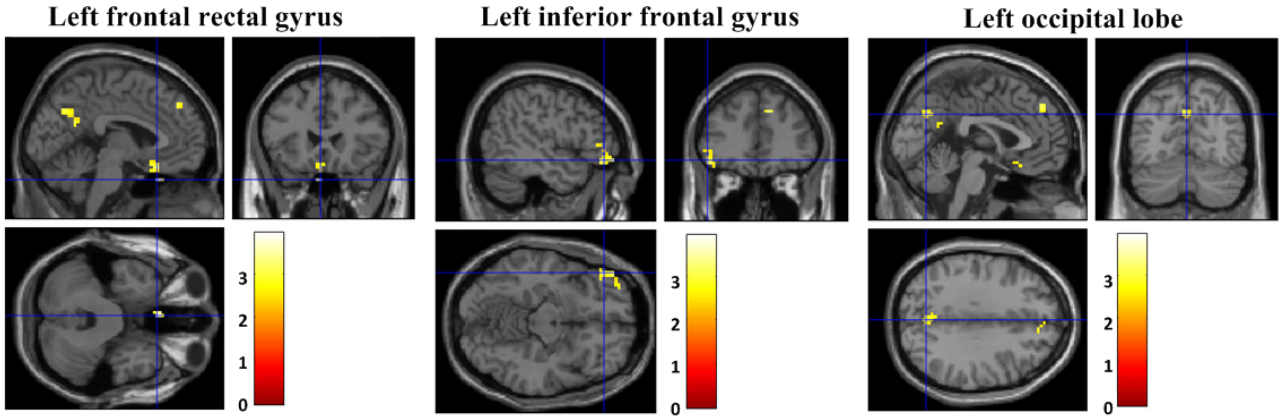
During the intervention period, the FC from the left thalamus to the right cerebellar tonsil (x, y, z: 12, −51, −45; T=3.18; $P_{uncorrected}$<0.001; k_E=24), right cerebellar inferior semilunar lobule (x, y, z: 30, −75, −39; T=3.08; $P_{uncorrected}$<0.001; k_E=26), and right insular (x, y, z: 36, 18, 3; T=3.01; $P_{uncorrected}$<0.001; k_E=21) had increased in all patients with OCD (Figure 5).

Figure 5. The changes in functional connectivity in all the patient groups (OCfree and offline cognitive behavior therapy group).



During the intervention period, the FC from the left thalamus to the left frontal rectal gyrus (x, y, z: −3, 24, −33; T=3.51; $P_{uncorrected}$<0.001; k_E=30), left inferior frontal gyrus (x, y, z: −48, 39, −12; T=3.39; $P_{uncorrected}$<0.001; k_E=53, BA 47), and left occipital lobe (x, y, z: 0, −69, 33; T=3.25; $P_{uncorrected}$<0.001; k_E=39, BA 7) was increased in the offline CBT group (Figure 6).

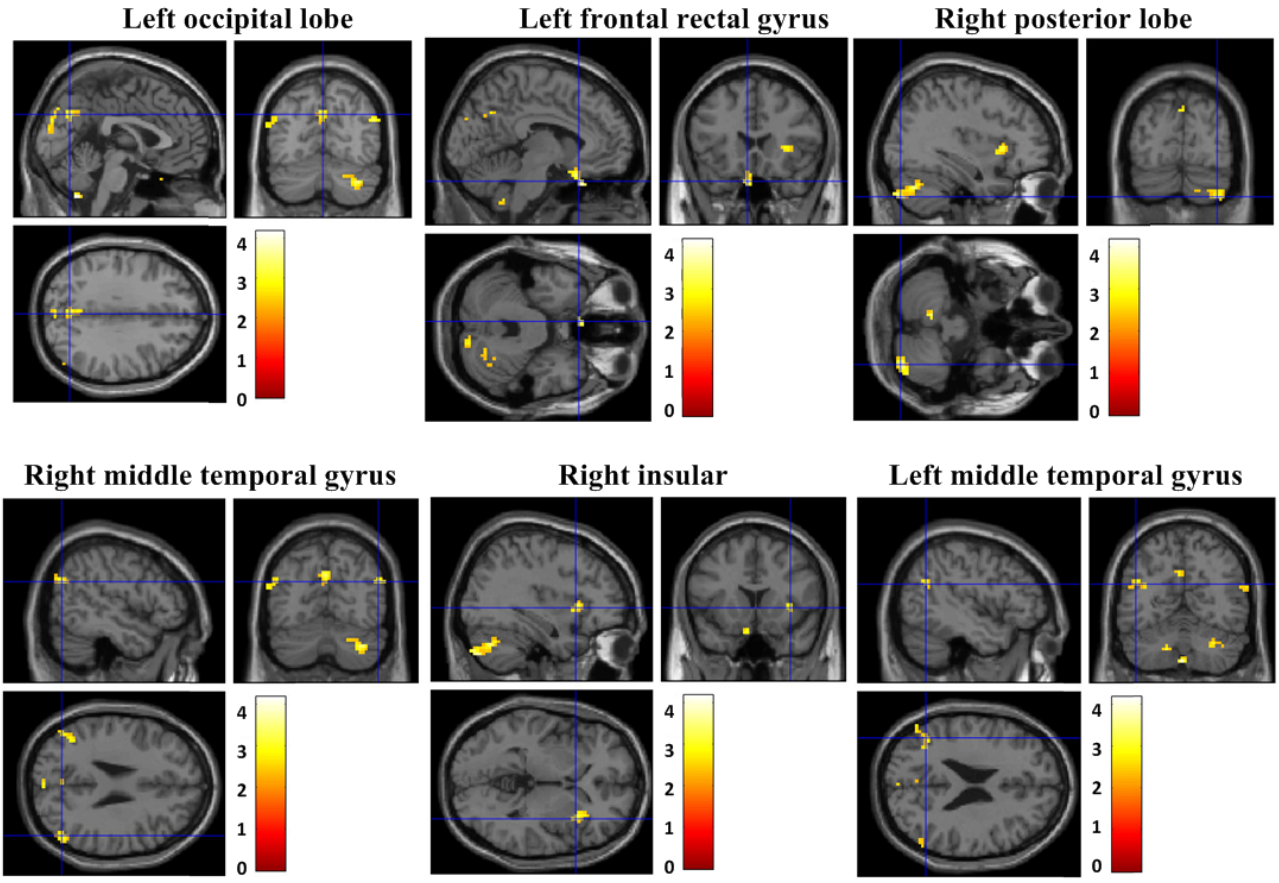
Figure 6. Changes in functional connectivity in the offline cognitive behavior therapy group.



During the intervention period, the FC from the left thalamus to the left occipital lobe (x, y, z: 0, −63, −51; T=4.18; $P_{uncorrected}$<0.001; k_E=47, BA 7), left frontal rectal gyrus (x, y, z: −6, 21, −30; T=3.95; $P_{uncorrected}$<0.001; k_E=30, BA 11), right cerebellar posterior lobe (x, y, z: 36, −81, −45; T=3.71; $P_{uncorrected}$<0.001; k_E=172, BA 47), right middle temporal gyrus (x, y, z: 51, −69, 27; T=3.05; $P_{uncorrected}$<0.001; k_E=35, BA 39), right insular (x, y, z: 36, 15, 0; T=3.02; $P_{uncorrected}$<0.001; k_E=31), and left middle temporal gyrus (x, y, z: −45, −60, 24; T=3.01; $P_{uncorrected}$<0.001; k_E=39, BA 39) had increased in the OCfree group (Figure 7).

During the intervention period, the OCfree group showed an increase in FC from the left thalamus to the left insular (x, y, z: −30, −39, 15; T=3.51; $P_{uncorrected}$<0.001; k_E=34, BA 13), compared to the offline CBT group.

Figure 7. Changes in functional connectivity in the OCfree group.



Discussion

Principal Findings

OCfree, an OCD treatment app program, was as effective at improving OCD symptoms as offline CBT for OCD. The severity of OCD assessed with the Y-BOCS scale in all patients was negatively associated with brain activity within the emotion perception network, including the thalamus and insular. Both offline CBT and OCfree CBT improved OCD symptoms and increased FC within the CSTC tract in all patients with OCD.

However, CBT using OCfree showed greater changes in fALFF within the thalamus and insular, compared to offline CBT.

The Effectiveness of OCfree, an OCD Treatment Program, on the Improvement of OCD Symptoms

The OCfree program was as effective as offline CBT for the improvement of OCD symptoms in OCD patients. Overall compliance with OCfree was 91.4% and overall satisfaction was rated 3.4 out of 5 stars. The internet delivery CBT system for OCD has already been reported to be as effective as offline CBT [12]. In our previous study, an ERP-inspired serious game for OCD improved symptoms in OCD patients [19]. Moreover, OCfree greatly improved anxiety compared to offline CBT. We believe that the OCfree web-based delivery system, including education and quests, may enable easy patient access to the treatment system, and serious games in OCfree may increase interest in treatment, as immersion is thought to be one of the merits of serious games. Easy access and frequent contact with patients in OCD management decrease patient anxiety [32-34]. In mood disorders, internet-assisted cognitive behavioral therapy is becoming an evidence-based cognitive treatment [35]. Serious game−assisted clinical treatments already suggest that serious games can increase affinity and treatment compliance in many areas, including cancer [36], obesity [37], and autism spectrum disorders [38].

Comparison of the Changes in fALFF Between the OCfree and Offline CBT Group

Comparisons before and after the treatment period in this study showed increased brain activity within the frontal and temporal lobes in all OCD patient groups. Compared to the offline CBT group, the OCfree group showed increased brain activity within the right parahippocampal gyrus. A deficit in emotional perception was reported in patients with OCD [39]. Due to this deficit, repetitive meaningless thoughts occurred in patients with OCD [39]. In several fMRI studies of OCD patients, decreased brain activity within the frontal and temporal lobes has been reported [40,41]. Chen et al reported that patients with OCD showed decreased brain activity within the left medial prefrontal cortex, compared to healthy subjects [42]. In patients with obsessive and compulsive symptoms due to temporal lobe infarction, SSRI treatment would improve the obsessive and compulsive symptoms [43]. The parahippocampal gyrus is known to play a crucial role in the perception of emotion [44]. Within the retrosplenial and posterior cingulate gyri, the parahippocampal gyrus is thought to play a crucial role in facial expression recognition [44]. Taken together, we believe that the OCfree program would improve OCD symptoms in patients with OCD. Moreover, the improvement may be due to the increased brain activity within the brain regions associated with emotional perception.

Comparison of the Changes in FC Between the OCfree and Offline CBT Group

The brain's FC within the CSTC tract was increased in all patient groups. In several studies, altered (disconnected) brain FC within the CSTC tract in OCD patients has already been reported [6,45]. Based on these results, we suggest that both OCfree and offline CBT may present similar treatment mechanisms of increased FC within the CSTC tract.

Interestingly, compared to the offline CBT group, the OCfree group showed increased brain FC from the thalamus and insular. This result may be associated with various and multiple sources of sensory stimulation via education, quests, and games during play. The thalamus is thought to act as a hub that receives sensory signals from every sensory system and sends them to the associated cortex [46]. The insular functions are associated with sensorimotor processing, socioemotional processing, and cognitive functions [47]. Decreased brain activity within the thalamus [48] and insular [49] have been reported in patients with OCD. Considered together, OCfree with various stimulation systems may increase the thalamus and insular activity, compared to offline CBT. Although there was no difference in the efficacy of treatment between OCfree and offline CBT, future studies with a larger number of subjects may show greater efficacy in symptom improvement with OCfree, compared to offline CBT.

Limitations

There were several limitations to this study. First, the small sample size and short-term intervention period were not sufficient for generalizing the results. Second, due to the exclusion criteria for medication use, OCD patients with severe anxiety symptoms were excluded from this study. These exceptions can affect the results of the anxiety comparison between the two groups. In addition, although we could not find any individual with co-occurrence of OCD and claustrophobia, lifetime comorbidity between OCD and specific phobias has been reported to be 22% [50]. Data from a Mexican mental health survey showed that 24.8% of adolescents with a specific phobia were afraid of closed spaces [51]. For the results of this OCD brain study, OCD patients who experience anxiety in closed spaces were excluded. For this reason, readers should be cautious about generalizing current results. Finally, this study did not recruit a true control group without any formal structured CBT due to ethical limitations. Future studies should recruit a larger number of participants and consider comorbid conditions, including anxiety and mood fluctuations, with a truer control group.

Conclusions

OCfree, an OCD treatment program, was effective in the treatment of drug-naïve patients with OCD. The treatment effects of OCfree are associated with increased brain connectivity within the CSTC tract. Multisensory stimulation by education, quests, and games in OCfree increased activity within the thalamus and insular regions in patients with OCD.

Conflicts of Interest

None declared.

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Abbreviations

BA: Brodmann area
BAI: Beck Anxiety Inventory
BDI: Beck Depression Inventory
CBT: cognitive behavior therapy
CSTC: cortico-striato-thalamo-cortical
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
ERP: exposure and response prevention
fALFF: fractional amplitude of low-frequency fluctuations
OCD: obsessive-compulsive disorder
REST: Resting-state functional magnetic resonance imaging Data Analysis Toolkit
ROI: region of interest
Rs-fMRI: resting-state functional magnetic resonance imaging
SPM12: Statistical Parametric Mapping 12
SSRI: selective serotonin reuptake inhibitor
Y-BOCS: Yale-Brown Obsessive Compulsive Scale

Edited by J Torous; submitted 06.09.20; peer-reviewed by M Choy, C Wilks; comments to author 19.10.20; revised version received 19.11.20; accepted 20.11.20; published 19.01.21.

Please cite as:
Hwang H, Bae S, Hong JS, Han DH
Comparing Effectiveness Between a Mobile App Program and Traditional Cognitive Behavior Therapy in Obsessive-Compulsive Disorder: Evaluation Study
JMIR Ment Health 2021;8(1):e23778
URL: http://mental.jmir.org/2021/1/e23778/
doi:10.2196/23778
PMID:33464208

Original Paper

Examining the Relationship Between the Use of a Mobile Peer-Support App and Self-Injury Outcomes: Longitudinal Mixed Methods Study

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Abstract

Background: Many individuals who self-injure seek support and information through online communities and mobile peer-support apps. Although researchers have identified risks and benefits of participation, empirical work linking participation in these web-based spaces to self-injury behaviors and thoughts is limited.

Objective: This study aims to investigate the relationship between behavioral and linguistic traces on a mobile peer support app and self-injury outcomes.

Methods: Natural use data and web-based surveys (N=697) assessing self-injury outcomes were collected from 268 users (aged 13-38 years; median 19; 149/268, 55.6% female) of a mobile peer-support app for 4 months. Participants were identified as having posted self-injury content using an internal classifier. Natural log data was used to predict self-injury outcomes in a series of multilevel logistic and linear regressions.

Results: Greater engagement on a mobile peer-support app was associated with a decreased likelihood of self-injury thoughts (odds ratio [OR] 0.25, 95% CI 0.09-0.73) and fewer intentions to self-injure (b=−0.37, SE 0.09), whereas posting triggering content was associated with an increased likelihood of engaging in behaviors (OR 5.37, 95% CI 1.25-23.05) and having self-injury thoughts (OR 17.87, 95% CI 1.64-194.15). Moreover, viewing triggering content was related to both a greater ability to resist (b=1.39, SE 0.66) and a greater intention to self-injure (b=1.50, SE 0.06).

Conclusions: To our knowledge, this is the first study to connect naturally occurring log data to survey data assessing self-injury outcomes over time. This work provides empirical support for the relationship between participation in online forums and self-injury outcomes, and it articulates mechanisms contributing to this relationship.

(JMIR Ment Health 2021;8(1):e21854) doi:10.2196/21854

KEYWORDS

self-injury; mobile apps; peer support; mHealth

Introduction

Background

Self-injury—the deliberate, self-inflicted damage of body tissue [1]—is a common and concerning behavior estimated to affect between 17% and 37% of adolescents [2,3]. Part of a larger spectrum of self-harming behavior, nonsuicidal self-injury (NSSI) does not include suicidal intent but is often comorbid with other mental health challenges, besides being a leading risk factor for future suicidal thoughts and behaviors [4,5]. For a variety of reasons, including stigma and a lack of readiness to change, many individuals who self-injure do not disclose their behavior to anyone, impeding potential for intervention.

Despite hesitancy to disclose self-injury offline, individuals discuss their experiences with self-injury relatively openly on the web [6-9]. Prior work has identified a number of benefits and risks of using online forums to seek self-injury-related support or information [7-10]. Implicit in this line of research is the assumption that web-based venues can meaningfully impact self-injury thoughts and behaviors. However, to date, only a few empirical studies have examined the effects of participation in online communities on self-injury outcomes [11,12], and the bulk of this literature has been descriptive, cross-sectional, and focused on relatively small samples.

Mobile apps are an increasingly common way for individuals to access self-injury communities and resources, and these technologies can be used to deliver interventions [13-16]. Several apps show promise in reducing self-injury behaviors [14,15]. However, by and large, the efficacy of most mobile apps for mental health is untested [17]. Advances in computational techniques enable researchers to track patterns of behavior on the web to predict mental health status and future risk [18,19], but such methods have not yet been robustly applied to understand contexts that contribute to and predict self-injury behaviors.

This work employs a mixed methods approach to address the gap in knowledge on the relationship between web-based self-injury support activity and self-injury outcomes. Specifically, we combine computational and survey methods to investigate the relationship between language and behaviors on a mobile peer support app, on the one hand, and self-injury behaviors, thoughts, intentions to self-injure, and ability to resist self-injury urges over time, on the other hand. This work provides empirical support for the relationship between participation in online forums and self-injury outcomes and articulates mechanisms contributing to this relationship.

Functions of Self-Injury

Self-injurious behaviors can serve a variety of intrapersonal and interpersonal functions [20,21]. Self-injury is most often enacted to regulate emotions, and this function is evidenced in affect modulation following self-injury episodes through laboratory and ecological momentary assessment (EMA) studies [20]. In contrast, interpersonal functions include signaling relational distress, soliciting social support, or escaping undesired interpersonal situations [22].

A functional understanding of self-injury is useful when interrogating the relationship between web-based activity and self-injury because it provides guidance on factors temporally associated with the behavior. Interpersonal functions are of particular interest because social and relational factors are likely salient in web-based spaces where people provide and receive peer support [23] and may play a role in the initiation, maintenance, and cessation of self-injury for adolescents. Relational factors (eg, the volume of support exchanged, group affiliation) also merit further attention as they could provide insights into participatory risks (eg, normalization) [10,12,24,25].

Potential Risks and Benefits of Web-Based Activity

The potential benefits of online peer-to-peer support networks for individuals with mental health conditions include receipt of social support, validation, an increased sense of belonging [6,26], and the ability to narrate, and reflect on personal experiences (eg, share experiences for personal clarity) [6]. Web-based venues may also provide a useful distraction to assuage self-injury urges [27] and facilitate the receipt of *just in time* support [28].

Other studies substantiate a growing concern over the potential for adverse effects. Risks of exchanging online support for self-injury include reinforcement of the behavior, excessive focus on emotional suffering and rumination, and exposure to triggering content [10,28,29]. Research has shown that participation in online communities can result in the normalization of self-injury and an overreliance on the community for support [30]. Individuals may also feel the need to maintain an *injury identity* [31] where the behavior is seen as critical for community membership and enacted to validate the severity of individuals' experiences [27,32,33].

There is also concern that exchanges in online communities may downplay the serious consequences of the behavior [28] and discourage professional help, either explicitly or implicitly, through sharing past negative experiences [30,34]. A risk that has received much attention recently is exposure to graphic and triggering content. Some members of online self-injury communities report that graphic content curbs the urge to injure because it presents them with severe cases and can dissuade them from future self-injury acts [9,33]. However, others describe seeking out content in online forums to trigger self-injury urges [7,25,35].

Regarding how participation in online communities modulates self-injury behavior, the evidence is mixed. Murray and Fox [35] found that just over 40% of 79 respondents reported that participation in a web-based discussion group reduced their self-injurious behavior, whereas 11% reported that it initiated behavior. Harris and Roberts [7] found a similar split in evidence. Other studies have shown that greater self-injury content exposure is associated with greater self-injury engagement [36]. Internet addiction [37,38] and cyberbullying [39] have also been associated with self-injurious behaviors. The largely cross-sectional nature of the relationships studied makes discerning temporal sequencing difficult.

Characteristics and Contexts Likely to Influence Self-Injury Outcomes

When thinking about characteristics and contexts associated with self-injury outcomes, 2 additional lines of work can be informative: (1) diary and EMA studies and (2) computational mental health research.

Diary and EMA Studies

A recent review of self-injury EMA studies identified emotional, cognitive, and social contexts associated with NSSI, motives that lead to NSSI, and mechanisms that influence or predict NSSI [40]. Several studies have found that self-injurious behaviors are flanked by changes in affect, which can be

apparent up to 15 hours before NSSI acts [41,42]. In general, negative affect often precedes self-injury [42-44], whereas increases in positive affect and decreases in negative affect follow [44,45]. Furthermore, NSSI thoughts have been linked to sadness and anxiety [46,47], whereas NSSI behaviors have been associated with rejection and anger [46,48]. Affective instability (sometimes referred to as affective lability)—the tendency to experience emotions in a dynamic manner with extreme shifts in emotion lasting up to a few days—adds another emotion-linked dimension to self-injury risk, with research showing that compared with individuals with no self-injury history, individuals who self-injure experience more affective instability [49,50]. Frequent shifts in emotional intensity and valence have been associated with more NSSI episodes [49].

Cognitive states and patterns are also empirically associated with self-injury [51]. For example, rumination and fluctuations in the intensity of ruminative thinking (known as rumination instability) are theorized to play a key role in NSSI [52,53]. Selby et al [54] found that rumination instability and fluctuations in negative affect, especially sadness, interacted to predict daily reports of NSSI in a 2-week EMA study. Similarly, Hughes et al [43] found that repetitive negative thinking and negative affect predicted NSSI thoughts and behaviors and amplified the effects of anxiety and overwhelm.

Finally, contextual factors, such as interpersonal conflict and feelings of rejection, are powerful predictors of same-day self-injury thoughts and behaviors. Interestingly, a study found that although the act of revealing NSSI to others is associated with greater perceived social support, perceiving support increases the likelihood of self-injury on the following day [55]. Therefore, interpersonal reinforcement is a risk factor for self-injury behaviors.

Although EMA studies provide insights into the complex temporal interplay between context, cognition, emotion, and behavior, by accessing data *in real time*, these methods often rely on self-reports, limited by participant awareness, and may not be apparent, or readily accessible, for individuals struggling with emotion regulation [41]. Methods that leverage modern computational and algorithmic capabilities can help produce a robust understanding of the complex sequencing and interplay between emotion, cognition, and behavior by analyzing log data in online communities.

Computational Mental Health Research

Previous studies have shown that behavioral patterns and linguistic features of posts in web-based communities can distinguish between people with and without a number of conditions [56-58] and can be used to infer risk [59,60]. Much of these studies have combined behavioral measures such as posting frequency, with linguistic features such as language use or themes embedded in published content. In several studies, individuals with depression showed greater negative emotion, higher self-attentional focus, and increased relational and medicinal concerns in posts than those without known depression [56]. Behaviorally, depressed members showed less engagement, social activity, and reduced reciprocity [57]. Suicidal ideation has also been associated with self-attentional focus and reduced social engagement and expressions of hopelessness, anxiety, impulsiveness, and loneliness [18]. Temporal patterns can also be discerned using this methodology. For example, research has found an increase in posting activity before a suicidal attempt, along with increases in anger and sadness in the posts. Conversely, declines in activity, anger, and sadness follow suicide attempts, at which point attempters' levels of activity and emotions mirror those of nonattempting peers [59]. In summary, the computational techniques employed in these studies have provided impressive predictive accuracy [61] and may be useful in disentangling the complex interplay of thought, emotion, and behavior that leads to self-injury.

Objectives

This study aims to leverage the strengths of the methodologies mentioned above—rich, naturally occurring web-based data and self-report survey data over 12 weeks—to explore how self-injury behaviors and thoughts are related to activity and language use of self-injurious users on the TalkLife platform, a free mobile app designed for young people with a variety of mental health concerns. The platform uses a crowdsourced peer-support model to provide users with affordable and timely support. Self-injury outcomes are modeled (eg, behavior, thoughts, intentions, ability to resist) as a function of web engagement and language manifested in content. We explore 2 dominant questions: What behavioral (research question [RQ] 1) and language (RQ2) patterns are associated with self-injury behaviors, self-injury thoughts, intentions to self-injure, and ability to resist self-injury? These 2 questions are further broken down into the following subquestions:

- *RQ1a*: What is the relationship between *activity level* on TalkLife in the preceding week and self-injury outcomes (behavior, thoughts, intentions, ability to resist, and frequency) in the subsequent reporting period?
- *RQ1b*:What is the relationship between *viewing triggering content* on TalkLife in the preceding week and self-injury outcomes (behavior, thoughts, intentions, ability to resist, and frequency)?
- *RQ1c*: What is the relationship between *posting triggering content* on TalkLife in the preceding week and self-injury outcomes (behavior, thoughts, intentions, ability to resist, and frequency)?

Next, we examine language that may be predictive of self-injury outcomes. On the basis of interpersonal models of self-injury [62,63], we probe the association between community involvement and themes of family and friends and self-injury outcomes. As a proxy for identification with the community, we assess affiliative language as in previous work [64].

- *RQ2a*: What is the relationship between using an *affiliative language* in the preceding week and self-injury outcomes (behavior, thoughts, intentions, ability to resist, and frequency)?
- *RQ2b*: What is the relationship between *mentions of family and friends* in the preceding week and self-injury outcomes (behavior, thoughts, intentions, ability to resist, and frequency)?

- *RQ2c*:What is the relationship between *specific emotional states* (eg, positive and negative emotions, rumination) in the preceding week and self-injury outcomes (behavior, thoughts, intentions, ability to resist, and frequency)?

Methods

To understand how the mobile app's use is related to self-injury outcomes, we employed a mixed-methods approach utilizing surveys and naturally occurring log data over 4 months; 3 types of data are included in the analyses: (1) responses to surveys, (2) behaviors on the platform, and (3) language use in posts and comments. A description of data acquisition, relevant measures, and treatment of these measures follows.

Survey Data

Surveys were issued on a rolling basis for 12 weeks. The first and last surveys were administered on October 25, 2018, and January 17, 2019. Survey administration was triggered internally by a classifier identifying suspected self-injury content. Once participants' posts were flagged, they received a prompt to answer surveys once a week for the duration of the study period. Due to this method, the total duration of the study for any given participant varied. Participants could opt out of weekly surveys at any point.

The final data set was constrained to participants who had completed at least two surveys and corresponding behavioral and language data were extracted based on this criterion. Participants who did not complete basic demographics or who did not complete at least one self-injury outcome variable in a survey were removed from the sample. The number of surveys participants completed varied (mean 2, SD 1.20; range 1-10 surveys), as did the time between surveys (mean 1.74, SD 2.15 weeks; range 1-11.6 weeks). The total number of participants included in the final analyses was 268 with 697 survey observations. Our institutional review board approved all study procedures and data security measures.

Surveys included 9 items that were administered weekly with a question to address the (1) presence of self-injury behaviors, (2) frequency of self-injury behaviors, (3) presence of self-injury thoughts, (4) intensity of self-injury intentions, and (5) ability to resist. Additionally, there were items for past experience with therapy, age of first self-injury, and demographics, including age (how old are you?), race (what is your race?), and gender (what is your gender?).

Self-injury items (1-5 above) were treated as dependent variables and demographics (age, race, and gender) were included as covariates in all models. Response categories for self-injury behavior and thoughts were binary: *Yes* or *No*. The ability to resist urges and intentions to injure were both answered on a 5-point scale ranging from 0 (not at all strong) to 4 (very strong) and treated as continuous variables. The frequency of self-injury behaviors required participants to enter a number; 4 participants reported engaging in self-injury at highly improbable rates (>500 times). To correct for these outliers, we reduced these values to 100. Thus, the final self-injury frequency variable ranged from 0 to 100.

Behavioral Data

Deidentified behavioral data for participants meeting the above criterion (2 or more surveys) were sourced with license and consent from the TalkLife platform. This included metadata and original posts and comments. Given that weekly surveys referred to self-injury activity in the previous week, behavioral data at 1 week before each weekly survey were extracted as the primary data for prediction. In addition to controlling for demographics, we controlled for differences in time (relative to survey number) in all analyses because of the survey administration's rolling basis.

We focus on several measures in analysis: (1) activity level (operationalized as averages of posts, gifts, reactions, comments, likes, and users followed in the previous week), (2) posting triggering content (operationalized as the number of posts a user published with trigger warnings), and (3) viewing triggering content (operationalized as the number of times a user dismissed trigger warnings when looking at others' posts). All of these variables were averaged at the day level and log-transformed to restore normality because of their high positive skew.

Given that variance in behavior has proven to be a meaningful independent predictor of mental health in previous work [56], 2 measures that capture fluctuations in activity were also included: variance and rate of change. The variance was computed at the day level for all behavioral measures in the week before a given survey. This measure was computed as σ^2, where the mean activity level in a given week (μ) was subtracted from the activity on a given day (χ) for all days of the week, this was squared, summed (Σ), and divided by 7 (N).

This variance measure provides a sense of how an individual's log data (eg, activity, publishing, and viewing triggering content) is distributed over the week. A high variance score is a proxy for instability or more change in activity over the course of the week (eg, users are very active one day, have no activity the next, and then are moderately active). Next, we computed a *change* score to capture the magnitude of change between proximal behavior (behavior in the week before the survey) and more distal behavior (the remaining time between surveys). This measure was adapted from previous work and is sometimes called the *rate of change* [56]. To account for differences in the amount of time in the remaining period, we averaged to the day level, that is, change (Δ) was equal to the mean activity in a week before a survey (A)—the mean activity in the remaining period (B). A positive change score indicates that there was more activity on a daily basis in the week before the survey, whereas a negative difference indicates more activity in the distal period.

$$\Delta = A - B$$

This change variable was entered into the models as continuous, including negative and positive values. Thus, the interpretation of this variable should be as a *rate of change* or the magnitude of difference between the 2 periods. A large value indicates a large difference between activity in the week before a survey,

relative to the time before, whereas a small value signals relatively similar activity in these 2 periods.

The final variables for the behavioral data include: (1) activity, (2) trigger posts, (3) trigger dismiss, (5) variance (×3), and (6) change between proximal and distal activity (3).

Language Data

All posts and comments made by participants within the study period were preprocessed and run through the Linguistic Inquiry and Word Count (LIWC) program, a psycholinguistic text analysis tool that is frequently employed in research on mental health [65].

Relevant dimensions were identified from the initial literature review, including: (1) affect (eg, positive emotion and specific negative emotions [sadness and anger]), (2) social or relational (eg, mentions of family or friends), (3) affiliative language (eg, affiliation and *we* pronouns based on [64,66]), (4) self-focus (eg, *I* language), (4) rumination (a composite score of negative emotion and focus on the past), and (5) efficacy (a composite score of focus present, future, and certain language as in a study by Bliuc et al [64]).

As with the behavioral data, variability and change were computed for select language dimensions based on previous research. On the basis of the emotional cascade model [54] and empirical findings on the role of instability of rumination and negative affect before self-injury episodes [52,53], we include variance and change for rumination, positive emotion, sadness, and anger.

Sample Characteristics

Descriptive statistics for the survey data are provided in Table 1. The sample consisted of 268 participants who were mostly female (149/268, 55.6%), White (164/268, 61.2%), and were around the age of 19 years (median 19; range 13-38). Over 40% of participants reported having received therapy at some point during the study period (113/268, 42.2%), and the median age at first self-injury was 14 years (range 5-37). On average, participants were registered on TalkLife for about 10 months (SD 12.8) and had posted a median number of 49 posts (mean 147.66, SD 309.72) and 360 comments (mean 1775.28, SD 4092.56).

Table 1. Participant characteristics (n=268).

Characteristic	Value, n (%)
Gender	
Male	83 (30.9)
Female	149 (55.6)
Transgender or nonbinary[a]	36 (13.4)
Race	
White	164 (61.2)
Black	13 (4.9)
Asian	43 (16.0)
Other[b]	47 (17.5)

[a]The response options of transgender male-to-female (n=2), transgender female-to-male (n=8), do not identify as male or female (n=12), and not sure (n=14) were combined because of small cell sizes.

[b]The response options of American Indian or Alaskan Native (n=6), Native Hawaiian or other Pacific Islander (n=3), and other (n=38) were combined because of small cell sizes.

During the 4 months of this study, 48.5% (130/268) of participants reported self-injury behaviors, and 84.7% (227/268) reported having self-injury thoughts. Of those who reported injuring, the median weekly frequency was 3 times. Overall, 79.5% (213/268) of participants reported having thoughts of self-injury without engaging in self-injury behavior, whereas only 2.6% (7/268) of participants reported self-injury behaviors without also reporting self-injury thoughts.

Data Analysis Plan

Before analysis, diagnostic tests were run to determine appropriate modeling and the need for further data transformation. As mentioned above, highly skewed predictor variables (activity, trigger posts, and trigger views) were corrected through log-transformation. Self-injury frequency was the only response variable to be abnormally distributed and was thus also log transformed. Multicollinearity was assessed for all variables in relation to each dependent variable, using the R package mctest. The highest variance inflation factor (VIF) factor was consistently reported for rumination (8.92-9.58), followed by self-referent language (4.22-5.18). The mean VIF for each outcome was acceptable (self-injury behavior, 3.48; self-injury thoughts, 3.43; intentions to injure, 3.32; ability to resist, 3.33; and self-injury frequency, 3.37). As multicollinearity was not detected, we proceeded with analyses without excluding any variables at the outset.

The relationship between TalkLife activity and self-injury outcomes was analyzed using multilevel analysis to account for the data's nested structure. Survey responses, log data, and language data were nested at the participant's level; therefore, we included random effect of participant in all analyses. A total of 5 models were run to predict (1) self-injury behavior, (2) self-injury thoughts, (3) ability to resist the urge to injure, (4)

intentions to injure, and (5) behavioral frequency. Logistic regressions predicting behavior and thoughts were analyzed using the R lme4 package, and linear models predicting the ability to resist, intentions, and frequency were analyzed with the nlme package. All models were adjusted for demographics (age, gender, and race) and time points.

Given this work's exploratory nature, we began with full models including the 31 variables described above (4 control variables, 3 log variables, 10 language variables, 8 variance measures, and 8 change scores). These full models were subsequently reduced via backward variable selection. The logged coefficients were exponentiated for easier interpretation for the binary dependent variables (behaviors and thoughts). We report the significant results in the following section.

Results

Self-Injury Behavior

In terms of behaviors on the web, the odds of engaging in self-injury behavior increased with the number of triggering posts published in the week before the survey. For every additional unit increase in the log of triggering posts, the odds of engaging in self-injury behavior increased nearly five-fold (OR 5.37, 95% CI 1.25-23.05; *P*=.02). In addition, as the rate of change for viewing triggering content increased (ie, viewing more triggering content in the week before the survey compared with the distal period), the odds of self-reported self-injury behavior decreased (OR 0.81, 95% CI 0.68-0.98; *P*=.03). In other words, for every 1-unit increase in change between the number of times individuals viewed triggering content in the week of a survey, the likelihood of self-injury behavior decreased by roughly 20% relative to the period before. No significant relationships were found between self-injury behavior and language dimensions (Table 2).

Table 2. Self-injury behavior.

Self-injury behavior	B	SE	OR[a] (95% CI)
Intercept	−0.07	0.64	0.93 (0.27-3.29)
Behaviors on the web			
Trigger posts	1.68[b]	0.74	5.37 (1.25-23.05)
Change			
Trigger views	−0.20[b]	0.10	0.81 (0.68-0.98)

[a]OR: odds ratio.

[b]The model was adjusted for demographics (age, gender, and race) and time point. Age and race were significant at *P*=.01.

Self-Injury Thoughts

For behaviors on the web, activity level emerged as a significant predictor of self-injury thoughts. Greater active use of the platform (as indicated by posts, comments, and likes) was associated with lower odds of reporting self-injury thoughts (OR 0.64, 95% CI 0.45-0.90; *P*=.01). For every 1-unit increase in the log of activity, the odds of self-injury decreased by 36%. In contrast, the number of trigger posts published was positively related to self-injury thoughts—for every additional log unit increase in triggering posts, the odds of self-injury thoughts increased by a factor of 17.87 (95% CI 1.64-194.15; *P*=.02). The rate of change of posting triggering content also predicted self-injury thoughts; as this change decreased (ie, less activity in the week before the survey relative to the distal period), the odds of having self-injury thoughts increased (OR 0.29, 95% CI 0.10-0.86; *P*=.02). In terms of language, greater variation in ruminative language was associated with greater odds of self-injury thoughts (OR 1.15, 95% CI 1.02-1.29; *P*=.02); see Table 3 for additional details.

Table 3. Self-injury thoughts.

Self-injury thoughts	B	SE	OR (95% CI)
Intercept	1.78[a]	0.67	5.91 (1.59, 21.97)
Web-based behaviors			
Activity	−0.45[a]	0.18	0.64 (0.45-0.90)
Trigger posts	2.88[a]	1.22	17.87 (1.64-194.15)
Change			
Trigger posts	−1.22[a]	0.55	0.29 (0.10-0.86)
Variance			
Rumination	0.14[a]	0.06	1.15 (1.02-1.29)

[a]The model was adjusted for demographics (age, gender, and race) and time point. Race was significant at P=.01.

Ability to Resist Self-Injury

For behaviors on the web, the number of trigger warnings dismissed was positively related to the ability to resist (b=1.39, SE 0.66; P=.03), that is, for every additional log unit increase in viewing trigger posts, the ability to resist self-injury also increased.

Several language dimensions also emerged as significant. In particular, the use of self-referent language (*I*) was negatively associated with the ability to resist (b=−0.07, SE 0.03; P=.01), whereas the use of *efficacy* language was positively associated with the ability to resist injuring (b=0.14, SE 0.06; P=.01). In addition, as the change score for positive emotional language increased (ie, more use of positive emotional language in the week before a survey relative to the distal period), the ability to resist also increased (b=.05, SE 0.02; P=.04). This means that the greater the magnitude of difference between positive language used in the week before a survey, relative to the period before, the more participants reported being able to resist urges. The variance in dismissing trigger warnings was negatively associated with the ability to resist such that lower variance (or more stability) across days in the week before a given survey was associated with greater ability to resist (b=−0.18, SE 0.08; P=.02). In contrast, greater variance in anger expression was associated with a greater ability to resist urges to self-injury (b=0.19, SE 0.09; P=.03); see Table 4 for additional details.

Table 4. Ability to resist self-injury.

Ability to resist self-injury	B	SE
Intercept	2.10[a]	0.24
Web-based behaviors		
Trigger views	1.39[a]	0.66
Language		
I[b]	−0.07[a]	0.03
Efficacy	0.14a	0.06
Change		
Positive emo	0.05[a]	0.02
Variance		
Trigger dismiss	−0.18[a]	0.08
Anger	0.19[a]	0.09

[a]The model was adjusted for demographics (age, gender, and race) and time point. Gender (P=.04) and race (P=.01) were significant.

[b]Self-referent language.

Intentions to Self-Injure

We noted a negative association between activity and intention to injure (b=−0.37, SE 0.09; P<.001). In contrast, there was a positive association between the number of trigger warnings dismissed and intentions to injure (b=1.50, SE 0.06; P=.01). We also found that familial language was negatively associated with intentions to injure (b=−0.32, SE 0.22; P=.01). We noted a negative relationship between the change in dismissing trigger warnings and intentions to injure such that greater changes in viewing triggering content (ie, more viewing triggering content in the week before a survey compared with a distal period) were related to less intention to injure (b=−0.06, SE 0.03; P=.04); see Table 5 for additional details.

Table 5. Intentions to self-injure.

Intentions to self-injure	B	SE
Intercept	2.43[a]	0.26
Web-based behaviors		
Activity	−0.37[a]	0.09
Trigger views	1.50[a]	0.61
Language		
Family	−0.63[a]	0.22
Change		
Trigger views	−0.06[a]	0.03

[a]The model was adjusted for demographics (age, gender, and race) and time point. Age and race were significant (P=.02).

Self-Injury Frequency

There was a positive relationship between the number of posts published with triggering content in the previous week and the frequency of self-injury behaviors reported in the following report period (b=0.45, SE 0.15; P=.002). A positive relationship also surfaced between *I* language and frequency of self-injury behaviors (b=0.02, SE 0.01; P=.04); see Table 6 for additional details.

Table 6. Self-injury frequency.

Self-injury frequency	B	SE
Intercept	0.59[a]	0.15
Web-based behaviors		
Trigger posts	0.45[a]	0.15
Language		
I[b]	0.02[a]	0.01

[a]The model was adjusted for demographics (age, gender, and race) and time point. Age was significantly different (P=.03).

[b]Self-referent language.

Discussion

Principal Findings

In this study, we employed survey responses and naturally occurring log data from a mobile peer-support platform to predict self-injury outcomes. This study fills an important gap in the research literature by connecting behavioral and language patterns to self-reported self-injury outcomes and offers new insights into the relationship between participation in online communities and self-injury.

Key Findings on Web-Based Behavior

One of the primary aims of this work was to shed light on what specific behaviors may be beneficial or detrimental; much of the work on risks and benefits of participation in online communities has been qualitative and has not rigorously examined specific web-based activities [67,68]. This study's findings are consistent with other studies suggesting that participation in online peer support forums may reduce self-injury thoughts by offering useful distraction and providing links to resources [9,27,33]. This study found that activity level predicted decreased thoughts and intent to injure. Participants who actively engaged in TalkLife—through posting content, liking, and generally interacting with others—were at lower odds of reporting self-injury thoughts and intentions. Activity did not, however, predict self-injury behavior or the ability to resist self-injury.

There are several possible explanations for these findings. The most direct explanation is that active use of TalkLife reduces self-injury thoughts and intent, which is in alignment with what the platform was designed to do. This is consistent with the work showing that individuals who engage in active use of social media derive important benefits, such as cultivating feelings of support, connections with others, and companionship [69]. Another possibility is that individuals active on TalkLife represent a self-selecting group with fewer than average day-to-day thoughts or urges to injure. These individuals may be in more advanced stages of recovery or may be qualitatively different from other users somehow. However, as previous work suggests that individuals who frequent online communities are often early in the stage-of-change process [70], it is more likely that users would report higher than average self-injury thoughts and behaviors.

Unlike being active on the app, posting triggering content was positively associated with self-reported self-injury thoughts and behaviors. In other words, although active use appears to be indicative of fewer thoughts and intentions to injure, the types

of content posted—specifically content that has been labeled as triggering—predicted an increased risk of self-injury behaviors and thoughts. Given the nature of these analyses, it is not possible to infer the causal direction of this finding as triggering posts may have been published before or after self-injury thoughts or behavior. Nevertheless, the high temporal correlation of posting triggering content and reporting self-injury thoughts and behaviors suggests that it could be leveraged to check in on users and provide support at key junctures. The directionality of this relationship should be explored in future work.

Interestingly, viewing triggering content appears to be positively related to both abilities to resist urges to self-injure and intentions to self-injure. Although seemingly contradictory, it may be that participants with a strong intention to self-injure dismiss trigger warnings to view triggering content and dissuade themselves from engaging in the behavior. In so doing, individuals may feel more capable of resisting self-injury. Indeed, this speculation is congruent with findings from other work in which seeing or reading graphic content in web-based forums appears to assuage urges to injure [9,27]. The directionality of this relationship should be explored in future work.

Variance in viewing triggering content was negatively associated with the ability to resist self-injury. The more varied an individual's viewing behavior was from day-to-day, the less they reported being able to resist self-injury. In contrast, the rate of change between proximal (the week before) and more distal (remaining time between surveys) viewing shows a negative relationship with the risk of self-injury behavior and intentions to injure. As the change score increased in magnitude (ie, more viewing in a week before a survey relative to a distal period), the likelihood of self-injury behavior and intention to self-injure decreased. Together, these findings reflect a nuanced relationship in which day-to-day variability in viewing triggering content is linked to poorer ability to resist urges—yet an increase in proximal to more distal viewing activity is related to less likelihood of self-injury and self-injury intentions. Variance reflects instability, so it may be that variance in viewing triggering content is characteristic of maladaptive coping. The change score represents a quantitative shift in weekly activity from more distal activity. Thus, from a prediction perspective, high rates of change should signal potential risk. Future work should probe this complex relationship more deeply.

Key Findings on Language

In response to the second set of research questions related to language, we found (1) no relationship between affiliative language and self-injury outcomes, (2) that mentions of family were negatively related to intentions to injure, (3) that variance of positive emotions and anger were related to the ability to resist self-injury, and (4) that ruminative variance was related to self-injury thoughts.

In addition to these larger themes, self-referent language in posts was negatively associated with self-reported ability to resist self-injury. This finding is consistent with work showing that self-referent language is associated with poor mental health status [18,71,72]. In contrast, the use of efficacy language (eg, will, soon, always) was positively associated with the ability to resist self-injury. These findings echo previous work on the importance of self-efficacy in behavior change and recovery [73]. How confident individuals feel about their capacity to change can vary significantly as one's relationship to self-injury changes [74,75]. This finding is promising because it provides further evidence for the role of efficacy in the ability to resist self-injury urges and provides some validity for the method of connecting language traces to self-report surveys.

Another key finding is that as familial language increased, intentions to injure decreased. This aligns with the literature citing family as a protective factor and family disharmony as a key risk factor for self-injury [76-78]. Understanding the link between familial language in web-based communication about self-injury and self-injury outcomes may be an important area for future research.

Patterns in emotional expressions were also observed for self-injury thoughts and the ability to resist. Specifically, participants were more likely to have thoughts of self-injury when posts in the week before a survey varied in the use of ruminative language. This is in line with other studies that found rumination instability predicted daily reports of NSSI [54]. In contrast, higher levels of variance in anger expressions were associated with a greater ability to resist self-injury. This finding is interesting in the absence of a main effect of anger. Many individuals who self-injure have trouble dealing with negative emotions, and anger is often cited as an affective state leading to self-injury [20]. It is possible that fluctuations in anger (or an ebb and flow of this affective experience) signal healthier adaptive processing or simply an ability to express anger and a variety of other emotions.

Finally, we found that as the rate of change of positive emotion increased, so did the ability to resist self-injury. Expressions of positive emotion have been associated with improved well-being in previous work [66], and we find that more positive emotion in proximal—relative to distal periods—is associated with a greater ability to resist.

Implications

The findings highlight implications for researchers working in digital mental health, clinicians working with young people who self-injure, and platform designers. In terms of research, much of the previous work investigating web-based communication about self-injury has focused on "static entities such as websites and forums rather than the fragmented, heterogeneous and dynamic current landscape of social media" [79]. This study uses a mixed methodological approach to capture the dynamic nature of activity on a mobile peer-support app in relation to how individuals manage urges and self-injury behavior in their daily lives. Although we focus on methodological limitations in the next section, we feel that the dynamicity captured in this study is a key strength that can be leveraged in future investigations. Lagged regressions and studies using platform-initiated push notifications may be particularly useful extensions of this work to further disentangle bidirectional temporal relationships and identify opportunities for timely intervention. The factors identified through this work, particularly those related to web-based behaviors and shifts in

self-injury behavior over time, if replicated, could inform future modeling to identify users who may be in need of additional resources.

Our findings also emphasize the importance of considering web-based activity, as it relates to self-injury recovery in the context of treatment [30,34,80]; 42% of our participants reported having been in therapy at some point throughout the study, yet clinical assessments do not routinely probe for web-based engagement [30]. When clinicians are not aware of their clients' web activity, they risk overlooking critical aspects of clients' social environment and sources that likely shape their motivation, or ambivalence, toward self-injury behavior change.

Specifically, our findings suggest that clinicians should check in with clients regarding posting and viewing self-injury content. Posting content labeled as triggering was related to self-injury behavior and thoughts in our study, and viewing such content was related to both greater ability to resist self-injury and greater intentions to injure. Of note, we found that exposure to such content is not necessarily related to greater self-injury frequency. Although these findings are preliminary, they are in line with other previous work, suggesting that conventionally *risky* activities may not always be harmful [79]. This relationship between exposure to content and effects is nuanced and likely depends on individual factors that are not well captured in our data but may surface in the context of a therapeutic relationship. Clinicians should strive for a nuanced understanding of the client's motivation to post and view content and react to client disclosures of web-based engagement in a curious but nonjudgmental way to encourage further dialog. As young people turn to digital tools to manage self-injury urges and related factors (eg, mood and interpersonal relationships) between treatment sessions, it is imperative that clinicians have a basic understanding and awareness of what resources exist and how clients use them. This awareness will enable clinicians to ask specific and relevant questions and regularly assess the impact web-based activities have on the client's progress toward recovery. Several useful guides have been designed to assess web activity in sessions with individuals who self-injure and could be adapted to reflect specific features of new platforms such as TalkLife [30,34].

Our findings also have relevance for platform designers. As confidence in being able to identify individuals engaging in, or at risk of, self-injury increases, we can begin to think about how to deliver timely and accessible interventions. Given that most of our participants were not currently in therapy, it may be beneficial to consider integrating elements of evidence-based treatment into the platform experience (eg, psychoeducation). These elements could be optional and be offered based on the individual's use patterns. Finally, although the tendency has been to remove graphic, or potentially triggering, content from platforms, there have been discussions about the dangers of overmoderation [79,81,82] and the benefits of self-expression [83]. Our findings suggest a need to consider safe ways of moderating content while also allowing free expression. Balancing user agency within systems that encourage positive behaviors is a challenge, but a worthy endeavor, as there is ample evidence that distressed individuals use online spaces to solicit support and connect with the community.

Limitations

This study has several limitations that should be acknowledged. First, the methodological design imposes limitations on causality. Survey questions were framed to ask about any self-injury in the week before but did not ask about specific days, or times of day, when these events (eg, thoughts, behaviors) occurred. Therefore, it was not possible to establish a detailed timeline for when the self-injury events occurred relative to the activities on TalkLife. Future work might consider daily surveys, either through diary or EMA, for a more nuanced understanding of these temporal relationships. We also chose to aggregate our data at the week level in this study, but it would be worthwhile for future work to explore associations between self-injury outcomes and web-based activity across other periods (eg, daily, monthly).

Second, while LIWC is widely used for language analysis, it does not account for context. Several key findings on language are tentative and should be more thoroughly explored in future work. One way to do this would be to triangulate with other language analysis techniques such as the tf-idf or word co-occurrence measures derived from n-grams.

Third, we operationalized web-based activity as *active* use. Owing to high correlations between active and passive measures in this data set, we restricted the analysis to active log data to avoid collinearity issues. However, research has shown that active and passive social media use can have differential effects on affective well-being [84,85]. Thus, future work should explore the influence of a more comprehensive spectrum of engagement on self-injury outcomes.

There are limitations to the generalizability of these findings. TalkLife is a platform specifically intended for the exchange of support related to mental health challenges, and the extent to which our findings generalize to other social platforms is unknown. In addition, there is potential for selection bias in this study. Participants were inclined to use support apps, willing to take weekly surveys on their self-injury, and engaged in active use of the app. This suggests that participants may have been similar in ways related to their use and their readiness to change self-injury behaviors. Future work may wish to consider recruiting and incentivizing a more diverse population for a broader picture of TalkLife activity.

Our findings should also be contextualized in light of the limitations of our analytical approach. Although variable selection procedures are common in psychological and social scientific research, alternative approaches, such as stochastic search variable selection or lasso regression, may enhance the reliability of models when selecting variables from a large number of predictors [86]. We note that these approaches would be useful in future work.

Finally, this exploratory work was meant to identify factors associated with self-injury outcomes that could be targeted in future confirmatory research with sufficiently powered samples. The methodological approach of combining naturally occurring web-based data with self-report survey data provides new insights into the relationship between the use of a web-based peer-support platform and various self-injury outcomes.

Conclusions

This study investigated the relationship between web-based support activities and self-injury outcomes to identify patterns that may be beneficial or harmful. To do so, we employed a novel mixed methods approach that utilized naturally occurring language and behavioral data from a mobile peer-support app and survey data collected over 4 months. Our findings point to a nuanced set of relationships. Specifically, participants who actively engaged in TalkLife were at lower odds of reporting self-injury thoughts and intentions. However, activity level was not predictive of self-injury behavior or the ability to resist self-injury urges. Posting triggering content was associated with greater odds of participants reporting self-injury thoughts and behaviors, whereas viewing triggering content was linked to both greater abilities to resist urges and greater intentions to injure. This work provides empirical support for the relationship between participation in a web-based support platform and 5 self-injury outcomes and articulates patterns that merit consideration in future work. We hope that insights from this study will inform future research on digital mental health and platform design.

Acknowledgments

This work was supported by the USDA National Institute of Food and Agriculture, Hatch project 1004268 and the Cornell Center for Social Sciences. KK completed final drafts of this manuscript while also receiving support from the National Institute of Mental Health (T32 MH115882). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Conflicts of Interest

None declared.

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Abbreviations

EMA: ecological momentary assessment
LIWC: Linguistic Inquiry And Word Count
NSSI: nonsuicidal self-injury
OR: odds ratio
RQ: research question
VIF: variance inflation factor

Edited by J Torous; submitted 26.06.20; peer-reviewed by S Lewis, K Machin; comments to author 23.09.20; revised version received 16.11.20; accepted 15.12.20; published 28.01.21.

Please cite as:
Kruzan KP, Whitlock J, Bazarova NN
Examining the Relationship Between the Use of a Mobile Peer-Support App and Self-Injury Outcomes: Longitudinal Mixed Methods Study
JMIR Ment Health 2021;8(1):e21854
URL: http://mental.jmir.org/2021/1/e21854/
doi:10.2196/21854
PMID:33507154

Original Paper

A Blended Electronic Illness Management and Recovery Program for People With Severe Mental Illness: Qualitative Process Evaluation Alongside a Randomized Controlled Trial

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Abstract

Background: We conducted a trial to test the electronic Illness Management and Recovery (e-IMR) intervention to provide conclusions on the potential efficacy of eHealth for people with severe mental illness (SMI). In the e-IMR intervention, we used the standard IMR program content and methodology and combined face-to-face sessions with internet-based strategies on the constructed e-IMR internet platform. During the trial, the e-IMR platform was sparsely used.

Objective: This study aimed to evaluate the added value of the e-IMR intervention and the barriers and facilitators that can explain the low use of the e-IMR platform.

Methods: This process evaluation was designed alongside a multicenter, cluster randomized controlled trial. In this study, we included all available participants and trainers from the intervention arm of the trial. Baseline characteristics were used to compare users with nonusers. Qualitative data were gathered at the end of the semistructured interviews. Using theoretical thematic analyses, the data were analyzed deductively using a pre-existing coding frame.

Results: Out of 41 eligible participants and 14 trainers, 27 participants and 11 trainers were interviewed. Of the 27 participants, 10 were identified as users. eHealth components that had added value were the persuasive nature of the goal-tracking sheets, monitoring, and the peer testimonials, which had the potential to enhance group discussions and disclosure by participants. The low use of the e-IMR platform was influenced by the inflexibility of the platform, the lack of information technology (IT) resources, the group context, participants' low computer skills and disabilities, and the hesitant eHealth attitude of the trainers.

Conclusions: The extent of eHealth readiness and correlations with vulnerabilities in persons with SMI need further investigation. This study shows that flexible options were needed for the use of e-IMR components and that options should be provided only in response to a participant's need. Use of the e-IMR intervention in the future is preconditioned by checking the available IT resources (such as tablets for participants) providing computer or internet guidance to participants outside the group sessions, evaluating the eHealth attitude and skills of trainers, and tailoring eHealth training to increase the skills of future e-IMR trainers.

Trial Registration: Netherlands Trial Register NTR4772; https://www.trialregister.nl/trial/4621

International Registered Report Identifier (IRRID): RR2-10.1186/s12913-016-1267-z

(JMIR Ment Health 2021;8(1):e20860) doi:10.2196/20860

KEYWORDS

mental health recovery; self-management; telemedicine; mental health services; qualitative research

Introduction

Background

In mental health care, eHealth is expected to have great potential to increase access to care while being economically and socially efficient [1]. eHealth can be defined as making use of information technology (IT). In meta-analyses, eHealth interventions for persons with depressive and anxiety disorders are accepted and proven to be effective [2]. eHealth is also used for persons with severe mental illness (SMI). Persons with SMI are diagnosed with a psychiatric disorder that causes, and is because of, serious impairments in social and occupational functioning that lasts longer than at least a couple of years and necessitates coordinated multidisciplinary care [3]. eHealth for persons with SMI is used in a wide range of interventions, such as self-management, relapse prevention, promoting adherence to medications and/or treatment, psychoeducation, supporting recovery, and promoting health and wellness and symptom monitoring [4]. eHealth interventions for people with SMI are accepted and feasible [4], and they have potential to deliver effective education [5]. Unfortunately, conclusions on their effectiveness cannot be drawn [4,6]. A number of difficulties and barriers have been addressed concerning eHealth for persons with SMI (eg, cognitive impairments, lower IT experience [7]), which may explain the high attrition rates [8]. Blending face-to-face contact with eHealth is supposed to increase the therapeutic relationship and prevent attrition [9].

To contribute to consumer-oriented development and delivery of self-management electronic support programs, we developed and tested a blended version of the standardized, curriculum-based Illness Management and Recovery (IMR) program for people with SMI [10,11]. The standard IMR program provides information and teaches the skills necessary for managing an SMI effectively and working toward achieving personal recovery goals [12]. In accordance with the intervention mapping (IM) protocol [13] and in collaboration with target group members, we developed the e-IMR intervention to evaluate whether persons with SMI could benefit more from the IMR when making use of eHealth strategies in combination with face-to-face sessions [11]. On the e-IMR internet platform, the IMR curriculum was integrated, and we blended the use of this platform with face-to-face, group-wise delivery of the standard IMR program [11]. To evaluate the effectiveness of the e-IMR intervention compared with the standard IMR program, we conducted a multicenter, cluster randomized controlled trial [10,11].

The most striking finding of the trial was the low use of the e-IMR platform [10]; therefore, we could not conclude the effectiveness of the e-IMR intervention. Sieverink et al [14] reported that many eHealth evaluations show no or limited positive effects, which is strongly related to not using technologies in the desired way. Ben-Zeev et al [6] advised that the development of eHealth interventions for people with SMI must be coupled with examining the barriers and possible solutions. In addition, the IM protocol advises testing the effectiveness of an intervention and conducting a process evaluation to understand why an intervention did or did not work [13]. Therefore, we conducted this process evaluation alongside a randomized controlled trial to gain insights that will ultimately help to make adjustments to facilitate proper use of the e-IMR intervention specifically or of eHealth for people with SMI in general.

Objectives

This study aimed to identify the added value of the e-IMR intervention and the barriers and facilitators that can explain the low use of the e-IMR platform.

Methods

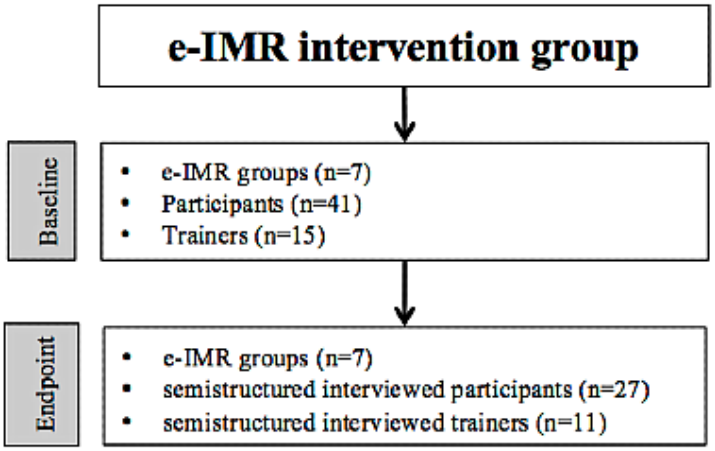
Study Design

We conducted a theoretical thematic analysis [15] alongside the trial. This qualitative method makes use of a pre-existing coding frame and provides a detailed analysis of the data [15]. Data were derived from semistructured interviews with participants and trainers held at the end point of the trial. This trial was registered in the Netherlands Trial Register (NL4621). We used the framework of Grol and Wensing [16-19], which frames the factors that potentially influence the effect of an intervention (Multimedia Appendix 1) [17]. Therefore, we focused on the e-IMR intervention itself and its implementation, the trial participants and their social context, the IMR trainers who provided the intervention, and their organizational context.

Study Population

In this study, we included all available participants and IMR trainers from the intervention arm of the e-IMR trial [10] (Figure 1). Information about inclusion, exclusion, and eligibility criteria and the effect of the e-IMR trial can be found elsewhere [10]. Participants in the intervention arm of the trial who completed at least the first module on the e-IMR platform or had logged into the e-IMR platform at least five times were defined as *users*. Nonusers either did not use the e-IMR platform or used it less than 5 times. Users were regarded as having had the opportunity to benefit from the e-IMR intervention and to reflect on it. The trainers of the group-wise–delivered e-IMR intervention were psychiatric nurses and peer professionals. A peer professional is a person with a lived experience of a mental illness, educated, and trained to become a professional capable of transferring knowledge and counseling other persons with a mental illness.

Figure 1. Study flow diagram. e-IMR: electronic Illness Management and Recovery.



The e-IMR Intervention

The e-IMR intervention started with a *welcome page* explaining the use of the e-IMR platform and leading participants to the 11 modules. On the e-IMR platform, participants could fill in e-versions of the forms in the standard IMR, such as goal-tracking sheets, problem-solving sheets, sheets for tracking successful coping strategies, and a symptom-monitoring page. In addition, the e-IMR platform contained illustrative videos showing peer testimonials to encourage participants to talk more freely about themselves and to take steps in their recovery process. Further detailed information about the e-IMR intervention is shown in Multimedia Appendix 2.

Implementation of the e-IMR Platform

The e-IMR platform was introduced to the trainers and participants by the first author at the second group session. Participants were invited to use the e-IMR platform but were not obliged to use it at home because of the possible lack of resources. The trainers were educated on how to support participants in the use of the e-IMR platform, how to install it on a computer in the session room, and how to use it during the sessions. The registration forms on successful coping strategies and the symptom-monitoring page were introduced after the second module on *practical facts about mental illnesses*. Weekly emails with a link to the e-IMR platform led the participants directly to the symptom-monitoring page. After finishing any module, one of the trainers provided feedback to the participants via the platform and guided the participants to the next module. Further detailed information about the implementation of the e-IMR intervention is presented in Multimedia Appendix 2.

Halfway through the trial, we discussed the low use of the platform with the trainers and asked them to reintroduce the platform in the sessions and to motivate and guide the participants to use it at home to get as much experience with it as possible. With regard to this request and in addition to the original implementation strategy, in 4 out of the 7 groups, extra e-IMR lessons were organized outside the current IMR sessions (Multimedia Appendix 2).

Data Collection

Data were collected between January 2015 and October 2016. Three types of data were gathered: participants' characteristics, log data of the use of the e-IMR platform, and qualitative data from semistructured interviews at the end point of the trial.

At baseline, the following data on participants' characteristics were gathered: age, gender, diagnostic classification according to the *Diagnostic and Statistical Manual of Mental Disorders* (4th edition) [20], physical comorbidities, treatment history, cultural background, socioeconomic status, highest education, computer and internet availability and use, computer literacy, perceived computer skills, and the need for guidance when using a computer or the internet. The last 2 items were scored on a 5-point Likert scale, with the answer options of *strongly disagree* (1) to *strongly agree* (5). In addition, the following data from trainers were collected at baseline and used for this study: age, gender, profession, highest education, years of experience in mental health, and eHealth experience.

Log data about the actual use of the e-IMR intervention were derived from the e-IMR platform. These data were used to identify *users* and *nonusers*.

We conducted semistructured interviews at the end point of the trial with all available participants and trainers. After the halfway discussions with the trainers about the low use of the e-IMR platform, we discussed the potential influential factors and adapted the framework of Grol and Wensing [17]. Within each factor, we formulated a number of relevant determinants and accordingly set up the interview questions (Multimedia Appendix 1). The framework and questions were used as the interview topic list in semistructured interviews at the end point. The first author (TB) and research assistants performed the interviews with participants at their preferred location. The first author conducted interviews with the trainers. All semistructured interviews were audio recorded and transcribed verbatim. The transcripts were uploaded in Microsoft Excel (R).

Data Analyses

Descriptive statistics were used to present the outcomes for the groups of users and nonusers. Chi-square and Student *t* tests were carried out to compare the baseline characteristics and IT attitudes of the groups of users and nonusers. Quantitative data from the structured interviews at baseline and end point were analyzed using the Statistical Package for the Social Sciences (R) version 23 [21].

Data from the transcripts of the semistructured interviews were analyzed deductively using theoretical thematic analysis [15]. We used the following 7 steps:

1. All 3 authors (TB, BG, and PG) independently read and reread the transcripts from the participants and from the trainers for one e-IMR group and identified meaningful statements.
2. All 3 authors grouped the statements into the categories of the modified coding frame of Grol and Wensing [17].
3. All 3 authors triangulated their analyses thoroughly until consensus was reached, which means that discussions lasted until all agreed without any doubts.
4. The first author completed the analyses of the subsequent e-IMR groups according to the first 2 steps.
5. The first author formulated a description of the findings within each determinant and added verbatim examples.
6. All 3 authors discussed the description of the findings thoroughly until consensus was reached.
7. Finally, a composite description of the experiences and the use of the e-IMR intervention was written and discussed with all authors.

Results

Characteristics of Participants and Trainers

From the 7 groups, baseline characteristics were collected from 41 participants and 15 trainers (Multimedia Appendix 3). The mean age of the participants at baseline was 46.9 years (SD 11.6; n=41) and the majority had minimal income. The mean age of the trainers at baseline was 46.7 years (SD 8.8; n=15). In total, 9 trainers were psychiatric nurses and 5 were peer professionals. Of the 41 participants, 14 (34%) were identified as e-IMR users. The groups of users and nonusers only differed significantly according to gender (P<.042), with more men being nonusers.

Process Evaluation

At the end point, 27 participants (10 of whom were users) and 11 trainers were available to be interviewed (Figure 1 and Multimedia Appendix 3). A total of 14 participants (4 of whom were users) were not interviewed because they were too burdened by being interviewed. From all the e-IMR groups, at least one trainer was interviewed; 4 trainers were unavailable because of busy work schedules. In the following sections, the findings are reported according to the framework (Multimedia Appendix 1). In our findings, we used the terms *users* or *nonusers* to make it clear that among the participants, only users or nonusers reported the mentioned statement. We used the term *participants* when both users and nonusers reported the statement. The following section details the findings for the e-IMR intervention and its implementation, the trial participants and their social context, and the IMR trainers who provided the intervention and their organizational context. The determinants for these factors are illustrated by using quotes from participants coded with a P followed by 4 digits and either U or N (standing for *user* or *nonuser*, respectively) and by quotes from trainers coded with a T followed by 5 digits and either Pe or Nu (standing for *peer professional* or *psychiatric nurse*, respectively).

The e-IMR Intervention and Its Implementation

Regarding the e-IMR intervention, the following determinants are described: added value, accessibility, implementation fidelity, and feasibility.

Added Value

Users and trainers reported that the components of the e-IMR intervention had added value. One user stated that because of the platform, the standard IMR curriculum was easier to understand. Explanations on relevant subjects in the different modules, for instance, about symptoms, were easy to find using the buttons on the platform. A trainer mentioned that the time-consuming search in the textbook was no longer necessary. In 4 out of the 7 groups, peer testimonial videos were shown during the group sessions. Watching these videos was of great value to trainers and participants, enhancing discussions and disclosure. Participants found the peer testimonials very interesting and experienced recognition:

> *Yes, those videos … I liked them. Watching them was the first we did, and it became easier to talk about the subject.* [T31002Pe]

However, sometimes the participants felt fearful when reminded of their own psychotic experiences.

Trainers and users reported the added value of the repetitive character of the goal-tracking sheets on the platform. Users easily tracked and celebrated their achievements. When only the hard copy module was used, the paper goal-tracking sheets were often lost, which hindered the monitoring of achievement over time:

> *So, your goals appear; that's not in the book. . . . it's not possible to drop your focus. You're reminded of them ...* [P1202U]

One user reported that the results of the weekly reminders to monitor symptoms led to a more objective interpretation of varying emotions, which increased personal insight. Another user did not benefit from this. A different user thought that the focus on symptoms was too strong, and one peer professional trainer mentioned that he experienced aversion to this assignment because of this focus on symptoms:

> *In every chapter it appears: How much did symptoms burden you? ... it's too negative. I know it is meant to be positive .... But, huh [shivering], these symptoms again; f[...] off!* [T51003Pe]

The users and trainers reported that they did not use the *coping strategies* and *problem-solving sheets*.

Accessibility

Most of the participants reported that the eHealth components were not easy to find. Out of 14 users, 6 reported having problems with logging on to the e-IMR platform at home. In 5 of the 7 groups, participants and trainers reported that accessing the platform during the sessions was problematic because of bugs when using certain browsers, problems with accounts, problems with logging in, and not having the appropriate IT resources:

> *Someone from technical services helped them, but the trainers couldn't get it running. The enthusiasm in the group to work with it was very low. So they stopped trying, and we worked with the book the rest of the time.* [P1106U]

Implementation Fidelity

Trainers stated that they gave enough attention to motivate participants to use the e-IMR platform. Both trainers and participants reported that because of problems with accessing the platform and the aversive reaction of nonusers, the actual use of the platform during the sessions was low, apart from the peer testimonial videos. Moreover, participants reported that using the e-IMR platform at home was not discussed in later sessions. Some users felt that the trainers did not stimulate them and that they linked this to the fact that the use of the e-IMR platform was not obligatory:

> *It was like: "It is no obligation, I can do it, but ...." I think that when it got more attention, you'll be able to see what it's bringing you.* [P1202U]

Feasibility

The participants and trainers reported the nonfeasibility of working on a computer with a projector and screen during the sessions. They estimated that it would be too time consuming to switch from 1 participant's account to another. Furthermore, participants could not read their own homework notes when they watched another participant's account on the projection screen. They thought that the use of a personal laptop or tablet could overcome this problem:

> *I wondered how a session would go when we do everything in the e-IMR, and nothing on paper. What if someone else is active on the screen, and then I can't see my own notes? What did I write down at home? I won't remember, unless we all have a tablet or laptop.* [P4202N]

Trainers and users reported inflexibility of the platform, such as not being able to amend notes or skip an uninteresting module or change the module order. As the platform was not used adequately during the sessions, participants easily lost synchronicity: doing the e-IMR intervention on the platform at home and during the group sessions became 2 separate things. Nonusers reported that they stopped or did not start using the platform to avoid duplication of effort and to prevent confusion by using 2 ways of working with the IMR:

> *There are two things ... I was afraid to mix them up ... So, you do double work. You choose either the book or the platform ... not both.* [P3104N]

The Participants

Regarding the participants, the following influencing determinants can be described: attitude, compliance, skills and knowledge, and resources.

Attitude

With regard to computers, nonusers reported that they postponed the use of computers, were not interested, did not have an affinity, felt that working with computers was impersonal, were too easily overstimulated by the overload of content on a computer screen, experienced a lack of control over what was happening in the computer, and had a preference for tangible paper and face-to-face communication. Some nonusers experienced fear and mistrust in the privacy protection of the e-IMR platform, not wanting to take the risk of others being able to read their notes:

> *I don't know where my information goes when I am on the world wide Internet. I need control, always and ever. ... I will get over-stimulated, all those things in my site, they really distract me.* [P4207N]

Compliance

Some users said that they got lost and confused when confronted with the platform's inflexibility or when they wanted to get through a backlog after a short period of not using the platform. Users missed additional stimuli from trainers to deal with this backlog. Not using or stopping use was related to vulnerability, such as wanting to avoid burdens because of duplication of effort, not feeling well enough, having sensory overload, a lack of concentration, dyslexia, perfectionism, or fear of failure:

> *Yes, in the group you can talk it out right away; that's easy ... I did not like doing it on the computer. I think because of the upcoming emotions ... and being alone here at home, no one to talk with ... It just was too much for me, and I decided to stop using it.* [P1207N]

In terms of vulnerability, the trainers added that the participants recently experienced psychosis, lived a chaotic life, lacked inquisitiveness and initiative, had low intelligence, or had learning disabilities. Learning new skills was reported to be too difficult when not feeling well. The opposite was also reported—feeling better halfway through the trial and then being able to use the platform:

> *First I thought: This looks handy; I can do it. I really intended to do so. But I got those mood swings and thought: Let me do it on paper; it's ... what I am used to do ... and I will do it later when I feel well enough — then I will. But that did not work.* [P4103N]

Skills and Knowledge

At baseline, 15% (6/41) participants reported that they had never used a computer and most participants (27/41, 66%) scored neutrally or agreed that they had good computer skills. At the end point, participants reported not being familiar with computers, being afraid of computer viruses from the internet, not knowing how to log in, and not being able to imagine how computers process their input:

> *I cannot work on the computer .... I did try to learn, but ... no. Terrible, I might be able in a year or so. Now I really cannot.* [P1103U]

At baseline, 34% (22/41) of the participants did not agree that they needed guidance in working with computers. Of these participants, 29% (14/41) became users. At the end point, participants with a need for guidance reported reluctance in asking for help. A total of 3 participants became a user halfway through the trial with considerable support from the trainer. One

trainer illustrated how a user was helped with working on the e-IMR platform:

> *Well, I (trainer) was at the computer. She (a user) was sitting next to me, and I asked: "Shall I click here or there?" I typed the text and repeatedly asked: "Is this correct?"* [T41001Nu]

IT Resources

In total, 8 participants (8/41, 20%) reported having no computer but one of them did become a user. Moreover, not having the internet, an email account, or finances to afford these resources was reported. Most (31/41, 76%) of the participants had minimal income:

> *No, really, I was angry; at that time, I had lost my computer. I did it the old-fashioned way. I was fed up with that d[...] computer....* [P3101N]

The Social Context of the Participants

Within the social context of the participants, the following determinants can be described: social support and group effect.

Social Support

A female user reported that getting help to use a computer from her partner caused irritation. She preferred the help of someone outside her family. Other participants reported that they had a partner with no computer skills. In total, 3 participants became users after getting help from relatives, friends, or trainers outside the group session:

> *I'll tell you, I just met him, and he fixed the necessary update. I did not dare to open it, and that's over now ....* [P1204N]

Group Effect

In 4 out of the 7 e-IMR groups, the participants decided not to use the e-IMR platform during the sessions. A nonuser decided not to use the e-IMR platform at home because another person in the group (a user) was struggling obsessively with using the e-IMR at home. The users and trainers experienced a negative group attitude toward the e-IMR platform, for instance, when nonusers expressed their irritation when the e-IMR platform was discussed during the sessions:

> *Yes, those participants who were not active on the e-IMR platform were irritated and said: "Why talk about the e-IMR again? ...."* [T11003Nu]

Trainers

Regarding trainers, the following determinants can be described: attitude and skills and knowledge.

Attitude

Most trainers reported not being computer minded or having a preference for face-to-face contact and tangible paper:

> *I 'm not that Internet-minded; nor is my colleague. ... My colleague prefers working with these flipcharts.* [T42002Pe]

The trainers estimated that helping participants with the use of the platform during the sessions would take too much time. They differed on whether offering individual guidance to the participants was part of their job as an IMR trainer. The trainers doubted, and some did not offer lessons on using the e-IMR platform outside the group:

> *Yes, ... a participant had intentions to start, but had troubles with the computer firewall .... I was wondering, ... what can I do to lower barriers? One option was to install things on her computer, but I considered this was going too far.* [T12001Pe]

Some trainers reported that they observed vulnerabilities, disabilities, lack of concentration, easy loss of self-esteem, lack of discipline, and struggle with computers in participants. The trainers suggested that participants belonged to a generation with less computer experience and thought that this was influential. Thus, some trainers stated that combining eHealth and SMI is a complete misfit, and they blamed the policy makers for this:

> *This trend is politically grounded ... this e-mental health, blah, blah. Well, I think people from behind their desk invented this. They do not know what people with SMI go through.* [T11003Nu]

The trainers reported that working with the e-IMR intervention and motivating participants was an extra, burdensome effort. They felt that working with the e-IMR intervention disturbed the group sessions and that doing the IMR regularly and working with a group were already difficult. The trainers reported cautiousness in opposing the resistance of nonusers to the e-IMR intervention. Their priority was to work with the IMR content and prevent participant attrition from the sessions, and the e-IMR platform became an afterthought:

> *I think most important in the group is that we go on and follow the book. In fact, working on the e-IMR platform was a sideshow.* [T12003Nu]

Skills and Knowledge

At baseline, one trainer had eHealth experience. Some trainers reported having had enough tools; however, others reported not having heard enough about the e-IMR intervention and the trial. The trainers gave differing reports on whether they had enough skills; some said they did not:

> *My colleague explained to me how to start the e-IMR platform, but when I am alone, like today, I can't manage.* [T42001Nu]

The Organizational Context of the Trainers

Regarding the organizational context of the trainers, the following determinants can be described: policy, IT resources, and workflow.

Policy

The trainers had difficulty logging on to the platform because of a privacy policy in their organization. The internet system of organizations had firewalls to protect the organizations' IT environment for internet viruses. Owing to this, some websites and email addresses were identified as unsafe and were blocked:

> *Here [via our intranet], I can't enter LinkedIn or Dropbox ...you can't enter hardly anything. ... They're afraid of viruses.* [T31001Nu]

IT Resources

At the start of the trial, one organization had an IT environment that was compatible with the e-IMR intervention but the other organizations did not. The session rooms often lacked a computer, a soundcard in the computer, Wi-Fi, a projector, and a screen. The trainers sought help from IT help desks in their organizations but could not resolve these problems. Some trainers were creative and determined to find a bypass outside the local IT environment:

> *S[...], to get the video's work, the sound card was blocked, but I thought: "I won't quit trying. I want to show them." ... In the end, we made it.* [T42002Pe]

Workflow

In the search for another session room, trainers were confronted with overly strict schedules. Another issue was about starting IMR groups and assigning IMR trainers on time. In a number of organizations, IMR groups could only be organized shortly before closing the trial period. The trainers reported that such workflow problems are *business as usual*. To fulfill the participants' need for guidance with the e-IMR intervention, a number of trainers reported not having enough time in their work schedule:

> *But this person needs guidance every day. I do not know how to manage that. I don't have time to do so.* [T52001Nu]

Discussion

Principal Findings

In this study, we evaluated the added value of the e-IMR intervention and the barriers and facilitators that can explain the low use of the platform. The users and trainers had negative and positive experiences with the e-IMR intervention. The added value of the e-IMR intervention consisted of the peer testimonial videos, the persuasive nature of the monitoring page, and the weekly confrontations with their personal recovery goals. There were barriers in the platform's inflexibility, the infeasible group-wise provision of the intervention, the hesitant attitude toward eHealth of the participants and trainers, the participants' lack of IT resources, their low skills and knowledge of using the internet, and their being too overwhelmed by symptoms or disabled cognitive functioning, causing problems with using the e-IMR platform.

Strength and Limitations

The strength of this study is that it included people with low computer use, which enabled us to obtain a broad picture of the added values, barriers, and facilitators. A limitation of this study is that we cannot draw conclusions about the potential feasibility of the e-IMR intervention in individual treatment settings. The e-IMR intervention might work better in individual sessions, as it can be better tuned and tailored to the personal needs of the person with SMI. We estimate that the influence of the group attitude and the e-IMR intervention's infeasibility in group settings were considerable. Unfortunately, the institutes where IMR is provided individually declined to participate in the trial.

Comparison With Previous Work

The weekly monitoring page worked out well for some users; however, for others, including a trainer, these reminders were disliked because of a strong focus on symptoms. For users, the weekly confrontations with personal recovery goals and actions worked better than the paper version. The peer testimonial videos were highly appreciated because of their potential to enhance group discussions and the disclosure of the participants. Peer testimonials fulfill the need for peer information and acknowledgment [22]; thus, watching this kind of video can be a pivotal experience that enhances reflection and discussion [23].

Users and trainers were confronted with the platform's inflexibility when they wanted to emend previous notes, skip uninteresting modules or the monitoring page, and change the order of the modules. Therefore, the next version of the e-IMR intervention should be flexible to fit individual needs. Addressing personalization seems to be a key issue for future eHealth interventions for people with SMI [24]. The group-wise provision of the e-IMR intervention was experienced as infeasible because it was too time consuming to switch between the accounts of participants and the fact that participants were not able to look at their own notes. In addition, because of their e-IMR–averse attitude, participants chose not to use the e-IMR platform during the sessions. Unintentionally, the e-IMR platform and the face-to-face IMR session became 2 separate things. To overcome this group barrier, providing a tablet to participants was a widely heard suggestion. Providing devices to persons with SMI is known to support engagement in e-interventions [23]. This may also overcome the lack of IT resources in persons with SMI, which in our study group was present in 20% (n=41) of participants, comparable with the percentages found by Thomas et al [25]. A lack of IT resources was also present in the participating institutes. Future e-IMR–providing institutes need an open IT environment, open soundcards, strong computers, Wi-Fi for multiple tablets, an available projector plus screen, and a help desk. Technological resources are necessary to facilitate eHealth interventions [24].

The lack of computer skills and the preference for tangible paper and face-to-face communication of the participants can also be seen as barriers. Belonging to a generation with less computer experience might be an influence because low computer literacy is associated with higher age [26]. Similar to Williams et al [23], we identified log-in problems and problems with finding e-components on the platform, which contributed to the low use of the e-IMR platform. The participants in our study thought that their problems with learning and using the e-IMR platform were because of being too overwhelmed by their symptoms or a disability in their cognitive functioning. Executive functions, working memory, and sustained attention play an important role in using websites [7], and these functions are also highly associated with psychiatric illnesses [27,28]. To gain a clear picture of the correlation between the psychiatric health status of persons with SMI and their eHealth readiness, more research is necessary. Taking our findings regarding participants'

attitudes, compliance, and skills and knowledge, we concluded that most participants in our study were not yet ready to engage with eHealth. Berry et al [29] drew a comparable conclusion that persons with SMI have relatively low interest in and willingness to engage with eHealth interventions. We also concluded that there is a need for guidance in persons with SMI. Implementation of the renewed e-IMR intervention must coincide with an eHealth support intervention for participants. Successful use of internet-based interventions for persons with SMI is facilitated by training, support, and encouragement [23].

The eHealth attitudes, skills, and knowledge of trainers toward the e-IMR intervention are also barriers. Their hesitant attitude toward eHealth is based on their preference for tangible paper and face-to-face contact and their own low computer skills. The trainers in this study stopped promoting the e-IMR intervention so they would not burden the participants and avoid causing the participants to withdraw from the sessions. Identifying with the participants' struggles and vulnerabilities might also have influenced the process. To illustrate, some of the trainers questioned the appropriateness of eHealth for people with SMI, blaming the policy makers. Dutch mental health nurses indicate that eHealth is not in line with the educational level, cultural background, or digital skills of mental health patients [30]. Williams et al [23] suggested a paternalistic attitude when workers determine the suitability of using eHealth interventions for persons with SMI. In this study, in 4 out of the 7 groups, trainers strived creatively to find solutions for showing the peer testimonial videos and organizing e-IMR lessons outside the group sessions. Owing to this effort, 3 of the non–computer-minded participants became *users*. Worker engagement is essential to the successful implementation of eHealth for persons with SMI [23]. Before implementing the renewed e-IMR intervention, it might be necessary to teach trainers how to use eHealth, become experienced, and resolve their hesitancy.

Despite our findings, the development of internet-based interventions is ongoing in our increasingly digitalizing society and health care. Strand et al [24] stated that the internet can play a transitional role in recovery-oriented practices, and Williams et al [23] identified its potential to elicit the personal values of persons with SMI and their treatment preferences. These promising statements make further development of the e-IMR intervention worthwhile.

Conclusions

The eHealth components of the e-IMR intervention that have added value are the persuasive nature of using goal-tracking sheets and monitoring and the potential of the peer testimonial videos to enhance group discussions and the disclosure of the participants. The low use of the e-IMR platform was influenced by its inflexibility, lack of IT resources, group context, lack of computer skills of the participants and their disabilities, and the hesitant eHealth attitude of the trainers. The extent of eHealth readiness and the correlations with vulnerabilities in persons with SMI need to be investigated further. Providing the e-IMR intervention in the future is preconditioned by the flexible use of components in response to a participant's needs, checking the available IT resources in institutions, providing tablets to participants in group settings, providing computer or internet guidance to participants outside the group sessions, evaluating the eHealth attitude of trainers, and providing the necessary eHealth training to increase the skills of future e-IMR trainers.

Acknowledgments

This study was funded by the ZonMW (the Netherlands Organisation for Health Care Research and Development) program *Tussen Weten en Doen* (grant 520001001). The funder had no influence on the study design; the collection, analysis, and interpretation of the data; the writing of the report; and the decision to submit the paper for publication.

Authors' Contributions

All authors contributed to the conception and design of the study. TB contributed to data collection. All authors contributed to the analysis and interpretation and provided drafting of the paper. All authors contributed to the critical revision of the paper for important intellectual content and the final approval of the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Conceptual framework based on the barriers and incentives for change of different levels of health care, interview items, and data source.
[DOCX File , 123 KB - mental_v8i1e20860_app1.docx]

Multimedia Appendix 2
An overview of the eHealth components and implementation of the electronic Illness Management and Recovery (e-IMR) intervention.
[DOCX File , 19 KB - mental_v8i1e20860_app2.docx]

Multimedia Appendix 3
Personal characteristics of participants and trainers.
[DOCX File , 20 KB - mental_v8i1e20860_app3.docx]

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Abbreviations

e-IMR: electronic Illness Management and Recovery
IM: intervention mapping
IMR: Illness Management and Recovery
IT: information technology
RCT: randomized controlled trial
SMI: severe mental illness

Edited by J Torous; submitted 30.05.20; peer-reviewed by N Thomas, M Zhang; comments to author 27.06.20; revised version received 23.09.20; accepted 06.10.20; published 20.01.21.

Please cite as:
Beentjes TAA, van Gaal BGI, Vermeulen H, Nijhuis-van der Sanden MWG, Goossens PJJ
A Blended Electronic Illness Management and Recovery Program for People With Severe Mental Illness: Qualitative Process Evaluation Alongside a Randomized Controlled Trial
JMIR Ment Health 2021;8(1):e20860
URL: http://mental.jmir.org/2021/1/e20860/
doi:10.2196/20860
PMID:33470945

Corrigenda and Addenda

Correction: Evaluation of a Mobile App to Enhance Relational Awareness and Change During Cognitive Analytic Therapy: Mixed Methods Case Series

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Related Article:

Correction of: https://mental.jmir.org/2020/12/e19888/

(JMIR Ment Health 2021;8(1):e27159) doi:10.2196/27159

In "Evaluation of a Mobile App to Enhance Relational Awareness and Change During Cognitive Analytic Therapy: Mixed Methods Case Series" (JMIR Ment Health 2020;7(12):e19888) the authors noted one error.

The paper was inadvertently published with an incorrect list of affiliations. The original paper listed the authors and affiliations as follows:

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The correction will appear in the online version of the paper on the JMIR Publications website on January 15, 2021, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

Edited by R di Santo; submitted 13.01.21; this is a non–peer-reviewed article;accepted 13.01.21; published 15.01.21.

Please cite as:
Kellett S, Easton K, Cooper M, Millings A, Simmonds-Buckley M, Parry G
Correction: Evaluation of a Mobile App to Enhance Relational Awareness and Change During Cognitive Analytic Therapy: Mixed Methods Case Series
JMIR Ment Health 2021;8(1):e27159
URL: http://mental.jmir.org/2021/1/e27159/
doi:10.2196/27159
PMID:33449906

Corrigenda and Addenda

Correction: A Mindfulness-Based Intervention for Student Depression, Anxiety, and Stress: Randomized Controlled Trial

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Related Article:

Correction of: https://mental.jmir.org/2021/1/e23491/

(JMIR Ment Health 2021;8(1):e27160) doi:10.2196/27160

In “A Mindfulness-Based Intervention for Student Depression, Anxiety, and Stress: Randomized Controlled Trial” (JMIR Ment Health 2021;8(1):e23491) the authors noted one error.

This paper was inadvertently published with an equal contribution footnote for the authors *Paul Ritvo, Farah Ahmad, Christo El Morr,* and the group author *MVC Team*. This was incorrect, as only the authors *Paul Ritvo*, *Farah Ahmad*, and *Christo El Morr* contributed equally. The equal contribution footnote for MVC Team has been removed.

The correction will appear in the online version of the paper on the JMIR Publications website on January 25, 2021, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

Submitted 13.01.21; this is a non–peer-reviewed article;accepted 13.01.21; published 25.01.21.

Please cite as:
Ritvo P, Ahmad F, El Morr C, Pirbaglou M, Moineddin R, MVC Team
Correction: A Mindfulness-Based Intervention for Student Depression, Anxiety, and Stress: Randomized Controlled Trial
JMIR Ment Health 2021;8(1):e27160
URL: https://mental.jmir.org/2021/1/e27160
doi:10.2196/27160
PMID:33493128

Original Paper

The Effects of Downloading a Government-Issued COVID-19 Contact Tracing App on Psychological Distress During the Pandemic Among Employed Adults: Prospective Study

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Abstract

Background: Downloading a COVID-19 contact tracing app may be effective in reducing users' worry about COVID-19 and psychological distress.

Objective: This 2.5-month prospective study aimed to investigate the association of downloading a COVID-19 contact tracing app, the COVID-19 Contact Confirming Application (COCOA), released by the Japanese government, with worry about COVID-19 and psychological distress in a sample of employed adults in Japan.

Methods: A total of 996 full-time employed respondents to an online survey conducted May 22-26, 2020 (baseline), were invited to participate in a follow-up survey August 7-12, 2020 (follow-up). A high level of worrying about COVID-19 and high psychological distress were defined by baseline and follow-up scores on a single-item scale and the Kessler 6 (K6) scale, respectively. The app was released between the two surveys, on June 17. Participants were asked at follow-up if they downloaded the app.

Results: A total of 902 (90.6%) of 996 baseline participants responded to the follow-up survey. Among them, 184 (20.4%) reported that they downloaded the app. Downloading of the contact tracing app was significantly negatively associated with psychological distress at follow-up after controlling for baseline variables, but not with worry about COVID-19.

Conclusions: This study provides the first evidence that using a government-issued COVID-19 contact tracing app may be beneficial for the mental health of employed adults during the COVID-19 pandemic.

(JMIR Ment Health 2021;8(1):e23699) doi:10.2196/23699

KEYWORDS

coronavirus disease; digital contact tracing; mental health; working population; longitudinal study; COVID-19; contact tracing; surveillance; tracking; anxiety; distress

Introduction

Contact tracing is one of the most effective methods of controlling infectious diseases. During the 2020 COVID-19 pandemic, many smartphone apps for digital contact tracing have been developed and widely used [1-3]. These contact tracing smartphone apps automatically record contacts with other people through smartphones during everyday life. A user will be notified if someone he/she contacted recently had a positive test result for COVID-19 infection, and be encouraged to take a test for COVID-19. The use of these apps is considered acceptable by a majority of the public [4], despite ethical concerns about people's privacy [5]. Such apps are expected to slow the transmission of COVID-19 [6], although more research is required to confirm their effectiveness. Psychological distress was reported to increase in the community during the nationwide spread of COVID-19 [7-10], partly due to fear of COVID-19 infection [7,9]. Poor mental health has been considered another public health problem related to the COVID-19 outbreak [9]. As a contact tracing app could help users identify their own risk of infection with COVID-19, users can be assured that they are at low risk when no notification comes from the system, indicating that they have not had close contact with people infected by COVID-19. Thus, the use of a COVID-19 contact tracing app may be effective at reducing fear of and worry about COVID-19 and reducing users' psychological distress. However, to date, no study has reported on the mental health effects of using a COVID-19 contact tracing app.

This prospective study aimed to examine the effect of the use of a COVID-19 contact tracing app released by the Japanese government in mid-June 2020 on the perceived threat from COVID-19 and psychological distress in a sample of employed adults in Japan. We examined the association between reported use of the COVID-19 contact tracing app and worry about COVID-19 and psychological distress at follow-up, adjusting for these variables at baseline.

Methods

Study Design and Participants

This study was a 2.5-month prospective study with two consecutive online surveys. Participants responded to an online "closed" survey conducted May 22-26, 2020 (baseline), which was part of a larger longitudinal study of full-time employees aged 20-59 years that were recruited by an internet survey company (Macrimill Inc) from a large pool (>1,300,000) of self-selected preregistered community-dwelling residents across Japan [11,12]. After excluding 36 respondents who were unemployed at baseline, as their financial or health condition may confound study findings, a total of 996 respondents were invited via email to participate in a follow-up survey on August 7-12, 2020 (follow-up). Between the two surveys, Japan experienced the second wave of the outbreak; in 78 days (May 27-August 12), the number of new COVID-19 cases per day increased from 22 (on June 8) to a maximum of 1595 (August 7), with an average of 440 per day [13]. All surveys were made using online questionnaires on a website that was specifically designed for the surveys and required an ID and password to log in. The survey system allowed each respondent to submit a questionnaire only once. Each questionnaire consisted of 73 questions displayed on one page, with automated completeness checks before the questionnaire was submitted; no review step was provided. The participants were given a small incentive (a token equivalent to 30 JPY [US $0.29]) for completing each questionnaire. Study participants were informed about the purpose of the study, the investigators, the length of the questionnaires, and processes related to the data (anonymization, place and duration of storage), and participated in the surveys voluntarily.

Use of the COVID-19 Contact Tracing App

On June 19, 2020, the Japanese government released a free contact tracing app for COVID-19, called the COVID-19 Contact Confirming Application (COCOA), for iOS and Android [14]. The app does not collect personal information such as phone numbers or location. Rather, the app records encounters with other phones that were within one meter and lasted for more than 15 minutes as encrypted data. The users are notified when a user who they have come into close contact with for more than 15 minutes reports a positive test result for COVID-19; the notification only occurs after the contact enters the positive result in the app and allows the result to be shared to other users anonymously. In addition, the validity of the app measuring the information was not reported and thus is unclear. The app had been downloaded 13.2 million times by August 14, 2020 [14]. By then, 252 (0.002%) users were confirmed to have COVID-19. Participants were asked if they downloaded this app (yes or no) at follow-up [14].

Measures

Worry About COVID-19

We used a single-item scale to measure worry about COVID-19 at baseline and follow-up, by asking "Do you worry about COVID-19?" and using a 6-point Likert-type response scale [11,12]. The responses were dichotomized into high ("strongly" to "somewhat positive") and low ("somewhat negative" to "not at all").

Psychological Distress

Psychological distress (depression and anxiety) in the last 30 days was measured using the Kessler 6 (K6) scale [15] at baseline and follow-up. Acceptable levels of reliability and validity of the Japanese version have been reported [16,17]. Psychological distress was defined as having a K6 score of ≥5, corresponding to a mild level of distress, according to a previous study [17]. For a sensitivity analysis, we also used severe psychological distress (K6 score ≥13) as an alternative outcome [18].

Demographic Variables

Participants were asked their sex (male or female), age (<35 years, 35-49 years, or ≥50 years), marital status (currently married or not), educational attainment (high school graduate and lower or university graduate and higher), and occupation (managers, non–manual workers, manual workers in non–health care settings, or health care workers); whether they work from home (yes including partially or never), live with a child up to

high school age (yes or no), or live in high-risk areas designated during the COVID-19 emergency between April and May 2020 by the government (yes or no) [19]; and if they had any chronic physical condition (any of 10 predetermined conditions) at baseline.

Statistical Analysis

The adjusted prevalence of worry about COVID-19 and high psychological distress at follow-up (controlling for baseline levels) were compared between those who did or did not use the COVID-19 contact tracing app (Mantel-Haenszel chi-square test). Multiple logistic regression analyses were conducted to estimate the effect (odds ratio [OR] and 95% CI) of worry about COVID-19 or high psychological distress at follow-up, adjusting for the baseline demographic variables and baseline values of these variables. No weighting was made to adjust for the nonrepresentativeness of the sample. Statistical significance was set at $P<.05$. SPSS (Version 26.0; IBM Corp) was used for analyses.

Ethical Considerations

Online informed consent was obtained from all participants with full disclosure and explanation of the purpose and procedures of this study. We explained that their participation was voluntary, and that they could withdraw consent for any reason, simply by not completing the questionnaire. This study was approved by the Research Ethics Committee of the Graduate School of Medicine/Faculty of Medicine at The University of Tokyo [number 10856-(2)(3)(4)(5)].

Results

A total of 902 (90.6%) of 996 participants at baseline responded to the follow-up survey. Among them, 184 (20.4%) reported that they downloaded the app. The respondents who downloaded the app were significantly more likely to be male, older, living with a child, university graduates or higher, and working from home than respondents who did not download the app (Table 1). Prevalence of high psychological distress was slightly but not significantly greater among app users at baseline, but the pattern was reversed at follow-up. Compared to the national labor force statistics in Japan, the sample was less represented by manual workers, while sex and age distributions were similar.

Downloading of the app was significantly negatively associated with psychological distress at follow-up after adjusting for psychological distress at baseline (adjusted prevalence of 42.2% and 49.6% for users and nonusers, respectively; OR 0.61, 95% CI 0.39-0.93; $P=.02$). Downloading of the contact tracing app was significantly negatively associated with psychological distress at follow-up in the group without high psychological distress at baseline ($P=.04$; Multimedia Appendix 1). Downloading of the app was not significantly associated with worry about COVID-19 at follow-up after adjusting for worry about COVID-19 at baseline (adjusted prevalence of 61.9% and 61.9%, respectively; OR 1.01, 95% CI 0.68-1.51; $P=.96$). Downloading of the app was significantly negatively associated with psychological distress at follow-up after adjusting for all covariates (OR 0.59, 95% CI 0.38-0.91; $P=.02$; Table 2). Downloading of the app was not significantly associated with worry about COVID-19 (OR 1.25, 95% CI 0.65-2.40; $P=.50$).

We conducted these multivariate analyses using age with a different categorization (20-29 years old, 30-39 years old, 40-49 years old, and 50-59 years old) and as a continuous variable, and obtained similar findings. When using the alternative definition of severe psychological distress (ie, K6 score of ≥13), downloading of the app was not significantly associated with severe psychological distress at follow-up (adjusted prevalence of 13.0% and 13.2% for users and nonusers, respectively; OR 0.88, 95% CI 0.54-1.44; $P=.71$) or after adjusting for all covariates (OR 0.95, 95% CI 0.54-1.69; $P=.92$).

Table 1. Demographic characteristics at baseline and psychological variables at baseline and follow-up among respondents who used or did not use the COVID-19 COntact COnfirming Application (COCOA) at follow-up.

Variables	Total sample (N=902), n (%)	Nonusers (n=718), n (%)	App users (n=184), n (%)	*P* value[a]	National Labour Force Survey[b], %
Sex (female)	434 (48.1)	361 (50.2)	73 (39.7)	.001	45.2
Age, years					
20-34	262 (29.0)	224 (31.2)	38 (20.7)	.01	30.3
35-49	375 (41.6)	294 (40.9)	81 (44.0)	—[c]	43.4
50-60	265 (29.4)	200 (27.9)	65 (35.3)	—	26.3
Marital status (married)	662 (73.4)	525 (73.1)	137 (74.5)	.78	ND[d]
Living with a child (yes)	228 (25.3)	167 (23.3)	61 (33.2)	.008	ND
Education (university or higher)	476 (52.8)	358 (49.9)	118 (64.1)	.001	ND
Occupation					
Managers	93 (10.3)	66 (9.2)	27 (14.7)	.16	1.3
Non–manual workers	480 (53.2)	384 (53.5)	96 (52.2)	—	35.5
Manual workers	232 (25.7)	190 (26.5)	42 (22.8)	—	57.7
Health care workers	97 (10.8)	78 (10.9)	19 (10.3)	—	5.6
Working from home (yes)	298 (33.0)	213 (29.7)	85 (46.2)	<.001	ND
Chronic condition (any)	298 (33.0)	213 (29.7)	85 (46.2)	.29	ND
Living in prior high-risk areas (yes)	635 (70.4)	508 (70.8)	127 (69.0)	.65	ND
Worry about COVID-19					
At baseline	513 (56.9)	403 (56.1)	110 (59.8)	.40	ND
At follow-up	559 (62.0)	442 (61.60	117 (63.6)	.67	ND
Psychological distress (K6 score of ≥5)					
At baseline	414 (45.9)	323 (45.0)	91 (49.5)	.28	ND
At follow-up	434 (48.1)	352 (49.0)	82 (44.6)	.28	ND

[a]Based on the chi-square test.

[b]Proportions among employed adults aged 20-59 years (N=51.8 million) based on the Japan National Labour Force Survey 2019.

[c]—: not available.

[d]ND: no data.

Table 2. The association between use of the COVID-19 contact tracing app and worry about COVID-19 and high psychological distress at follow-up, adjusting for covariates at baseline.

Variables	Worry about COVID-19 (high)		High psychological distress (K6 score of ≥5)	
	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Use of the contact tracing app (yes)	1.25 (0.65-2.40)	.50	0.59 (0.38-0.91)	.02[a]
Sex (female)	2.77 (1.56-4.93)	.001[a]	1.13 (0.77-1.67)	.52
Age (years)				
20-34	1.00	N/A[b]	1.00	N/A
35-49	1.12 (0.63-1.99)	.71	1.21 (0.79-1.86)	.38
50-60	2.44 (1.16-5.15)	.02[b]	0.98 (0.60-1.59)	.94
Marital status (married)	0.63 (0.34-1.15)	.13	1.54 (1.02-2.33)	.04[b]
Living with a child (yes)	1.22 (0.65-2.27)	.54	1.16 (0.75-1.80)	.50
Education (university or higher)	1.10 (0.63-1.92)	.75	1.10 (0.75-1.61)	.64
Occupation				
Managers	1.00	N/A	1.00	N/A
Non–manual workers	1.03 (0.44-2.41)	.95	1.83 (0.95-3.53)	.07
Manual workers	1.37 (0.51-3.70)	.54	1.96 (0.95-4.03)	.07
Health care workers	1.02 (0.32-3.24)	.97	2.54 (1.10-5.84)	.03[b]
Working from home (yes)	1.60 (0.90-2.84)	.11	1.30 (0.87-1.96)	.20
Chronic condition (any)	1.12 (0.56-2.23)	.75	1.62 (1.03-2.55)	.04[b]
Living in prior high-risk areas (yes)	0.56 (0.31-1.03)	.06	0.80 (0.54-1.18)	.25
Baseline psychological status				
COVID-19 anxiety	3.03 (0.26-135.83)	<.001[a]	N/A	N/A
Psychological distress (K6 score of ≥5)	N/A	N/A	20.64 (14.39-29.60)	<.001[a]

[a]*P*<.05.

[b]N/A: not applicable.

Discussion

Principal Findings

This study found that downloading of the COVID-19 contact tracing app released by the Japanese government was significantly negatively associated with psychological distress in a sample of employed adults in Japan. This is the first evidence indicating that a COVID-19 contact tracing app may be beneficial for people's mental health during the COVID-19 pandemic. Unexpectedly, downloading of the COVID-19 contact tracing app did not significantly influence worry about COVID-19. This may be interpreted as the users of the app becoming better able to cope with worry about COVID-19 (a stressor) and reduce their psychological distress, even though they still worry.

A contact tracing app decreased the prevalence of mild psychological distress by 7.4 points on average (a 15% reduction from its prevalence among nonusers). The effect size was rather small, but it might have a large impact on mental health (which has been reported to have deteriorated during the pandemic [7-9]) because there are a large number of potential users. However, we could not replicate the finding when using severe psychological distress (K6 scores of ≥13) as an indicator of poor mental health. This is partly attributable to the small sample size, with a lower prevalence of severe psychological distress than mild physical distress in the sample. Another possibility is that the effect of the app may be less clear for those with a severe level of psychological distress or recovering from it. This corresponds to our observation that downloading the app was significantly negatively associated with high psychological distress at follow-up only in the group without high psychological distress at baseline. The present finding should be replicated with mental health indicators measuring different levels of distress severity in a larger sample. The mechanism underlying the negative association between downloading the app and psychological distress is unclear. Downloading the app itself may serve as an attempt at active coping against the threat of COVID-19 infection for the users, which could improve their sense of control or self-efficacy and reduce psychological distress [20]. Another possibility is that users may have a better personal relationship with family, friends, or colleagues as a result of downloading the app because the users could be seen as "trustworthy" by those around them due to them taking

preventive measures (ie, using the app). This may be quite important in circumstances where physical distancing is encouraged and discrimination and stigma related to COVID-19 are increased [20]. Improved social relationships may lead people to have better social support, and thus their psychological distress could be reduced. The psychological effects of downloading a COVID-19 contact tracing app as well as the underlying mechanisms behind those effects should be investigated using relevant psychological theories and scales in future research.

While the app certainly provides users with objective information about the risk of COVID-19 infection, participants' worry about COVID-19 (ie, perception of the risk of infection) was not different at follow-up between users of the contact tracing app and nonusers. In fact, the number of notifications that users had been in contact with a COVID-19–positive person was very limited (only 0.002% of users registered as having COVID-19 as of August 14, 2020, in the case of the COCOA app) [14]. However, users who do not receive contact notifications may not be assured that they have a low risk of being infected because there are many other opportunities for infection that the app cannot inform them about. This finding is consistent with a previous report indicating that implementing measures to protect against COVID-19 in the workplace was not associated with a reduction in the perceived risk of COVID-19 infection [11]. The effect of using the app may not be strong enough to decrease uncertainty [21] and change the perceived risk of infection.

Although this study indicated a possible benefit to mental health related to using a contact tracing app, there are other issues to be considered before encouraging the use of the app [21]. There are still privacy concerns because the anonymization process may not be perfect; it is unclear how long the collected data will be stored; and the system may be vulnerable to a cyberattack [5,22]. There are also concerns about the transparency and accuracy of such apps; it is hard for people to judge the quality and trustworthiness of the apps, even if the source code is published. Therefore, the apps should be pretested to indicate how accurately they measure proximity to and meaningful contacts with positive cases [22]. It is necessary to investigate the extent to which privacy concerns and possible measurement errors are ethically and psychologically acceptable. There is also concern about unintended side effects. Related to our study finding, for instance, the apps may increase the psychophysiological arousal of users as they continuously await the arrival of a notification, which could lead to physical complaints and sleep problems. Such an adverse effect of downloading this type of app should be investigated and if adverse effects exist, warnings should be communicated to the users. As all these issues could influence the use of the app itself, as well as the possible mental health benefit of using the apps, future research should be conducted to fully explore the ethical and behavioral aspects of the use of a contact tracing app.

Limitations

First, although the study employed a prospective design, downloading of the contact tracing app was measured at follow-up. Thus, the direction of causality between use of the app and psychological distress is unclear; it is conceivable that participants whose mental health has improved are more likely to start using the app. In addition, users had to complete a few steps after downloading the app to approve the use of the app and allow it to access the Bluetooth function. Thus, downloading the app may not necessarily be equal to use of the app. Some may have uninstalled the app soon after they downloaded it. Research using a more accurate assessment of the use of the app is needed to confirm our findings. Second, we investigated the effect of a government-released contact tracing app in this study. The findings may not be applicable to similar contact tracing apps released by commercial entities, which may be less trusted by people than government-released ones. Third, because the study sample included only employees, and might be demographically biased in some other way, the findings may not be generalizable to the general population (eg, they might not apply to unemployed individuals who might be experiencing financial hardship or have severe health conditions). The prevalence of psychological distress in this sample (40%-50%) was slightly higher than that reported in previous studies (34%-38%) [10]. The sample may be more distressed than the general population. Furthermore, the finding may not be generalizable to other countries with different policies, cultural norms, and behaviors (such as wearing masks) in response to the COVID-19 pandemic. The risk of infection and mortality may also be different from other countries, as Japan had a less stringent policy on social distancing (eg, lockdown), a higher proportion of people wearing masks [23], and a lower proportion of confirmed cases per capita [13] during the study period. Fourth, while the sampling ratio of the respondents to the total employed population of Japan was extremely small, it is unlikely that some respondents were from the same family, social group, or workplace. However, if that was the case, it could result in an overestimation of the effect of the app. Fifth, behavioral patterns underlying the use of the app [24,25] and social desirability may confound the findings. For instance, participants may respond favorably to both questions about downloading the app and psychological distress. A relationship between the motivation to use the app or the duration of app use and psychological distress was not investigated in this study. The living environment, family environment, and social environment of the respondents may confound the findings. We could not investigate differences in the effect of using the app among various demographic groups, such as sex, age, and educational attainment, due to the small sample size. Future research should address these issues.

Conclusion

This prospective study found that downloading of the COVID-19 contact tracing app released by the Japanese government was significantly negatively associated with psychological distress in a sample of employed adults in Japan. Downloading of a COVID-19 contact tracing app may reduce psychological distress among users during the COVID-19 pandemic. However, other ethical and psychological issues related to contact tracing apps need to be fully discussed and resolved before recommending the app to public health officials.

Acknowledgments

This work was supported by a JSPS KAKENHI grant (number JP18H04072) and internal funds of the Department of Mental Health, Graduate School of Medicine, The University of Tokyo. These sponsors had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; or the decision to submit the manuscript for publication.

Authors' Contributions

NK was in charge of this study, supervising the process and providing his expert opinion. NS and NK organized the study design and analyzed the data. RK, KT, and KI ensured that questions related to the accuracy or integrity of all parts of the work were appropriately investigated and resolved. All authors participated in conducting the survey. NK wrote the first draft of the manuscript, and all other authors critically revised it. All authors approved the final version of the manuscript.

Conflicts of Interest

NK reports grants from Fujitsu LTD and SBAtWork Corp, and personal fees from the Occupational Health Foundation, Japan Dental Association, Sekisui Chemicals, Junpukai Health Care Center, Osaka Chamber of Commerce and Industry, as well as nonfinancial support from the Japan Productivity Center, none of which are related to the submitted work. The other authors declare no conflicts of interest.

Multimedia Appendix 1
Supplementary table.
[DOCX File , 15 KB - mental_v8i1e23699_app1.docx]

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Abbreviations

K6: Kessler 6
OR: odds ratio

Edited by G Eysenbach; submitted 26.08.20; peer-reviewed by D Korngiebel, J Weissert; comments to author 13.10.20; revised version received 19.11.20; accepted 03.12.20; published 12.01.21.

Please cite as:
Kawakami N, Sasaki N, Kuroda R, Tsuno K, Imamura K
The Effects of Downloading a Government-Issued COVID-19 Contact Tracing App on Psychological Distress During the Pandemic Among Employed Adults: Prospective Study
JMIR Ment Health 2021;8(1):e23699
URL: http://mental.jmir.org/2021/1/e23699/
doi:10.2196/23699
PMID:33347424

Original Paper

Psychological Impact of the COVID-19 Pandemic on Chinese Health Care Workers: Cross-Sectional Survey Study

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Related Article:

This is a corrected version. See correction statement: https://mental.jmir.org/2021/2/e27596

Abstract

Background: The outbreak of COVID-19 has dominated headlines worldwide. The number of infections has continued to rise and had reached 30,000 worldwide at the time this paper was written. Because of the high risk of nosocomial transmission, medical health care workers may be experiencing substantial psychological stress. This descriptive study aimed to identify psychosocial effects on hospital staff associated with working in a hospital environment during the COVID-19 outbreak.

Objective: Our survey participants included 57 frontline clinicians working at Wuhan First Hospital and 157 medical students working at Jiangsu Provincial People's Hospital during the COVID-19 outbreak. The questionnaire we adopted included questions regarding the participants' personal well-being, sociodemographic characteristics, and psychological status.

Methods: 57 frontline clinicians working in Wuhan First Hospital and 157 medical training students working in Jiangsu Provincial Peoples Hospital during this outbreak participated in our survey. The questionnaire we adopted included questions regarding the participants' personal well-being, sociodemographic characteristics and the psychological status.

Results: The COVID-19 outbreak had psychological impacts both on formal workers and medical students. The psychological effects included sleep disorders, anxiety, and depression. There was no significant difference between the group of formal workers and medical students (P=.85), and more than 50% (30/54, 56%, vs. 83/157, 52.9%) of the respondents reported pandemic-related mental disorders.

Conclusions: Our study indicates that the high risk of SARS-CoV-2 exposure caused substantial psychological stress among health care workers. This finding emphasizes the need to promote psychological crisis intervention for medical personnel during this epidemic.

(JMIR Ment Health 2021;8(1):e23125) doi:10.2196/23125

KEYWORDS

2019-nCoV; COVID-19; frontline clinician; medical students; psychology

Introduction

A novel pneumonia associated with a coronavirus broke out suddenly in Wuhan, China in December 2019 [1]. The Chinese government reported that approximately five million residents left Wuhan and traveled to other provinces within China, while thousands of people reached other countries before the lockdown. The number of infections continued to rise and had reached 30,000 at the time of the writing of this paper according to real-time data on Weibo.com [2]. Along with the rapid expansion of the number of patients, health care systems worldwide were faced with difficult predicaments, including severe shortages of health care workers and medical materials [3]. Furthermore, health care providers had a greater likelihood of being exposed to the virus [4]. Research on the impact of previous epidemic outbreaks on the psychological well-being of health care workers showed that many health care workers presented high levels of psychological distress [5]. Although the Chinese government endeavored to guarantee the security of frontline clinicians, including organizing strict training, providing adequate medical facilities, and discouraging off-work contact, little is known about the psychological effects of the COVID-19 outbreak on hospital workers. The main objective of our study was to investigate whether medical personnel were experiencing significant psychological conflict between their duties and their concern for their own safety [6] and to evaluate whether psychological intervention was necessary.

Methods

Sample

This was a cross-sectional study including 57 frontline clinicians working at Wuhan First Hospital and 157 medical students working at Jiangsu Provincial People's Hospital in Nanjing during the COVID-19 outbreak. First, we distributed the web-based questionnaire among the Wuhan First Hospital frontline staff, and we collected 57 valid questionnaires on March 4, 2020. Later, we conducted a survey among young medical students to investigate their psychological changes associated with the COVID-19 pandemic, and we collected 157 valid surveys. The questionnaire administered to the frontline clinicians consisted of 4 main sections: basic demographic data, the Athens Insomnia Scale, the Self-Rating Anxiety Scale (SAS), and the Self-Rating Depression Scale (SDS). The questionnaire administered to the medical students did not contain the Athens Insomnia Scale. Owing to resource constraints, the distribution of the questionnaire was limited to only those who received the questionnaire on day 2 of data collection. We coded the response categories using the scoring method recommended by Goldberg and Williams [7] and calculated a total score. We used a threshold score of greater than 50 to identify the presence of emotional anxiety and a threshold score of greater than 53 to identify the presence of emotional depression.

Procedures

The questionnaires were completed on a voluntary basis by all willing respondents (physicians, nurses, and medical students working in hospitals during the crisis). We retrieved the completed questionnaires at a computer terminal. Reminders to complete the survey were sent to the volunteers by email.

Ethics Approval and Consent

The studies involving human participants were reviewed and approved by the Ethics Committee of Nanjing Drum Tower Hospital. Written informed consent to participate in this study was provided by the participants.

Statistical Analysis

We analyzed the data using SPSS 25.0 (IBM Corporation). Descriptive statistics were employed to organize the data collected from the survey. Chi-square tests were performed to compare the differences between groups. *P* values <.05 were considered statistically significant.

Results

Demographics

Wuhan Frontline Clinicians

A total of 54 physicians and nurses completed our survey voluntarily. The 54 respondents comprised 45 women (83%) and 9 men (17%) (Table 1). Among these medical staff, 26/54 (48%) were single, 26/54 (48%) were married, and 2/54 (4%) were divorced. Most of the 54 respondents were nurses (n=45, 83%), and physicians represented 17% of the sample. Among the physicians, 2 (22%) held senior professional titles; 6 (67%) held middle titles, and 1 (11%) held a junior title. Among the nurses, 2 (4%) had senior professional titles; 3 (7%) held middle titles, and 40 (89%) held junior titles. In this sample, 12/54 respondents (22%) had a master's degree or above, and 42/54 (78%) had a bachelor's or associate degree.

Table 1. Demographic characteristics of the frontline clinicians at Wuhan First Hospital (N=54).

Characteristic	Respondents with mental disorders (n=30), n (%)	Respondents without mental disorders (n=24), n (%)	*P* value
Sex			.07
Male	2 (7)	7 (29)	
Female	28 (93)	17 (71)	
Age (years)			.75
20-30	14 (47)	11 (46)	
30-40	14 (47)	10 (42)	
≥40	2 (7)	3 (13)	
Education			.44
College or bachelor's degree	25 (83)	17 (71)	
Master's degree or above	5 (17)	7 (29)	
Occupation			.27
Nurse	27 (90)	18 (75)	
Physician	3 (10)	6 (25)	
Tenure in current occupation (years)			.76
≤5	12 (40)	9 (38)	
5-15	16 (53)	12 (50)	
≥15	2 (7)	3 (13)	
Employment title			.44
Junior	23 (77)	17 (71)	
Middle	6 (20)	4 (17)	
Senior	1 (3)	3 (13)	
Marital status			.95
Single	14 (47)	12 (50)	
Married	15 (50)	11 (46)	
Divorced	1 (3)	1 (4)	

Nanjing Clinical Medicine Students

After excluding respondents who had a history of anxiety, depression, or sleep disorders, we included 157 clinical medicine students in our study. From the received data, we found that none of the participants in our study had any symptoms of COVID-19 or a history of direct contact with SARS-CoV-2.

Sleep and Psychological Status

In contrast with the Nanjing clinical medicine students, Wuhan frontline clinicians were asked to complete an additional examination item: the Athens Insomnia Scale. In the group of frontline clinicians, the anxiety-related analysis showed that 9% (5/54) of participants had mild anxiety. Regarding the depression-related results, 35% (19/54) of the medical staff had mild depression, and 7% (4/54) had moderate depression. Synthesizing the results overall, we found that working experience, which was represented by work life, job title, and age, was highly associated with the survey results. People with more work experience had lower anxiety and depression rates. The results also showed that mental disorders were more common in nurses (Table 1).

When the risk of psychological symptoms was analyzed in a subsample of Nanjing clinical medicine students, we calculated that 47.1% (74/157) had mild depression and 1.2% (2/157) had moderate depression. Regarding the anxiety aspect, 4.0% (6/157) generally had mild depression. The distributions of the scores on the SAS and SDS for the medical students who participated in the study are shown in Table 2 and Table 3, respectively.

The high risk of psychological problems among health care providers observed in this study should evoke concern among psychologists.

Table 2. The distribution of the Self-Rating Anxiety Scale scores of the surveyed medical students (N=157).

Symptom	Score, n (%)			
	1	2	3	4
Anxiousness	100 (63.7)	50 (31.8)	3 (1.9)	4 (2.5)
Fear	128 (81.5)	24 (15.3)	2 (1.3)	3 (1.9)
Panic	125 (79.6)	27 (17.2)	3 (1.9)	2 (1.3)
Mental disintegration	142 (90.4)	14 (8.9)	1 (0.6)	0 (0)
Apprehension	68 (43.3)	15 (9.6)	23 (14.6)	51 (32.5)
Tremors	151 (96.2)	5 (3.2)	0 (0)	1 (0.6)
Body aches and pains	124 (79.0)	23 (14.6)	10 (6.4)	0 (0)
Easy fatiguability, weakness	108 (68.8)	42 (26.8)	6 (3.8)	1 (0.6)
Restlessness	50 (31.8)	11 (7.0)	34 (21.7)	62 (39.5)
Palpitation	120 (76.4)	30 (19.1)	5 (3.2)	2 (1.3)
Dizziness	141 (89.8)	15 (9.6)	1 (0.6)	0 (0)
Faintness	151 (96.2)	6 (3.8)	0 (0)	0 (0)
Dyspnea	100 (63.7)	8 (5.1)	7 (4.5)	42 (26.8)
Paresthesia	150 (95.5)	6 (3.8)	0 (0)	1 (0.6)
Nausea and vomiting	126 (80.3)	27 (17.2)	4 (2.5)	0 (0)
Urinary frequency	132 (84.1)	21 (13.4)	4 (2.5)	0 (0)
Sweating	83 (52.9)	19 (12.1)	18 (11.5)	37 (23.6)
Face flushing	136 (86.6)	18 (11.5)	2 (1.3)	1 (0.6)
Insomnia	38 (24.2)	14 (8.9)	38 (24.2)	67 (42.7)
Nightmares	111 (70.7)	44 (28.0)	2 (1.3)	0 (0)

Table 3. The distribution of the Self-Rating Depression Scale scores of the surveyed medical students (N=157).

Symptom	Score			
	1	2	3	4
Feeling downhearted	123 (78.3)	25 (15.9)	6 (3.8)	3 (1.9)
Morning severity	69 (43.9)	32 (20.4)	35 (22.3)	21 (13.4)
Easily crying	138 (87.9)	16 (10.2)	2 (1.3)	1 (0.6)
Insomnia	113 (72.0)	31 (19.7)	11 (7.0)	2 (1.3)
Lack of appetite	53 (33.8)	10 (6.4)	19 (12.1)	75 (47.8)
Decreased interest in sex	54 (34.4)	13 (8.3)	24 (15.3)	66 (42.0)
Weight loss	140 (89.2)	16 (10.2)	1 (0.6)	0 (0)
Constipation	118 (75.2)	31 (19.7)	7 (4.5)	1 (0.6)
Palpitation	131 (83.4)	22 (14.0)	3 (1.9)	1 (0.6)
Exhaustion	113 (72.0)	38 (24.2)	5 (3.2)	1 (0.6)
Difficulty in thinking	45 (28.7)	14 (8.9)	28 (17.8)	70 (44.6)
Scare capacity	51 (32.5)	13 (8.3)	26 (16.6)	67 (42.7)
Uneasiness	123 (78.3)	29 (18.5)	5 (3.2)	0 (0)
Despair	41 (26.1)	16 (10.2)	32 (20.4)	68 (43.3)
Emotion evoked	119 (75.8)	29 (18.5)	7 (4.5)	2 (1.3)
Hesitation	48 (30.6)	27 (17.2)	37 (23.6)	45 (28.7)
Futility	39 (24.8)	18 (11.5)	41 (26.1)	59 (37.6)
Feeling of living in a void	34 (21.7)	81 (51.6)	42 (26.8)	0 (0)
No value	145 (92.4)	10 (6.4)	1 (0.6)	1 (0.6)
Interest loss	40 (25.5)	10 (6.4)	28 (17.8)	79 (50.4)

Discussion

The COVID-19 epidemic is one of the most virulent events that has ever threatened health care systems worldwide [8]. The results of this study show that hospital staff were significantly anxious during the pandemic, and their degrees of concern were moderately high. The greatest concerns of health care workers during the COVID-19 pandemic have been found to be infection and the potential consequences of the disease on their health [9]. At the time of writing of this paper, there had been over 3000 confirmed cases among health care workers [2]. The infection rate of medical personnel in Hubei was eight times higher than that of the general population for many reasons. Firstly, hospitals were the focus of confirmed patients; therefore, health care workers were by necessity susceptible to be exposed to the virus as well as to high exposure doses [3]. It has been proved that SARS-CoV-2 is transmitted through respiratory droplets, contact, and fecal-oral contact; even the eye is a possible transmission channel [10]. The generation of aerosols which only existed in hospital wards greatly exacerbated health care workers' risk of infection [10]. As a result, the perceived risk of being infected was moderately high, and more than 50% (30/54, 55.6%) of respondents had psychological disorders.

Our results showed that relatively high numbers of health care workers experienced moderately high levels of worry during the pandemic, with nurses being more worried than physicians. This phenomenon is reasonable and can be explained by the following causes: (1) the nurses had more and closer contact with patients, and operations such as suctioning and collecting throat swabs exposed them to the disease; and (2) the nurses were generally younger and less educated than the physicians, so they lacked rich clinical experience and had received inadequate mental health education to cope with the difficult situation of the pandemic.

The results of this survey results revealed that the health care workers that came from other cities had higher rates of sleep problems. It is reasonable that the medical staff from outside Hubei Province were not familiar with the particular operation mode in this province compared with local workers. Furthermore, it was inevitable that they would feel fear when they left family and friends, not to speak of going to a dangerous place on their own [11]. Psychological counseling for frontline clinicians should be given attention, especially for those who left their original working environment and assisted during the outbreak in Wuhan.

In general, our research showed that frontline clinicians and clinical medicine students all tended to have higher rates of depression than of anxiety, and more research must be performed to determine the reasons for this finding. There was no significant difference in the rate of psychological disorders between frontline clinicians and medical students (P=.85). It

was evident that frontline clinicians were at greater risk of infection; however, they had a stronger mentality.

Fortunately, most designated hospitals admitting patients infected with SARS-CoV-2 had established a shift system to allow medical staff to obtain sufficient rest. The government and people in general are making their best efforts to provide adequate backup resources for hospitals. We are hopeful that the psychological problems of medical workers can be alleviated if sufficient attention is given to this issue.

Conflicts of Interest

None declared.

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Abbreviations

SAS: Self-Rating Anxiety Scale
SDS: Self-Rating Depression Scale

Edited by G Eysenbach; submitted 02.08.20; peer-reviewed by D Hu, P Liu; comments to author 04.08.20; revised version received 09.11.20; accepted 14.12.20; published 20.01.21.

Please cite as:
Ni J, Wang F, Liu Y, Wu M, Jiang Y, Zhou Y, Sha D
Psychological Impact of the COVID-19 Pandemic on Chinese Health Care Workers: Cross-Sectional Survey Study
JMIR Ment Health 2021;8(1):e23125
URL: http://mental.jmir.org/2021/1/e23125/
doi:10.2196/23125
PMID:33341754

Original Paper

Impact of the COVID-19 Pandemic on Disordered Eating Behavior: Qualitative Analysis of Social Media Posts

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Abstract

Background: A growing body of evidence is suggesting a significant association between the COVID-19 pandemic and population-level mental health. Study findings suggest that individuals with a lifetime history of disordered eating behavior may be negatively affected by COVID-19–related anxiety, and prevention measures may disrupt daily functioning and limit access to treatment. However, data describing the influence of the COVID-19 pandemic on disordered eating behaviors are limited, and most findings focus on individuals in treatment settings.

Objective: The aim of this study is to characterize the experiences of Reddit users worldwide who post in eating disorder (ED)–related discussion forums describing the influence of the COVID-19 pandemic on their overall mental health and disordered eating behavior.

Methods: Data were collected from popular subreddits acknowledging EDs as their primary discussion topic. Unique discussion posts dated from January 1 to May 31, 2020 that referenced the COVID-19 pandemic were extracted and evaluated using inductive, thematic data analysis.

Results: Six primary themes were identified: change in ED symptoms, change in exercise routine, impact of quarantine on daily life, emotional well-being, help-seeking behavior, and associated risks and health outcomes. The majority of users reported that the COVID-19 pandemic and associated public health prevention measures negatively impacted their psychiatric health and contributed to increased disordered eating behaviors. Feelings of isolation, frustration, and anxiety were common. Many individuals used Reddit forums to share personal experiences, seek advice, and offer shared accountability.

Conclusions: Reddit discussion forums have provided a therapeutic community for individuals to share experiences and provide support for peers with ED during a period of increased psychiatric distress. Future research is needed to assess the impact of the COVID-19 pandemic on disordered eating behavior and to evaluate the role of social media discussion forums in mental health treatment, especially during periods of limited treatment access.

(JMIR Ment Health 2021;8(1):e26011) doi:10.2196/26011

KEYWORDS

eating disorders; anorexia nervosa; binge eating disorder; COVID-19; coronavirus; Reddit; social media; disorder; eating; qualitative; experience; mental health; theme

Introduction

The COVID-19 pandemic has disrupted daily living on a global scale, impacting people's routines, living environments, and physical, mental, and emotional well-being. Many countries have implemented public health measures designed to reduce disease spread, including travel restrictions, quarantine or social distancing policies, and face mask regulations. Media outlets, as well as government and public health officials, are frequently publishing news updates and health recommendations to inform and advise the general public [1]. In response to the stress of ongoing events, individuals may be experiencing unfamiliar or worsening feelings of anxiety, anger, loneliness, and uncertainty. Accordingly, there is increasing concern among health professionals regarding the impact of this pandemic on population-level mental health [2].

Unfortunately, research being conducted during the COVID-19 pandemic indicates that the concern regarding the increase in negative psychiatric symptoms is warranted. In a web-based population survey of more than 1200 respondents from nearly 200 cities in China, the first country to report a cluster of novel coronavirus pneumonia, one in two individuals (53.8%) reported moderate to severe psychological impacts from the pandemic; more than one in four (28.8%) reported moderate to severe symptoms of anxiety, and one in six (16.5%) reported moderate to severe symptoms of depression [3]. Symptoms of anxiety and depression, insomnia, and distress are exacerbated among those particularly vulnerable to COVID-19 exposure, such as frontline health care workers [4,5]. However, those at lower risk for adverse outcomes have also reported increased mental health burden resulting from global prevention measures implemented to reduce COVID-19 transmission. Among Chinese youth, the prevalence of both anxiety and depressive symptoms during home confinement exceeds prevalence rates published in studies prior to the COVID-19 pandemic [6]. In the same sample, low optimism regarding the epidemic was associated with increased risk of depressive symptoms.

In addition to increasing symptoms of depression and anxiety, there is concern that the negative emotional effects of the pandemic and associated public health measures will exacerbate eating disorder (ED) triggers and symptoms. Qualitative exploration of ED patients conducted during the initial stages of home confinement supports this presumption; of 32 recovering patients, nearly all expressed concern regarding the negative influence of increased uncertainty related to the pandemic on their daily lives and treatment progress [7]. More than one-third of surveyed patients reported exacerbation of ED symptomatology, and over half reported an increase in anxiety-related symptoms. Large population-based studies have observed similar changes in disordered eating behaviors during the pandemic among people with and without ED. Indeed, of 180 Australian respondents with a self-reported ED history, two in three reported increased restriction, one in three reported increased binge-eating, one in five reported purging more frequently, and nearly half reported increased exercise behavior [8]. Although the majority of people without ED (n=5289) reported no change in disordered eating behaviors, nearly one-third (28%) reported increased food restriction and 35% reported an increase in binge-eating. Notably, for a large number of individuals with current or past ED, living environment, daily routine, and positive coping behavior has been negatively impacted by COVID-19 prevention measures, resulting in a decreased sense of control and the worsening of ED symptoms [9-11]. In contrast, as confinement measures are gradually reduced, significant decreases in ED symptomatology and emotional dysregulation have been observed [12].

Rodgers and colleagues [13] have proposed three distinct pathways through which the COVID-19 pandemic may worsen ED risk. First, it is predicted that public health prevention measures used to decrease COVID-19 spread will adversely affect access to care and social support networks needed for people with ED symptomology. While the medical community has focused its attention on managing the spread of COVID-19, the already difficult challenge of reaching individuals with ED may worsen, treatment-seeking and diagnosis may be delayed, and treatment uptake and engagement may be less effective [14,15]. For many patients receiving psychiatric care, consultation and treatment via telemedicine have become commonplace in recent months [16,17]. Some clinicians have expressed concerns regarding the effectiveness of web-based therapy, especially among those unfamiliar with telehealth [18]. Similarly, despite evidence that most ED patients express favorable attitudes toward teletherapy [14,19], some may question treatment quality or view telehealth as "second best," and willingness to engage in treatment may be reduced [18]. In two separate investigations related to the telehealth transition, ED patients reported feeling like a burden or an inconvenience following dismissal from or suspension of treatment due to the COVID-19 pandemic [10,11]. Some individuals further endorsed the belief that telehealth was not equivalent to in-person treatment [10,11] and reported emotional distress and negative body image stemming from the video requirements of telehealth [10]. Additionally, acceptance of telemedicine may vary by ED subtype, with evidence suggesting that individuals with the anorexia nervosa subtype may be least content with the transition to remote treatment [12]. In inpatient settings, care teams have been reduced in size, visitations have been limited, and admission criteria have become more stringent [16,17,20]. To abide by social distancing guidelines, group therapy sessions have been cancelled or conducted remotely, limiting patients' access to familiar social support networks, though also reducing opportunity for body comparisons [20]. Additionally, physical and financial barriers to treatment may arise among patients with limited computer or internet access [18] and among those whose income has been adversely affected by business closures. For some, web-based ED information and self-help materials may serve as important resources during the pandemic [14]. However, it is noted that high-quality and easy-to-comprehend web-based content may be difficult to obtain [14,21].

Second, it is possible that people who have or are at risk of having an ED may experience increased exposure to ED-specific media or media which increases anxiety related to food, exercise, and weight [13]. In recent months, researchers have identified more than 15,000 Instagram posts referencing the "quarantine-15," a phrase that mirrors the more common "freshman 15," which is often used to describe weight gain

among first-year college students [22]. Some social media posts display indulgent foods that may trigger binge eating, and other posts imply that it is vital to avoid increased body weight by exhibiting weight-stigmatizing content and negative characteristics stereotypically associated with obesity, such as laziness and lack of self-control [22]. In combination with increased media consumption during periods of social distancing, it is likely that greater attention to weight- and food-related content may trigger or exacerbate ED symptoms, given the negative influence of the thin ideal frequently romanticized on social media [23]. In one study, more than half of participants with ED reported the worsening of ED symptoms following increased exposure to food and exercise social media content since implementation of public health prevention and lockdown measures [10]. Although some ED patients, particularly those in recovery, may modify social media accounts to turn attention to positive or recovery-focused content [7], those with untreated ED and those at risk for ED may be especially harmed by these media trends. Across existing studies, ED individuals consistently reported anxiety related to physical activity and the inability to exercise [9-11,24], especially after exposure to exercise-related media content [10].

Third, fear of COVID-19 infection may increase anxiety over food quality, quantity, and potential transmission via certain food products. Specifically, Rodgers and colleagues [13] hypothesize that restriction may occur via reduced purchasing of specific food items and reluctance to leave home to purchase groceries given one's fear of contagion. A positive association between fear of COVID-19, eating restraint, and concerns related to weight or shape emerged from an investigation among both the general population and individuals attending diet clinics for weight loss management [25]. Grocery shopping during the pandemic may prove difficult for those with disordered eating. Touyz and colleagues [26] postulate that problematic relationships with food, including both restriction and binge eating may be exacerbated by food shortages and panic buying. Rigid and inflexible eating behaviors may be challenged by purchasing restrictions and low supply of certain products or brands deemed "safe" by those with restrictive EDs. In one study of 1021 individuals with lifetime ED, more than two-thirds reported being slightly or very concerned about accessing foods consistent with their current meal plan or style of eating [9]. At the same time, food hoarding and the inability to distance oneself from food at home may prove challenging to those with binge eating disorder [15,26,27]. If food is shared among members of the household, bingeing on the family's food supply may introduce unnecessary family conflict [15,26]. Furthermore, as pandemic-related economic strains spread worldwide, financial hardship may give rise to food insecurity—a known correlate of binge-eating behavior [14,23].

Although a number of researchers have expressed similar concerns regarding the impact of the pandemic on disordered eating behaviors, data supporting these hypotheses are limited. Accordingly, this qualitative analysis characterizes the anonymous experiences of Reddit users posting original content in ED-related discussion forums, in which they describe the ways that the COVID-19 pandemic has influenced their mental health and engagement in disordered eating behaviors.

Methods

Data Collection

Reddit, an internet-based social media platform consisting of news stories, web content ratings, and discussion communities, has been denoted as a valuable tool for collection of high-quality psychological research data [28]. This web-based forum is divided into communities of registered users expressing interests in unique discussion topics (ie, subreddits). In this analysis, data were collected from three popular subreddits that acknowledge EDs as their primary discussion topic: r/EatingDisorders (43,500 members), r/AnorexiaNervosa (19,200 members), and r/BingeEatingDisorder (35,700 members). Unique discussion posts dated from January 1 to May 31, 2020, that referenced the COVID-19 pandemic (ie, containing one or more of the keywords *coronavirus*, *COVID*, *quarantine*, or *pandemic*) were extracted using the R RedditExtractoR package (R Project). In addition to the title and content of the public posts, the username of the posting entity, posting date, and number of reply comments were collected. Only the initial posts, and not subsequent replies, were included for data analysis. All discussion posts were written in the English language; thus, language-based exclusions were not applied. As this secondary data analysis is limited to publicly available, web-based content, this research was determined by the University of Florida's Institutional Review Board to be exempt from human subject review. Although the discussion threads are publicly available, usernames have been omitted from this report to protect user anonymity.

Statistical Analysis

Inductive, thematic data analysis was used to elucidate patterns in the data and construct themes describing thoughts and behaviors common to users of ED subreddits during the COVID-19 pandemic [29]. All posts were initially reviewed by one member of the research team (SN). The researcher coded posts line-by-line to gain familiarity with the data and to identify commonalities between threads. Posts representative of multiple thematic constructs were coded into multiple categories as applicable. The researcher (SN) independently developed an initial codebook to outline the scope of topics discussed by users. Two-thirds of the discussion posts (206/305, 67.5%) were then randomly selected to be coded by two additional members of the research team (AF and RH; ie, one-third to each member) to determine disagreement and to finalize codes. Similar codes were grouped into common categories, which were used to construct overarching themes. These themes and associated codes were discussed as appropriate to reach consensus. If consensus was not achieved, a third member of the research team (VS, CS) was consulted for review of discrepant items, and consensus was reached between the three coders. A clinician was available to provide expertise as needed (CM). Once all discrepancies were discussed and agreement was met, a final copy of the codebook was developed (Multimedia Appendix 1) and applied to the data for final code frequency reporting.

Results

Characteristics of Discussion Posts

In total, we identified 33 relevant posts from 33 unique users in r/AnorexiaNervosa, 180 posts from 172 users in r/BingeEatingDisorder, and 92 relevant posts from r/EatingDisorders (restricted subreddit: username and count unknown) that were published between January 1 and May 31, 2020. Collectively, the posts consisted of 66,877 words. The posts were approximately 215 words in length and received between 1 and 73 replies (mean number of comments: 6 [SD 7.7]).

Themes

Six primary themes were identified: change in ED symptoms, change in exercise routine, impact of quarantine on daily life, emotional well-being, help-seeking behavior, and associated risks and health outcomes. Primary themes comprised subordinate themes (secondary themes), as detailed in Table S1 in Multimedia Appendix 1.

Change in ED Symptoms

Content that fell under this overarching theme was specifically related to disordered eating behavior and thought patterns that were influenced by the COVID-19 pandemic and the corresponding preventative measures.

Increased ED Symptomatology

Users often experienced a worsening of ED symptoms corresponding to the onset of the global COVID-19 pandemic. With limited opportunity to leave the home or engage in personal and social activities as a result of quarantine and social distancing guidelines, in two-thirds of posts (201/305, 65.9%), users struggled to ignore obsessive thoughts related to food and weight and to refrain from engaging in disordered eating behaviors prompted by loneliness, anxiety, and boredom. For example, users with self-reported binge eating disorder often described quarantining at home as being “surrounded by food” and described “feeling as if [they wouldn’t] be able to control [themselves] around all the food.” Additionally, many users with ongoing ED symptoms relied on increased frequency of compensatory behaviors (ie, restriction, purging) to cope with changes in their day-to-day routine introduced by the pandemic. One user wrote,“I feel like since I'm not going to be walking and active as much, I need to be even more ‘diligent’ with calorie/counting, etc.”

Some users who described themselves as recovered or in recovery sought comfort in a time of heighted emotional distress by engaging in ED behaviors previously associated with feelings of comfort and control. These users found the newly implemented COVID-19 restrictions to be very disruptive to the recovery mindset and other recovery-oriented practices. One user who described themselves as currently in recovery stated:

> *Quarantine has given me too much time to think about my loss of control and all of the negatives I've held against myself over the years. […] As the days go on, I feel myself slipping into loneliness, depression, and anorectic tendencies.*

For a small number of individuals, disordered eating behavior was not present prior to the pandemic. These users primarily sought to gauge the severity of their diet behavior and their newfound anxieties related to food and weight:

> *With this quarantine going on and everyone in my country are required to stay at home, I didn't get the chance to exercise. I lost control, ate a lot of snacks and every time I weigh myself I see the numbers fluctuating. […] I started to restrict even more, I stopped having my dinners and I purchased weeks worth [sic] of meal replacements. I just wanted to get to the weight I at least liked myself in.*

Decreased ED Symptomatology

One in ten users (n=37, 12.1%) reported less frequent or less severe ED symptoms corresponding to the onset of the COVID-19 outbreak. These users primarily discussed using the pandemic as an opportunity to focus on ED recovery and had successfully reduced the frequency or severity of disordered eating behaviors. However, many of those with decreased ED symptomatology expressed concern regarding reversion to ED behavior, as COVID-19 prevention measures were lifted. For one user who experienced a decrease in ED behavior while in quarantine, this concern was particularly relevant:

> *Since the covid started I tried to focus on my eating disorder and bringing myself to have a healthier relationship with food. I thought I was doing pretty good, because my mom was home and she was the one that made meals and pushed me to eat. This week she has gone back to work, and I’ve sort of been struggling a lot. I struggle with depression so it’s just really hard to bring myself to make a meal.*

Negative Body Image

In approximately one-fifth of posts (64/305, 21.0%), users reported having more time to scrutinize their bodies and eating behaviors. An increase in body-checking behavior while confined at home was frequently discussed. For some, body dissatisfaction negatively affected daily functioning. One user wrote:

> *I’m scared to look in a mirror, and taking a shower sounds practically terrifying at this point. My body dysmorphia is killing me, much to the point where I can’t even get up to change clothes.*

For a large majority of users reporting negative body image, discomfort with subjective changes in body weight or shape led to increased frequency or severity of compensatory behaviors, including restriction, overexercising, vomiting, and laxative use. One user posted,

> *With the recent quarantine, I am unable to work out the same… just running and doing as much as I can. I’ve found my body changing in ways I am very uncomfortable with. I’m waking up daily weighing myself, logging my food, and checking my Fitbit constantly. I recently started staring in the mirror more and despising the person who looks back.*

Exercise Routine

Content that fell under this overarching theme was specifically related to the influence of COVID-19 on exercise behavior.

Change in Exercise Behavior

Users who engaged in regular exercise often reported difficulty maintaining their exercise routine (41/305 posts, 13.4%). While some users reported decreased motivation to engage in regular exercise, others reported difficulty avoiding excessive exercise. One user described their need to engage in additional exercise to "earn" food—a habit that the user described as both exhausting and anxiety-inducing.

Since the beginning of my forced social isolation, exercise has ramped up to now four hours a day of walking […] It has become consuming and I can't stop no matter what I do. […] Please, please someone help me.

Changes in exercise behaviors had large ramifications for appetite that many users struggled to cope with. Some users aiming to increase physical activity reported discomfort responding to increased appetite. For some, this internal struggle resulted in binge eating behavior, which then tempted them to exercise excessively.

Exercise Facilities Closed or Inaccessible

A small portion of users who engaged in regular exercise expressed frustration with exercise facility closure mandates (13/305 posts, 4.3%). Users explained that their exercise routine served as an alternative to dangerous purging behaviors (eg, vomiting, laxative use) and often helped them manage their ED thoughts and behaviors. Many of those who lost access to exercise facilities as a result of COVID-19 closures experienced difficulty adjusting their exercise routines and reported significant loss in motivation to exercise. Emotional distress and feelings of guilt were common, with a number of users communicating fears of "falling into old habits" without access to the gym.

Impact of Quarantine on Daily Life

Content that fell under this overarching theme described the influence of COVID-19 restrictions on participants' daily routines, living environments, purchasing behaviors, and interpersonal relationships.

Change in Routine/Environment

More than one-third of users (119/305 posts, 39.0%) discussed the ways in which COVID-19 prevention measures directly disrupted their everyday routine. Unable to attend work, school, and social gatherings, many users grappled with boredom and loneliness. As a result of business closures, a small number of users experienced job loss. These individuals felt very defeated and reported experiencing obsessive thoughts related to food and body weight while trying to avoid engaging in ED behaviors.

Some individuals were frustrated by the routines of their friends and family members. Being in close proximity to friends and family members for an extended period of time, some users described a loss of privacy. Some users reported that their family members were unaware of their disordered eating behavior and reported feeling anxious or frustrated when they were unable to engage in compensatory behavior. Other users reported being negatively influenced by the coping behaviors of their family and friends with whom they were quarantining. For example, one user shared,

> *I have been quarantined with my grandmother for the past 3 weeks and will continue to be quarantine with just her for the next month. She keeps cooking out of boredom and trying to hand me giant plates of food every few hours. […] Her CONSTANTLY making me food is so beyond triggering I can not [sic] handle being around it anymore.*

In terms of environment, some users were required to relocate to an alternate living space due to quarantine and social distancing guidelines. For example, a number of college-aged users discussed the need to return to their parents' homes as a result of university closures. For some, this change resulted in the loss of social networks guiding recovery efforts. One user wrote,

> *My college is closed for the remainder of the semester and with that went my support system and all of my friends. School is where I have made the most progress in terms of recovery because I had my boyfriend and friend provided nothing but positivity and support. However, I can't say that's the same at home.*

Users in similar situations anticipated that the home environment would increase personal anxieties and trigger ED behaviors. Many communicated fear of relapse, with one user discussing their fear of reverting to ED behavior while "trapped with those who only make things worse for [them]." In addition to personal relocation, some users experienced changes within their environment, such as roommate travel or relocation.

Food Hoarding or Shortages

Some users experienced significant distress related to changed food availability (34/305 posts, 11.1%). In preparation for citywide or nationwide quarantine mandates, users reported pressure to purchase nonperishable food items in excess of their immediate needs. For these users, the stockpiling of food items, especially those deemed "binge-worthy," instigated intense negative reactions and compulsive urges to act on disordered thoughts and feelings. One user wrote,

> *As a binge eater, it is really hard to grocery shop right now. I know I should go in with a list/plan. But it's like, oh should I get pasta? That will keep for any quarantine. But I'm probably gonna eat a box tonight, so should I get 5 boxes to stockpile? Well then I'll eat a box of pasta every night… then it's like, well might as well get some ice cream and chocolate cuz I already [expletive] up and am eating a box of pasta tonight.*

When the supply of nonperishables was meant to serve the entire household, users often grappled with the guilt they associated with diminishing the family's stockpile. Many felt they were "wasting" food and worried that household conflict would arise

if family members knew they were binge-eating or purging the "COVID food."

Other users responded negatively to the limited food supply available in grocery stores and supermarkets. As the supply of "safe" or routine foods dwindled, users expressed concern that they would be unable to find foods they felt comfortable eating, or that they would be able to maintain the meal plan administered by their treatment provider. Similarly, some users expressed frustration with the inability to binge eat as a result of restaurant closures and reduced availability of "binge" or "trigger" foods in grocery stores and supermarkets.

Navigating Triggering Relationships

As a result of quarantine restrictions, users sometimes faced more frequent interaction with friends or family members who instigated feelings of anxiety, shame, or loss of control (45/305 posts, 14.8%). Unable to eat in private or avoid family meals, many users expressed feelings of sadness and anger after being subjected to criticism regarding their eating behaviors. A large number of individuals reported that their family members did not understand their relationship with food and often felt that their concerns were easily dismissed or ignored by family members. One user explained,

> *My mom is taking my anxiety and depression as a joke and I don't know what else to do. I've tried talking to her about how I'm having harmful thoughts and how I can't stand eating all this food and not going to work to work any of it off and how I'm starting to gain weight… what does she do she calls her friend and is laughing with her friend because "oh she being dramatic and just has cabin fever" like what? No! It's not something that should be taken as a joke.*

Users frequently experienced disordered thoughts after being "forced to eat something" by parents or family members, especially if the meal was deemed a "forbidden" or "triggering" food. For many, body dysmorphia and fear of weight gain was reinforced by increased consumption. Negative body image was further triggered by family members who criticized the body weight or shape of users. One user stated,

> *My mom had always joked about my body/weight (since I used to be overweight, she would joke about me not being able to fit through my door). She don't mean any harm, but I get really devastated when she mentioned that I've gained weight during quarantine. I started to restrict even more.*

Emotional Well-Being

Content that fell under this overarching theme specifically referenced users' moods and emotional health.

Negative Affect

In nearly two-thirds of the posts (191/305, 62.6%) users reported that they experienced negative emotions in response to current events or disordered thoughts and behaviors. Commonly endorsed emotions included fear or anxiety, loneliness and isolation, anger or frustration, guilt or shame, and hopelessness or depression. A large number of users had difficulty reasoning through their emotions. For example, one user wrote,

> *all I've been doing is just lying around. i love movies, but i can't even bring myself to watch a lot for some reason, I'm just really sad. as for my ED, i keep struggling with the same relapses over and over again […] i feel disgusting! i don't know what to do at this point, i feel so alone.*

In general, users felt very defeated by negative emotions. Many users sought support from the Reddit community; others stated they did not seek guidance, but rather a means through which they could convey their thoughts and feelings without judgment.

Help-Seeking Behavior

Content that fell under this overarching theme detailed users' attempts to seek professional or informal help for disordered eating behavior during the COVID-19 pandemic.

Willingness to Recover

In 78/305 posts (25.6%), users communicated a strong willingness to use quarantine mandates as an opportunity to focus on eating disorder recovery. These individuals felt that the absence of a daily routine allowed additional time to curb addictive habits and develop healthier habits. One user described two options for his or herself during quarantine:

> *1. I continue to binge eat and worsen my habits out of boredom and depression.* […]
>
> *2. I use these 2-4 (who knows how long) months to finally adopt the habits I've yearned for and become the person I want to be. I eat right and exercise. I have small daily goals that I accomplish to keep myself distracted.*

Introspection of disordered behavior was common among those aiming to reduce eating disorder symptoms. Many users discussed the identification of triggering food, people, environments, and media. Some provided a short plan to avoid such triggers. Some provided other subreddit members with progress updates and celebrated recovery-focused accomplishments.

Currently Receiving Treatment

Approximately one-tenth of users (30/305 posts, 9.8%) mentioned participating in ongoing treatment programs. However, a small number of these individuals reported discontent with their provider, felt that their provider did not understand the severity of their disorder, or reported that their treating professional did not specialize in eating disorders. Some users expressed concern that telemedicine and internet-based treatment were not sufficient for the level of care they required. One user described treatment during COVID-19 as lacking sufficient structure and support necessary to stifle disordered thoughts and behaviors.

Unable to Receive Treatment

In approximately one-tenth of posts included in this analysis (31/305, 10.2%), users reported the inability to receive ED treatment as a result of the COVID-19 pandemic. For some, this entailed disruption to their ongoing treatment plan or

treatment schedule. A few users were negatively influenced by the sudden loss of access to higher-level care. One user posted,

> *I have been mentally preparing myself for residential treatment […]. Today I found out that my move in date is cancelled until further notice due to covid-19. Trying to navigate this disorder everyday is exhausting and now I have to keep trying to do it at home. It has me feeling completely hopeless and defeated.*

Other users lost access to treatment conducted in the group setting, which left them feeling increasingly isolated. In general, users felt that it had become increasingly difficult to remain in contact with their treatment providers.

Those not currently in a treatment program often reported that traditional barriers to care, such as fees and waiting lists, were exasperated by the ongoing medical crisis. These individuals reported feeling hopeless and often sought advice and support from other Reddit users in lieu of treatment.

Requesting Advice or Accountability From Other Reddit Users

In many posts (152/305, 50.2%), users called for support or guidance from others experiencing similar thoughts and behaviors. The request for an "accountability buddy," a fellow user committed to helping another user confront challenges during recovery efforts, was common. Some users requested support in unraveling difficult emotions and responding to challenging or triggering persons or environments.

Words of Encouragement

In 29/305 posts (9.5%), individuals aimed to encourage and uplift others by discouraging disordered thoughts and behaviors and reaffirming users' ability to recover and develop normalized eating patterns. Most users described their own experiences with ED before offering support to other users. Some discussed their own recent victories and offered motivational comradery, often by reminding one another that they were not alone. One user wrote,

> *I just wanted to let those of you guys really struggling mentally right now that I'm right here with you and that we're gonna make it through this.*

In some cases, users appeared to provide words of self-encouragement using journal-style entries. Prior to journaling food consumption for the day, one user recorded their personal mantras, which included statements such as "It is worth it" and "It will get better."

Seeking Help on Behalf of Another Individual

Ten users (3.3%) posted in search of advice of how to help a loved one with an eating disorder as they dealt with pandemic-related anxiety. These users reported noticing their family member or friend engaging in ED behavior for the first time or to a greater extent than what was observed prior to the pandemic. Users struggled to find ways to support those with ED without encouraging ED behavior. One user wrote,

> *My GF and I started dating about 2 weeks before she went to treatment for Ana. […] This Covid-19 scare has her wrecked. […] How can someone be supportive, but not be enabling?*

Many of these individuals also provided words of encouragement to those with ED. One user stated,

> *Be compassionate and patient with yourself! I don't want to lecture anyone of ED's when I don't have one myself, but my heart goes out to anyone reading this. Anyway, good luck peeps and keep up the good work!*

Associated Risks and Outcomes

Content that fell under the final overarching theme described adverse health behaviors and outcomes that individuals with ED grappled with during the pandemic.

Substance Use Behavior

A small number of users (20/305 posts, 6.6%) described using psychotropic medications to alleviate symptoms of depression or anxiety. Some of these users reported misusing these medications in an effort to suppress weight gain. Other reported using cigarettes, Adderall, or laxatives in an effort to suppress one's appetite or lose weight. Some users were recently prescribed or were currently seeking a prescription for weight loss medication. Most of these individuals were hopeful that weight loss medication would reduce the urge to binge-eat.

Adverse Health Outcomes

In approximately 1 in 10 posts (31/305, 10.1%), users reported experiencing physical pain, gastrointestinal distress, dental distress, or dehydration symptoms as a result of disordered eating behavior. Many felt ashamed of the associated health outcomes and were reluctant to notify others of their physical distress or seek medical attention. Only one user reported that experiencing adverse health events would increase willingness to reduce disordered eating behavior. A small number of individuals expressed concern that their ED (and associated health conditions) would increase their vulnerability to COVID-19.

Discussion

Principal Findings

The objective of this analysis was to characterize the impact of the COVID-19 pandemic on disordered eating behavior using inductive, thematic analysis of ED-related Reddit forums. Consistent with previous investigations [7-12,24,25,30], our findings indicate that the COVID-19 pandemic and associated public health prevention measures negatively impacted the psychiatric health of most users. Users frequently sought comfort in a time of heighted emotional distress by engaging in ED behavior, which was exacerbated by abrupt and involuntary changes in daily routine, exposure to food shortages and panic buying, closure of exercise facilities, and reduced access to care and social support networks. Feelings of isolation, frustration, and anxiety were common, and users frequently sought advice or encouragement from other Reddit users to overcome negative thought patterns. Despite negative emotionality, a small number of users reported using the quarantine mandate as an opportunity to focus on ED recovery and reported successfully decreasing ED symptomatology since the onset of the pandemic.

The findings of this analysis partially align with the hypotheses of Rodgers and colleagues [13], which posit that the COVID-19 pandemic worsens ED risk via limited access to care and social support networks, increased exposure to ED-specific media, and anxiety related to changing food quantity and quality. Reddit users included in this analysis frequently discussed the disruption to or cessation of ED treatment following the onset of the pandemic and struggled with limited access to both formal and informal support networks—a finding that supports the first hypothesis of Rodgers and colleagues [13] and expands on findings from a similar qualitative investigation conducted using a smaller sample of adults with self-reported ED [31]. Our findings also supported the third hypothesis of Rodgers and colleagues and suggested that changed food availability contributed to increased anxiety and ED behavior. Although fear of contagion did not appear to increase food-related anxieties, low supply of certain food products deemed "safe" by those with restrictive ED increased feelings of fear and frustration. Additionally, home stockpiling of food items instigated intense negative reactions and compulsive urges among those engaging in binge-eating and purging behaviors. However, our findings do not support the second hypothesis of Rodgers and colleagues, who postulate that increased exposure to ED-specific media during the COVID-19 pandemic increases risk of ED behavior. In part, this may be the result of data collection via social media.

Notably, this analysis found that peer-based encouragement and role modeling of positive behavior was also common among users of ED subreddits, which may be expected of a social media forum. Users eager to reduce ED behavior shared encouraging stories and messages of support and offered one another shared accountability. In this way, our findings indicate that Reddit forums may function as a positive, therapeutic community for individuals with ED symptoms during periods of heighted emotional distress. This may be especially important during the COVID-19 pandemic, given users' reports of limited access to professional psychiatric care, ED group therapy, and informal social support networks. However, there is evidence that all ED Reddit forums, even those specifically promoting ED recovery, should be carefully moderated to minimize exposure to harmful content promoting ED behavior and to maximize effectiveness as a helpful platform for individuals with ED [30]. Thus, our findings add to the growing body of research that considers the potential role of health care providers in web-based discussion forums. Certainly, health providers treating individuals with ED would benefit from increased understanding of the unique challenges common to those with ED during the pandemic. Therefore, there may be an emerging role for clinicians to monitor such forums as a means to understand the effects of important events such as the COVID-19 pandemic. Additionally, individuals with ED, especially younger patients, may find value in patient-provider communication through such venues, which may be considered more accessible and less anxiety-provoking [32]. However, ethical concerns remain (ie, privacy concerns, professionalism, quality of information), and clinicians have no way to be remunerated for such a role. As social media grows as an integral form of communication between health providers and their patients, it has been recommended that medical professionals receive education to effectively communicate with users and patients via the internet, such that the spread of misinformation is minimized and quality of care is maximized [33]. This may be especially important for ED, as high-quality and easy-to-comprehend internet-based information related to ED is often difficult to obtain [14,21]. In addition to ethical concerns, there is no guarantee that those who use Reddit would be open to clinical guidance via discussion forums; such posts could divert the Reddit platform from its established social function. While acknowledging these concerns, further research should address the acceptability, availability, and effectiveness of clinician participation in such forums.

Limitations

Our findings should be considered in the context of our study's limitations. First, it is possible that additional Reddit discussions related to eating disorder behavior and the COVID-19 pandemic were not considered in our thematic analysis. For example, posts in ED forums referencing the COVID-19 pandemic using terms such as *SARS-CoV-2*, *epidemic*, or *infection* were not included in this study; however, they may contain discussion whose topic or emotion differs from those included in this investigation. Further, posts including only misspelled variations of keywords were not considered. Similarly, only three ED-related subreddits were included in this analysis (ie, r/EatingDisorders, r/AnorexiaNervosa and r/BingeEatingDisorder). It is possible that subreddits without a specific focus on disordered eating behavior may host conversation detailing the influence of the COVID-19 pandemic on eating disorder symptomatology. For example, subreddits such as r/AskReddit and r/AskDocs provide a platform for general health inquiries and patient conversation with nonexperts in medical matters. Individuals posting in such discussion forums may differ from those using ED-specific forums, especially in terms of ED awareness, diagnostic history, and treatment schedule. Future investigation would benefit from a broader investigation of disordered eating behavior during the COVID-19 pandemic among Reddit users posting in non-ED discussion forums. Third, we were not able to confirm the diagnostic history of the Reddit users. Additionally, the demographic characteristics of users included in this investigation is not clear; the users may not be representative of the diverse spectrum of individuals with ED registered to the Reddit community.

Conclusions

For the majority of individuals participating in ED discussions on Reddit, the COVID-19 pandemic has contributed to increased psychiatric distress, disordered eating behavior, and negative body image. In general, Reddit discussion forums have provided a therapeutic community for individuals to share their experiences, seek advice, and provide support for peers with ED. Future research is needed to further assess the impact of COVID-19 on disordered eating behavior and to evaluate the role of social media discussion forums in mental health treatment, especially during periods of limited treatment access, when the already difficult challenge of reaching individuals with ED is exacerbated.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Table S1. Primary and secondary themes of the Reddit posts with descriptions and examples.
[DOCX File , 18 KB - mental_v8i1e26011_app1.docx]

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Abbreviations

ED: eating disorder

Edited by G Eysenbach; submitted 24.11.20; peer-reviewed by T Freeman, M Roncero, L Southwick; comments to author 29.12.20; revised version received 04.01.21; accepted 16.01.21; published 27.01.21.

Please cite as:
Nutley SK, Falise AM, Henderson R, Apostolou V, Mathews CA, Striley CW
Impact of the COVID-19 Pandemic on Disordered Eating Behavior: Qualitative Analysis of Social Media Posts
JMIR Ment Health 2021;8(1):e26011
URL: http://mental.jmir.org/2021/1/e26011/
doi:10.2196/26011
PMID:33465035

Publisher:
JMIR Publications
130 Queens Quay East.
Toronto, ON, M5A 3Y5
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Email: support@jmir.org