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Exploring the Association Between the "Big Five" Personality Traits and Fatal Opioid Overdose: County-Level Empirical Analysis

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Abstract

Background: Opioid-related deaths constitute a problem of pandemic proportions in the United States, with no clear solution in sight. Although addressing addiction—the heart of this problem—ought to remain a priority for health practitioners, examining the community-level psychological factors with a known impact on health behaviors may provide valuable insights for attenuating this health crisis by curbing risky behaviors before they evolve into addiction.

Objective: The goal of this study is twofold: to demonstrate the relationship between community-level psychological traits and fatal opioid overdose both theoretically and empirically, and to provide a blueprint for using social media data to glean these psychological factors in a real-time, reliable, and scalable manner.

Methods: We collected annual panel data from Twitter for 2891 counties in the United States between 2014-2016 and used a novel data mining technique to obtain average county-level "Big Five" psychological trait scores. We then performed interval regression, using a control function to alleviate omitted variable bias, to empirically test the relationship between county-level psychological traits and the prevalence of fatal opioid overdoses in each county.

Results: After controlling for a wide range of community-level biopsychosocial factors related to health outcomes, we found that three of the operationalizations of the five psychological traits examined at the community level in the study were significantly associated with fatal opioid overdoses: extraversion (β=.308, P<.001), neuroticism (β=.248, P<.001), and conscientiousness (β=.229, P<.001).

Conclusions: Analyzing the psychological characteristics of a community can be a valuable tool in the local, state, and national fight against the opioid pandemic. Health providers and community health organizations can benefit from this research by evaluating the psychological profile of the communities they serve and assessing the projected risk of fatal opioid overdose based on the relationships our study predict when making decisions for the allocation of overdose-reversal medication and other vital resources.

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KEYWORDS

opioid addiction; personality traits; community health; text mining; opioid; addiction; psychological

Introduction

Background

According to the Centers for Disease Control and Prevention (CDC), "Opioid abuse and overdose deaths are at epidemic levels in the United States" [1] and are now outpacing car accident fatalities [2]. To address this crisis, government agencies, health care providers, and university researchers alike have considered both big data and technological innovation as sources of solutions. Ingestible sensors monitoring opioid intake,

tracking opioid dispensing rates, and pairing electronic health records with e-prescribing data [3] are some of the promising ways that information systems can help advance medical understanding and action in the context of a fatal opioid overdose. Although existing opioid overdose programs such as those providing Naloxone address the problem in a reactive fashion (ie, when the patient has already taken a nearly fatal dose of medication), this study proposes an approach that could allow health care providers and officials to act proactively in a preventive manner (eg, by prescribing higher-schedule drugs to people in higher risk categories). In particular, we seek to model fatal overdose by taking into account psychological and behavioral traits that often assume the role of invisible underlying factors. As our theoretical foundation, we use the five-factor model (FFM) of the "Big Five" personality traits. Its dimensions are often referred to as OCEAN (openness, conscientiousness, extraversion, agreeableness, and neuroticism). OCEAN and their relationship to substance use has been studied extensively in both the medical and psychological literature [4].

The effect of the FFM dimensions on substance use has been demonstrated across different contexts, including but not limited to age and gender groups [5,6], nationalities [7,8], length and intensity of use [9,10], and types of substance [11,12]. Contextual differences notwithstanding, research shows that personality traits represent a significant factor in understanding various types of substance use, including opioids [10,13]. The effects of the personality traits have been fairly consistent and stable in predicting different aspects of substance use [4] (except for extraversion, which has shown less clear and often inconsistent results). Keeping the relationship between opioid use and personality in mind, we focus on a nascent stream of the FFM inference literature, which emphasizes the feasibility of inferring the Big Five personality traits from self-expressive written artifacts such as social media posts [14,15] due to the moderate to high correlations between the linguistic features of such social media messaging and personality trait measurements established through conventional psychological test surveys [16]. To this end, our study uses extensive unstructured data available from Twitter (we collected and analyzed nearly 19 million geo-tagged tweets) in combination with a literature-driven linguistic analysis approach [17] to derive unique personality profiles on US counties (known as geo-personality).

The potential of social media content for epidemiological surveillance has been demonstrated in the cases of influenza [18] and HIV [19], as well as in the context of adverse behaviors such as suicide [20] and drug abuse [21]. Unlike traditional methods of epidemiology and surveillance (which require significant time and resources to collect and analyze medical diagnostic information, thereby increasing the gap between emergency and response), social media surveillance offers quicker detection and response [22]. Among social media platforms, Twitter has emerged as the leading source of digital surveillance data. In particular, the level of granularity of its data coupled with the ease of data retrieval through the official application programming interface make it feasible to integrate the spatial, temporal, and text models into a unified framework for detection [23].

To ensure the reliability and consistency of our model, which seeks to explore the relationship between personality traits inferred from social media text data and fatal opiate overdose, we used an extensive set of control variables identified by prior literature and relied on a rigorous econometric specification. To alleviate the endogeneity concerns caused by the omitted variable bias, we used a control function approach.

Our analysis yields several important results that illustrate the potential of social media surveillance for improving drug safety and offer theoretical and practical implications for improved patient care, public health, and well-being. Specifically, this study demonstrates the feasibility of assessing the Big Five personality traits from user-generated online content at scale in real time and extends the health informatics literature on the association between personality and opioid fatality, which has thus far only explored this relationship at the state level [24], to a more granular, county-level context. Our results are largely consistent with medical and psychological theory: we find that the traits of extraversion and neuroticism have a significant positive impact on the number of opioid deaths. A divergent finding is the positive effect of conscientiousness on opiate mortality, which persists even with an alternative data mining personality trait inference technique, thereby pointing to the need for a critical examination of the extant computational methods for personality assessment. This surprising outcome notwithstanding, the study shows that personality is a factor that cannot be ignored in the analysis of opioid use behaviors and provides an effective way to infer and integrate it into a comprehensive yet easy to implement model.

Literature Review

Opioids are a class of psychoactive medicinal substances that include semisynthetic prescription pain relievers, synthetic opiates such as methadone and fentanyl, and the illicit drug heroin. Opioids interact with opioid receptors on nerve cells in the brain and nervous system to produce pleasurable effects and relieve pain [25]. Unfortunately, these beneficial effects are often outweighed by the risk of opioid drug dependency—a treacherous path toward addiction and possibly death.

The first stream of literature related to our study focuses on the factors contributing to fatal and nonfatal opioid overdose. Looking through the prism of the *biopsychosocial* model of health and disease proposed by Engel [26], these factors can be broadly categorized as *biological* (age, gender, and comorbidity [27]; history of substance use disorders [28]; or medication intake [29]), *psychological* (sexual identity [30], sexual behavior [31], and history of psychiatric problems [32]), and *socioeconomic* (socioeconomic status [33], educational attainment [28], and history of criminal charges and detention [34]). Despite these three factors' long history in medical research on opioid overdose, research in to personality's influence on fatal drug overdose is lacking.

A second stream of literature examines the role of personality in health care decision making. Specifically, psychology has assembled a compelling body of evidence in support of the link

between personality and health behaviors and outcomes [35]. In longitudinal studies, the best-known taxonomy of personality, the "Big Five" Factor model, has been found to be predictive of health care decision-making styles [36], physician visits and hospitalization probability [37], longevity [38], and obesity [39], among other things.

In the context of substance use specifically, a rich body of literature in both the medical and psychological domains has amassed ample evidence of the relationship between the five FFM traits and various aspects of substance use and dependence. To facilitate comprehension of the role (positive, negative, or insignificant) of each personality trait in substance use established in the extant literature, we provide Table 1. We further use information inferred from this table in the hypotheses development section that follows.

Table 1. The effects of "Big Five" personality traits in the context of substance use.

Study	Substance	Openness	Conscientiousness	Extraversion	Agreeableness	Neuroticism
[40]	Lifetime diagnosis of substance abuse or dependence (including nicotine)	+[a]	–[b]	–	–	+
[41]	SCID[c] substance dependence severity; polydrug use; alcohol	+	–	–	–	+
[42]	Male substance-abusing veterans	N/A[d]	–	N/A	–	+
[43]	Cocaine, alcohol, and heroin	N/A	–	N/A	–	+
[12]	Alcohol abuse	N/A	–	+	N/A	N/A
[12]	Marijuana abuse	+	N/A	–	N/A	N/A
[44]	Alcohol and drug dependence	N/A	–	+	–	N/A
[5]	Youth with conduct and substance use disorders	N/A	–	N/A	–	+
[13]	Opioid dependence	N/A	–	–	N/A	+
[11]	Tobacco, cocaine, and heroin use	N/A	–	N/A	N/A	+
[11]	Marijuana use	+	–	N/A	–	+
[45]	Substance abuse	–	–	+	N/A	+
[46]	Alcohol use	N/A	–	+	–	N/A
[9]	Longitudinal substance use, including tobacco, alcohol, and illicit drugs	+	–	+	–	+
[47]	Nonmedical prescription drug use in young adults	+	–	N/A	N/A	+
[10]	Longitudinal pain and prescription opioid medication use	–	N/A	–	N/A	+
[48]	First-time and subsequent illicit drug use	+	–	+	–	+
[6]	Alcohol use disorder	N/A	N/A	–	–	N/A
[6]	Drug use disorder	N/A	N/A	N/A	–	N/A

[a]Indicates a positive effect.

[b]Indicates a negative effect.

[c]SCID: Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders IV.

[d]N/A: not applicable.

Despite these compelling findings, there is, to the best of our knowledge, a dearth of research exploring personality's role in fatal opioid overdose behavior specifically.

A methodological commonality between the aforementioned streams of literature is their preferred research design: experimental or quasi-experimental cross-sectional or longitudinal cohort studies. Although this design is the "gold standard" for establishing internal validity, health care researchers have long emphasized the need for increased generalizability (ie, external validity) of research findings [49]. Relatedly, new research opportunities provided by the Big Data analytics suggest an avenue for enhancing generalizability through the analysis of unstructured social data at the population level, as opposed to a limited group of individuals [50]. This analytical approach is justified due to the well-documented intrapersonal stability of Big Five traits [51] and the established feasibility of capturing population psychological characteristics through social media [52]. Specifically, the Big Five personality trait scores predicted using psycholinguistic computational modeling have been shown to moderately (.48) to strongly (.65) correlate with the ground-truth personality measurements

obtained through personality questionnaires [16]. The mean absolute error of the scores predicted by this psycholinguistic approach was approximately 11% for each personality trait, suggesting that personality inference based on user-generated text can detect a trait to within slightly more than a tenth of its actual value [16]. Therefore, to address the gap created by the lack of studies investigating the link between personality traits and opioid fatalities at the community (county) level, our study uses a novel and reliable methodology that relies on an expansive survey of social data from the majority of counties in the United States. Our research question, then, is "How can we use the Big Five personality traits in mitigating the opioid overdose crisis?"

Our investigation of this research question contributes to health informatics by demonstrating the feasibility of intelligently mining unstructured (Twitter) data for epidemiologic discoveries. In particular, we make a theoretical contribution by elucidating the relationship between personality and health-related outcomes. Specifically, we provide a more nuanced understanding of personality's influence on fatal opioid overdose through the five distinct dimensions of the five-factor personality trait model. To do so, we build on a burgeoning stream of health care informatics, which establishes social media posts on the topic of opioid substances as a timely indicator of opioid overdose mortality [24,53], by using a combination of advanced computational techniques (cloud computing and text mining) and robust econometric analysis to expand the scope of user-generated content relevant to infoveillance beyond posts directly mentioning opioids. Our study also has several practical implications for health care providers and administrators, as its findings can be applied in opioid overdose prevention and surveillance based on the local counties' prevalent personality traits.

Hypotheses Development

The principal theoretical foundation for this paper derives from the extensive body of research on personality traits. *Personality traits* are enduring styles of thinking, feeling, and acting that characterize an individual [54]. The relative stability of these traits points to consistent and recurrent patterns of acting and reacting that both characterize individuals and differentiate them from others. Similarly, they lead to empirical generalizations about how people with similar traits are likely to act and react [55]. Personality traits have consistently been shown to influence a wide variety of interests and behaviors, such as vocational, social, and artistic interests [54]; brand trust and affect [56]; and internet use [57]. Furthermore, in the health care context, the robust predictive capacity of the personality traits has been established in such complex behaviors as alcohol consumption, exercise routine and obesity index [58], smoking and BMI [59], overall substance use [60], and general health and functional status [59]. The strong link between personality traits and human behaviors, which makes possible the extrapolation of potential future behavioral outcomes based on a given set of personality traits, warrants an in-depth investigation of personality's impact on opioid overdose patterns. Specifically, we used the "Big Five" FFM of personality, considered the most robust categorization of personality traits to date [61]. Notably, the Big Five have demonstrated to be universally representative and to exhibit the same structure across different regions and cultures [62].

The use of the FFM in the study of opioid overdose is particularly salient because of the long-standing stream of studies exploring its relationship with various substance use behaviors, summarized in Table 1. As the table shows, all five traits have a statistically significant effect on substance use, documented across studies spanning different research settings, such as age and gender groups [5,6], nationalities [7,8], length and intensity of use [9,10], and types of substance [11,12]. As evident from the findings of prior studies, different personality traits in the FFM framework play a different role in substance-related behaviors. We further formulate a set of testable hypotheses informed by the extant literature.

Openness is characterized by a high degree of intellectual capacity, wide interests, and unconventional thought [63]. Meta-analyses of the relationship between the Big Five and substance use disorders have largely failed to find a significant impact of openness on substance abuse [4] and mental illness [64]. However, multiple individual studies have found a statistically significant relationship between openness and various types of substance use. Only two studies to date have documented a negative effect of openness on substance use [10,45], while the majority have established a positive effect for the following behavioral constructs: substance abuse and dependence [40,41], marijuana use [11,12], first-time and subsequent illicit drug use [48], and longitudinal drug use [9]. Since the overwhelming majority of FFM studies on substance use point to a positive role for openness, we hypothesize the following:

- Hypothesis 1: Openness will have a positive impact on fatal opioid overdose.

Conscientiousness combines the traits of being diligent, thorough, and being governed by one's conscience [65]. It has a negative relationship with mental illness [64] and various substance use disorders [66]. Specifically, conscientiousness has a known negative effect on alcohol abuse and dependence [12,44,46], longitudinal substance use [9,40], and drug use in particular [11,48]. In addition to the consistent and robust findings in this domain, high scorers on this dimension are expected to shun intentional overdose due to imminent feelings of guilt and this trait's strong underlying facets of responsibility, traditionalism, and self-control [67]. This leads us to hypothesize the following:

- Hypothesis 2: Conscientiousness will have a negative impact on fatal opioid overdose.

Extraversion is characterized by positive affectivity, adventurousness, energy, warmth, and gregariousness [65]. Although this trait has been found to be negatively associated with psychopathology (eg, depression and anxiety) [68] and higher levels of extraversion have been associated with better self-rated health [69] and greater physical activity [59], its role in substance use behaviors remains unclear in the literature [9]. This lack of clarity is evident from the inconsistent empirical findings for this personality indicator—a phenomenon not observed for the other four traits. In particular, some studies

found a positive relationship between extraversion and substance use [44,48], while others document a negative one [13,41] or do not detect an effect [5,11]. Some studies found opposite effects for different substances, namely, a positive effect for alcohol abuse but a negative one for marijuana abuse [12], but it is also possible to detect opposing effects even for the same substance, as in the case of alcohol use disorder, dependence, and abuse, which is positively associated with extraversion in some studies [12,44] but negatively in others [6]. In light of these conflicting findings and the well-documented lack of consistency in this indicator's effect on substance use, we contend that when it comes to fatal intake of opioids, the role of extraversion is best captured in a set of competing hypotheses. We therefore hypothesize the following:

- Hypothesis 3a: Extraversion will have a positive impact on fatal opioid overdose.
- Hypothesis 3b: Extraversion will have a negative impact on fatal opioid overdose.

Agreeableness comprises traits such as trust, modesty, compliance, caring, and emotional support [65]. It is negatively associated with substance use [70], substance dependence severity and polydrug use [41], lifetime substance abuse or dependence [40], alcohol and drug dependence [44], marijuana use [11], cocaine and heroin use [43], first-time and subsequent illicit drug use [48], and substance use and addictive disorders [6,71]. In keeping with the extant literature, we hypothesize the following:

- Hypothesis 4: Agreeableness will have a negative impact on fatal opioid overdose.

Neuroticism (also referred to as emotional range) is reflected both in a person's tendency to experience distress and in the cognitive and behavioral styles that stem from it. Individuals scoring high on this dimension tend to experience chronic negative effects and are prone to various psychiatric disorders [65]. Neuroticism has a strong positive relationship with mental illness, anxiety disorders, internet addiction, smoking, distress, and internalizing problems [72]. Moreover, several studies have found a positive relationship between neuroticism and substance use disorders [4,70,72], opioid abuse [73], and nonmedical prescription drug use [47,74]. Perhaps most telling of this trait's potential role in opioid overdose is its documented positive effect on longitudinal pain and prescription opioid medication use [10]. Death due to opioid overdose can be viewed as another facet of the inherent risk of self-harm associated with the depressive states characteristic of neuroticism. We therefore hypothesize the following:

- Hypothesis 5: Neuroticism will have a positive impact on fatal opioid overdose.

Methods

Mortality Data

The first step in our data collection is related to the dependent variable: opioid overdose deaths. These yearly (2014-2016) panel data were obtained through the WONDER (Wide-Ranging Online Data for Epidemiologic Research) online database [75] from the CDC. This is the primary (and only) publicly available source that provides mortality data based on underlying cause of death, especially at the *county* level. Data are based on death certificates for US residents. Each death certificate contains a single underlying cause of death (and as many as 20 additional contributing causes) and demographic data.

Importantly, due to confidentiality constraints enforced by the CDC, all subnational data points representing zero to nine deaths or births are suppressed [76]. Given this constraint, our sample includes complete mortality data on 701 out of 3007 counties in the United States. To get a sense of opioid-related deaths across counties by year, consider the descriptive statistics in Table 2. To address the limitations associated with data suppression, we used appropriate econometric modeling techniques (discussed later in this paper).

Table 2. Descriptive statistics of the number of opioid-related deaths.

Year	Nonsuppressed counties (>9 deaths), n	Observed number of deaths per county, mean	Observed total deaths across all counties, n	Actual[a] total deaths across all counties, n
2014	585	41	23,923	28,647
2015	617	46	28,185	33,091
2016	701	54	37,526	42,249

[a]Although data on counties with fewer than 10 individuals affected were not available, we were able to obtain data on the total number of deaths across all counties. We subtracted the number of known opioid-related deaths from the total deaths and then divided the result by the "suppressed" counties' populations. The resulting (approximated) mean number of deaths in the suppressed counties equaled 0.8 (SD 1.7).

Twitter Data

In the second step, we obtained unstructured text data for language analysis from Twitter and integrated it with the mortality data. For the purpose of our analysis, we used the publicly available snapshots of Twitter traffic known as "spritzer." This type of Twitter grab provides a vast volume of data for incisive analysis. For example, consider the structure of a single monthly data archive (file) that was preprocessed for text mining purposes: January → 31 days → 24 hours → 60 minutes → 1 minute → *JavaScript Object Notation* (*JSON*) *file.* Each single JSON file contains 1% of Twitter traffic grabbed in a given minute. Each monthly archive (about 450 GB) contains 43,800 (ie, the number of minutes in a month) JSON files with Twitter data (tweets). Extensive data collection and preprocessing (of nearly 17 TB of text data) was accomplished by means of powerful cloud computing resources provided by Amazon Web Services.

Notably, for the purpose of our analysis, we extracted only those tweets that were in English and included a geo-tag (metadata with information on the latitude and longitude associated with the location where the tweet originated). Having preprocessed 36 months of data, we were able to extract nearly 19 million tweets satisfying the aforementioned requirements. Given the structure of the spritzer data set, we found no two tweets that originated from the same account. In other words, the almost 19 million tweets used in our analysis represent unique accounts. Next, we excluded duplicate tweets that were posted by the same author and those that contained less than three words (such tweets accounted for approximately 2% of the whole data set). Further, for the purpose of our county-level analysis, we linked tweets to their origins in the respective counties in the United States. To accomplish this, we linked the geographic coordinates contained in the geo-tags to the respective county Federal Information Processing System (FIPS) codes using the *-geoinpoly-* module [77] for Stata statistical package.

Finally, to increase the validity and reliability of our personality mining approach (which is dependent on the volume of text used for mining), we created personality profiles of the individual counties (vs individual tweets at the user level) by aggregating (ie, concatenating) the resulting text data extracted from tweets at the FIPS code level by year. The resulting mean number of words was about 7000 (SD 11,000).

Given that our final sample includes approximately 18.7 million unique users, our sample represents approximately 26% of the total number of Twitter users in the United States (about 69 million). It also represents approximately 6% of the US population (about 316 million in 2013-2014).

It shall be noted that the actual origin of the tweet might not necessarily have a relationship with that county's incidence. For example, a person might reside in one county (eg, a rural one) but receive a diagnosis or treatment in another county (eg, an urban one); in this case, it would be unclear in which county the tweet actually originated. Therefore, to ensure the robustness of our assumption that tweets in our sample originated from the corresponding counties, we conducted the following analysis. First, we identified those users who self-reported their "location" in their Twitter profiles; they represented approximately 7% of the sample. Second, we compared the "location" value with the tweet origin (as indicated by the geo-tag). The result showed that, of the 7% of users who specified their location, almost 98% tweeted from the same geographic location. These findings confirmed the plausibility of our assumption that the vast majority of the tweets in our sample originated from the counties where the Twitter users in our sample resided.

To ensure that we had approximately equal amounts of data from different types of counties (ie, rural vs urban), we converted the FIPS codes identifying the counties in our sample to the National Center for Health Statistics Urban–Rural Classification Scheme and then examined the distribution of tweets (in terms of word count, because number of individual tweets is a weaker approximation due to the varying number of characters, which range from 1 to 140) across six categories of urban–rural classification (1=large central metro; 2=large fringe metro; 3=medium metro; 4=small metro; 5=micropolitan; 6=noncore). Our results suggest a relatively equal split of the data across all six categories except for the noncore counties, where the total number of tweets is lower due to sparse populations.

Population Characteristics Data

In the final step of data collection, we merged the opioid-related mortality data and Twitter data with an extensive set of county-level population characteristics provided by County Health Rankings and Roadmaps (CHRR). The CHRR program is a collaboration between the Robert Wood Johnson Foundation and the University of Wisconsin Population Health Institute, which provides granular yearly (2014-2016) panel data on health outcomes and behaviors, clinical care, social and economic environments, and physical environments for the more than 3000 US counties [78]. Using a combination of Twitter data along with population characteristics (including those related to health) has been used in a multitude of recent studies [64,79,80].

Dependent Variable

The dependent variable in our study is the *number of deaths associated with opioid drug overdose*. When selecting the underlying causes of death for this variable (based on the recommendations provided by a CDC WONDER official representative in a personal communication), we used the number of deaths for the following International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) codes: T40.0 (opium), T40.1 (heroin), T40.2 (other opioids), and T40.3 (methadone). These data included the following underlying cause of death classifications: drug/alcohol-induced causes: drug poisonings (overdose) unintentional (X40–X44); drug poisonings (overdose) suicide (X60–X64); drug poisonings (overdose) homicide (X85); and drug poisonings (overdose) undetermined (Y10–Y14). As noted previously, the data for counties with fewer than 10 deaths were *suppressed*; that is, the data were not available to the public under any circumstances due to the CDC's privacy policy.

Such a limitation imposes a substantial constraint on the number of observed counties for which data are available (approximately 23% of all US counties), negatively influencing the generalizability of our analysis and findings. One way to address this issue is to impute the missing values using a state-level opioid-related death rate [81] and treat them as left-censored data. However, an even more advantageous approach that relaxes the underlying assumptions on censoring is to treat our outcome as an interval. That is, because the number of deaths cannot be negative, we can treat the missing observations in the outcome as an interval censored between zero and nine. Therefore, to model our dependent variable, we used an interval regression approach. To account for possible limitations associated with our imputation approach and ensure consistency of our estimates, we also ran a fixed-effects model on the reduced sample (see Table B1, Multimedia Appendix 1).

Independent Variables: Personality Traits Mining

Although the analysis of personality traits constitutes an important facet of our understanding of opiate addiction and recovery, measuring latent personality characteristics is a

challenging process [17]. Particularly, traditional personality trait inference involves conducting in-depth personality tests and surveys—a resource-intensive task that is not easily scalable [15]. Such analysis becomes even more complicated when the goal is to assess personality traits of population *groups* (eg, communities, counties, or states) versus individuals.

Computational advances over the past decade have, however, presented an alternative approach that relies on widely available data sources including user-generated content. Specifically, it has been shown that the language one uses, which can be retrieved from their blog posts or other social media messages, is linked to their unique psychological profile [14,82]. This makes possible the use of unstructured text processing methods for assessing personality traits in a reliable and scalable way [83]. Indeed, recent studies have not only demonstrated the feasibility of a lexicon-based approach for personality trait inference but have also shown that this approach is comparable in its effectiveness to the traditional survey-based personality assessment approach and able to predict actual personality traits to within nearly a tenth of their true values [15,16]. Following this promising approach, we adopted a robust lexicon-based implementation well established in the information systems literature [17,84]. We operationalized our main predictor variables—OCEAN—by analyzing a vast unstructured body of tweets obtained from Twitter. Tweets (short messages) represent a form of user-generated content in which individuals' written speech samples might contain a variety of psychological, emotional, cognitive, and structural components that can provide clues to these characteristics. To extract information on the Big Five personality traits associated with individual US counties, we used tweets aggregated (concatenated) at the county level and merged into a single vector per county to infer the latent personality traits by means of linguistic analysis [24]. Specifically, after a preprocessing step including stop word removal, stemming, and lemmatization, the content of each vector was matched with the Linguistic Inquiry and Word Count (LIWC) psycholinguistic dictionary, which had undergone several iterations and presently contains more than 90 distinct variables grouped into categories, including 41 categories capturing psychological constructs such as affect, cognition, and drives [85].

Once the LIWC linguistic dimensions for each vector were available, we followed the procedure in Adamopoulos et al [17] and matched them with their corresponding weighted coefficients developed by Yarkoni [14] by estimating the relationships between OCEAN dimensions obtained from traditional psychological test assessments and LIWC items from user-generated content by the same individuals. The product of each LIWC item score and its corresponding weighted coefficient was used to calculate the dot product for each OCEAN trait for each county, which was then rendered as a percentile score to obtain a comparable indicator for each psychological trait across counties [17,86].

This method for personality trait inference has several important advantages over both traditional psychological test assessments and other self-expression approaches. Compared to traditional survey-based inference, it does not burden respondents with lengthy tasks that are sometimes prohibitive, hamper scalability, and are prone to social-desirability bias whereby the respondent might provide answers about an ideal self rather than their actual character [17]. On the other hand and unlike other self-expression methods, which often include the analysis of writing samples collected in laboratory settings, the analysis of social media data does not impose any restrictions on the length or topic of the writing sample, which makes it more naturalistic and able to more fully reveal underlying personality traits [14].

Control Variables

To ensure correct identification of the focal effects, we included an extensive set of county-specific control variables associated with the health and well-being of the counties' populations (Table 2). Furthermore, based on the prior literature, we considered two essential correlates of the Big Five: *alpha* and *beta* "superordinate" (high-order) factors [61,87]. These factors are based on the *facets* that underlie the corresponding personality traits. Numerous replications have confirmed the correspondence of alpha, or stability, to neuroticism, conscientiousness, and agreeableness, and that of beta, or plasticity, to extraversion and openness [88,89]. To extract data on a plethora of personality facets underlying the corresponding alpha and beta dimensions, we used the IBM Watson Personality Insights service, a tool used in prior studies [90]. (We provide relevant descriptive statistics and operationalizations in Table B1, Multimedia Appendix 1.)

To account for the reflective nature [89] of alpha and beta, we employed principal component analysis to reduce the dimensions of the discovered facets. First, we examined the interitem correlations, the vast majority of which were above the .3 threshold. Second, we employed the Kaiser-Meyer-Olkin measure of sampling adequacy, resulting in satisfactory values (.83 and .70) above the 0.5 threshold for alpha and beta dimensions, respectively. Next, we estimated the internal consistency using Cronbach α, which resulted in satisfactory coefficients of .92 and .80, respectively. For further analysis, we retained four components for each of the two dimensions with eigenvalues greater than 1 (alpha: 8.4, 4.1, 1.7, and 1.2 account for 86% of variation; beta: 4.2, 2.6, 2.1, and 1.2 account for 83% of variation).

Table 3 presents the definitions and descriptive statistics of the variables.

Table 3. Descriptive statistics (N=2891).

Variables	Mean (SD)	Minimum	Maximum
Dependent variable			
Fatal opioid overdose (lower)	10.6 (36.8)	0	972
Fatal opioid overdose (upper)	17.6 (34.9)	9	972
Independent variables			
Openness	74.8 (6.88)	0	100
Conscientiousness	78.2 (6.48)	0	100
Extraversion	19.4 (4.28)	0	100
Agreeableness	33.8 (3.72)	0	100
Neuroticism	44.0 (5.75)	0	100
Control variables			
Age-adjusted years of potential life lost rate per 100,000	7994 (2306)	2397	23,850
Births with low birth weight (<2500g; %)	8.2 (2.0)	2.8	18.8
Adults who reported BMI≥30 (%)	30.8 (4.3)	12	48.1
Indicator of access to healthy foods: 0 is worst, 10 is best	7.2 (1.0)	0	10
Adults who report no leisure time physical activity (%)	27.4 (545)	9.2	44.9
Population with access to places for physical activity (%)	59.6 (23.2)	0	100
Driving deaths with alcohol involvement (%)	31.2 (13.7)	0	100
Sexually transmitted disease (chlamydia cases/population per 100,000)	355.8 (246.7)	34.7	2854.3
Teen births/females aged 15-19 years per 1000	43.4 (19.3)	3.7	130.4
Population younger than 65 years without insurance (%)	17.4 (5.3)	2.9	39.5
Discharges for ambulatory care sensitive conditions/Medicare enrollees per 1000	69.9 (27.7)	153.9	280.6
Diabetic Medicare enrollees receiving HbA_{1c}[a] test (%)	84.3 (6.0)	17.5	97.3
Female Medicare enrollees having at least one mammogram in 2 years (age 67-69; %)	60.8 (8.0)	24.1	84.6
Adults aged 25-44 years with some postsecondary education (%)	55.3 (11.3)	18.7	88.3
Population 16 years or older that are unemployed and looking for work (%)	7.2 (2.5)	0.8	28.2
Children (younger than 18 years) living in poverty (%)	24.4 (9.1)	3.3	65.9
Children living in single-parent households (%)	32.8 (9.7)	0.6	78.6
Households with at least one of four housing problems: overcrowding, high housing costs, lack of kitchen, or lack of plumbing facilities (%)	14.5 (4.3)	4.2	52.4
People who drive alone to work (%)	79.6 (6.0)	6.2	95.3
Among workers who commute in their car alone, those that commute more than 30 minutes (%)	30.4 (11.8)	0.3	71.2
Words contained in aggregated tweets by county (language control variable)	7364 (11,974)	104	46,560

[a]HbA_{1c}: glycated hemoglobin.

Econometric Model Specification

Our estimation method is based on the nature of our dependent variable. Given the privacy constraints resulting in data suppression when the number of reported deaths is less than 10, we decided to treat the missing observations in the outcome as an *interval* censored between zero and nine. Therefore, for an interval type of outcome, we chose a linear regression model with panel-level random effects to test our hypotheses. Note, the fixed-effects specification was not feasible for this because Stata's -xtintreg- command (which we used for estimation) relies on Gauss-Hermite quadrature to estimate the likelihood function, which ultimately keeps the locations and weights of clusters fixed during optimization. To at least partially adjust for this effect, we accounted for yearly fixed effects by including year dummies in the model.

$$y_{it} = X_{it}\beta + C_{it}\beta + \upsilon_i + \varepsilon_{it} \quad \textbf{(1)}$$

for $i = 1,...,n$ counties, where $t= 1,...,n_i$; y_{it} is the outcome of interest; X_{it} is a vector of focal regressors corresponding to the Big Five personality traits; C_{it} is a vector of observed controls; υ_i is a random effect; and ε_{it} is the error term. The observed data consist of the pairs (y_{1it}, y_{2it}), such that $y_{1it} \leq y_{it} \leq y_{2it}$, where y_{1it} is 0 and y_{2it} is possibly $+\infty$. To account for yearly fixed effects, we added year dummies in the estimated models.

Although we made a significant effort to control for observed confounders, there might still be endogeneity caused by omitted variable bias. For example, cognitive abilities [91] and cultural norms [92] are likely to be correlated with the Big Five and to affect drug overdose behavior. To alleviate omitted variable bias concerns, given the nonlinear outcome distribution and the continuous nature of the endogenous Big Five, we used a control function method [93]. First, we needed instruments that are theoretically associated with the personality traits but not with the error term (ε_{it}) in fatal opioid overdoses. Relatedly, the prior literature has emphasized that personality traits are associated with aspects of natural language use and linguistic styles [82,94] as well as grammar and punctuation [95,96]. Neither of these factors is directly related to the behavior leading to drug overdose. We therefore identified multiple language-related characteristics as candidates for instrumental variables. To extract linguistic and writing characteristics from tweets, we used an advanced text analysis application called LIWC2015 [83]. We obtained a set of 46 characteristics (eg, analytic, clout, tone, six-letter words, words per sentence, nouns, verbs, and punctuation). For further analysis, we selected only those measures that were correlated moderately or strongly with the corresponding personality traits and weakly with the outcome, and significantly predicted the corresponding personality traits (Table A1 in Multimedia Appendix 1). Second, to estimate the first-stage residuals, we regressed each of the Big Five personality traits on the selected sets of instruments, Z_{it}, including all second-stage observables (C_{it}):

$$X_{it} = Z_{it}\beta + C_{it}\beta + \alpha_i + \varepsilon_{it} \quad \textbf{(2)}$$

To ensure the validity of our instruments, we further subjected them to a series of weak identification tests. The results are summarized in Table 4.

Our test results provide suggestive evidence in favor of the validity of the selected instruments and, therefore, the plausibility of our endogeneity correction strategy. Therefore, to correct for omitted variable bias in equation 1, we included the first-stage residuals (denoted R_{it}) obtained from equation 2.

Table 4. Weak identification tests of the instrumental variables.

Variables	Anderson underidentification test, *P* value	Stock-Yogo weak-identification test (5%)	Sargan overidentification test, *P* value	Davidson-MacKinnon test of endogeneity, *P* value
Openness	<.001	21.0	.31	.35
Conscientious-ness	<.001	20.9	.30	.59
Extraversion	<.001	19.8	.28	.14
Agreeableness	<.001	18.4	.26	.07
Neuroticism	<.001	20.7	.38	.19

Results

The results of our analysis reveal several insights, including a counterintuitive finding. In Table 5, we present our estimates obtained across several models. First, to establish a baseline for model fit assessment, we proceeded by introducing our control variables only (model 1; refer to part B of Multimedia Appendix 1 for more details related to the selection of the control variables). Second, we included the main effects (model 2) followed by the main effects and control function (model 3) models. Additionally, in Multimedia Appendix 1, we include several models with alternative specifications to account for outcome variable distribution, imputation bias, and additional observed confounders (models 4-6, respectively). These models ensure consistency of our estimates and robustness of our modeling approach.

Table 5. Panel interval regression models of fatal opioid overdose (bootstrapped SEs).

Variables	Model 1		Model 2		Model 3[a]	
	Treatment effect, β (SE)	*P* value	Treatment effect, β (SE)	*P* value	Treatment effect, β (SE)	*P* value
Years of potential life lost rate	–.001 (.0001)	<.001	–.001 (.0001)	<.001	–.001 (.0001)	<.001
Low birth weight (%)	.946 (.185)	<.001	.934 (.176)	<.001	.970 (.221)	<.001
Adult obesity (%)	–.597 (.074)	<.001	–.596 (.085)	<.001	–.638 (.139)	<.001
Food environment index	3.235 (0.655)	<.001	3.184 (0.873)	<.001	4.606 (3.127)	.16
Physically inactive (%)	–.130 (.084)	.12	–.128 (.071)	.07	–.076 (.107)	.48
Access to exercise opportunities (%)	.077 (.011)	<.001	.076 (.001)	<.001	.072 (.019)	<.001
Alcohol-impaired driving deaths (%)	.009 (.013)	.47	.012 (.015)	.43	.014 (.017)	.42
Sexually transmitted infections rate	.008 (.001)	<.001	.008 (.001)	.43	.008 (.002)	<.001
Teen birth rate	.033 (.028)	.24	.041 (.029)	.16	.144 (.191)	.45
Uninsured (%)	–.311 (.128)	.02	–.332 (.154)	.03	–.232 (.293)	.43
Preventable hospital rate	.040 (.008)	<.001	.040 (.011)	<.001	.057 (.035)	.10
Diabetic monitoring (%)	.015 (.037)	.69	.017 (.041)	.68	.003 (.045)	.96
Mammography screening (%)	.041 (.027)	.14	.035 (.027)	.20	.039 (.034)	.24
Some college (%)	.335 (.037)	<.001	.336 (.038)	<.001	.338 (.057)	<.001
Unemployed (%)	–.265 (.097)	.01	–.285 (.124)	.02	–.016 (.594)	.98
Children in poverty (%)	.171 (.068)	.01	.167 (.075)	.03	.204 (.098)	.04
Single-parent households (%)	.142 (.035)	<.001	.144 (.037)	<.001	.133 (.063)	.04
Severe housing problems (%)	1.151 (0.130)	<.001	1.162 (0.179)	<.001	1.232 (0.133)	<.001
Driving alone to work (%)	–.416 (.120)	.001	–.419 (.135)	.002	–.500 (.166)	.003
Long commute–drives alone (%)	.338 (.048)	<.001	.336 (.043)	<.001	.292 (.077)	<.001
Word count (language control variable)	.001 (.0001)	.01	.001 (.0001)	.05	.001 (.0001)	.07
Alpha component 1	.046 (.386)	.91	–.060 (.418)	.89	–.213 (.484)	.66
Alpha component 2	–2.088 (.342)	<.001	–2.102 (.383)	<.001	–2.183 (.389)	<.001
Alpha component 3	1.565 (.472)	.001	1.569 (.471)	.001	1.822 (.595)	.002
Alpha component 4	.259 (.192)	.18	.304 (.231)	.19	.365 (.250)	.14
Beta component 1	.809 (.468)	.08	.893 (.509)	.08	.999 (.555)	.07
Beta component 2	–1.150 (.276)	<.001	–1.279 (.276)	<.001	–1.372 (.330)	<.001
Beta component 3	.700 (.408)	.09	.733 (.366)	.05	.866 (.429)	.04
Beta component 4	1.992 (0.371)	<.001	2.049 (0.382)	<.001	2.165 (0.340)	<.001
Openness	N/A[b]	N/A	.049 (.049)	.32	.060 (.060)	.31
Conscientiousness	N/A	N/A	.229 (.056)	<.001	.243 (.061)	<.001
Extraversion	N/A	N/A	.308 (.076)	<.001	.331 (.098)	.001
Agreeableness	N/A	N/A	–.048 (.060)	.42	–.060 (.064)	.35
Neuroticism	N/A	N/A	.248 (.063)	<.001	.261 (.057)	<.001
Year dummies	Yes	N/A	Yes	N/A	Yes	N/A
First-stage residuals (control function)	No	N/A	No	N/A	Yes	N/A
Observations, n	8317	N/A	8278	N/A	7809	N/A

Variables	Model 1		Model 2		Model 3[a]	
	Treatment effect, β (SE)	*P* value	Treatment effect, β (SE)	*P* value	Treatment effect, β (SE)	*P* value
Counties, n	2891	N/A	2884	N/A	2717	N/A
Akaike information criterion	45,123.1	N/A	44,992.4	N/A	43,157.9	N/A
Bayesian information criterion	45,362.0	N/A	45,266.3	N/A	43,464.3	N/A

[a]Since residuals are estimated for each of the Big Five, there are differential patterns of missing values that ultimately result in missing values when added in model 3.

[b]N/A: not applicable.

Hypothesis 1 predicts a significantly positive impact of openness on fatal opioid overdose. However, the results of our main (conservative) analysis reveal an insignificant relationship (*P*=.32). Although the coefficient is not significant, the sign is positive, as we hypothesized. This is consistent with prior literature that shows a positive relationship between openness and substance dependence [40,41] and use [9,11,12,48]. Although different OCEAN traits uniquely influence substance use, and different substances account for different levels of intensity of each personality trait, extant literature consistently reports the presence of high impulsivity and sensation-seeking in the personality profiles of substance users [97]. This finding is particularly relevant to openness, since the central facet of this trait is being open to new experiences and an elevated willingness to try new things—markers of impulsivity. Therefore, despite the lack of statistical significance for this indicator, we caution clinicians and public health experts in counties with high prevalence of this psychological trait to be mindful of the correlation between certain dimensions of openness and substance use. Clinicians in regions with higher levels of openness may need to engage in more limit-setting counseling and institute more intensive screening practices to monitor opioid use.

In *hypothesis 2*, we hypothesized a negative effect of conscientiousness on the outcome. Surprisingly, however, the coefficient is significantly (and consistently) positive ($\beta_{Conscientiousness}$=.229, *P*<.001), contrary to both *hypothesis 2* and prior literature demonstrating the negative effect of conscientiousness on multiple types of substance use disorders such as alcohol abuse and dependence [12,44,46], longitudinal substance use [9,40], and drug use [11,48]. *Hypothesis 2* is therefore not supported. Given the consistent findings regarding the negative relationship between conscientiousness and substance use in the medical and psychological literature, rather than undermining the robust theoretical link between the two constructs in search of a plausible explanation for the counterintuitive result for conscientiousness, it is more helpful to explore the operationalization of this variable in greater detail instead. A closer look at the lexicon-based personality inference model reveals, for instance, that whereas the average number of LIWC categories associated with each of the five traits in the FFM is 21, only 15 categories significantly correlate with conscientiousness [14]. This peculiarity suggests that this personality trait may not lend itself to measurement with a psycholinguistic dictionary as well as the other four traits. To further investigate this issue, we used an alternative, open vocabulary, big data approach for personality trait inference implemented by the IBM Watson "Personality Insights" service [90]. Interestingly, despite their computational differences—one using LIWC and the other a global vectors approach for word representation (the GloVe word embedding technique)—both operationalizations of OCEAN show a positive sign for the effect of conscientiousness on fatal opioid overdose. Given a mean conscientiousness value of .3 for the alternative operationalization, it is plausible to assume that the model is not very confident in determining whether someone should be attributed this personality trait or not. These findings point to the need for a critical examination of the way linguistic methods for personality trait inference operationalize the construct of conscientiousness. Although we would expect higher levels of conscientiousness to be associated with fewer fatal overdose cases due to the consistent negative relationship between conscientiousness and substance use in the extant literature, our results indicate high concentrations of this psychological trait may point to higher opioid overdose mortality. More work may be needed to help clinicians in counties with particularly high levels of conscientiousness implement specific communication strategies designed to engage in problem solving in the context of pain and opioid therapy. For instance, one of the facets of conscientiousness that may be related to opioid mortality is a persistence-like factor, perseverance, which is not confined to this personality trait alone but rather overlaps with neuroticism, a known risk factor for substance use [98]. It is therefore plausible to expect that areas where this dimension of conscientiousness is elevated might benefit from focused habit-breaking counseling such as cognitive behavior therapy techniques.

Hypotheses 3a and *3b* are a set of competing (positive and negative) hypotheses, which account for the conflicting empirical evidence provided in the existing literature about the relationship between extraversion and substance use. Our model shows a positive statistically significant coefficient for extraversion ($\beta_{Extraversion}$=.308, *P*<.001), thus supporting *hypothesis 3a*. This result suggests that, approximately for a 3-unit increase (percent) in the relative standing of a county on neuroticism, the expected number of overdoses increases by 1 death. Similar positive correlations for extraversion have been found in the context of alcohol use disorder, dependence, and abuse [12,44], as well as first-time and subsequent illicit drug use [48]. A possible explanation for this relationship could be the underlying factors of this personality trait, including high energy and high preference for excitement and stimulation, personality dimensions that have consistently been found to be related to addiction [97]. To curb opioid mortality in regions

with high levels of extraversion, it might be beneficial to engage in problem-solving and limit-setting therapeutic techniques of the kind suggested for high-openness individuals.

Based on *hypothesis 4*, agreeableness will have a significantly negative effect on the outcome. However, our main (conservative) results previously presented demonstrate insignificant impact (*P*=.42). Consistent with the literature [6,40,41,48,71] and our expectations, the direction of the effect is negative. Although the results of our main analysis presented here do not show a statistically significant effect, the results of our robustness analysis (Table B1, Multimeida Appendix B) provide suggestive evidence of the partial support that the effect of the agreeableness personality trait on fatal opioid overdose is significant (*P*=.04). The strong theoretical support for a negative relationship between agreeableness and substance use could be explained by the personality profile of individuals who score low on this trait: hostile, self-centered, and spiteful [6]. This profile correlates with recent findings about the positive association between opioid overdose deaths and high levels of anger [24]. Specifically, although anger and irritation are transient emotional states rather than stable personality traits, individuals experiencing these negative emotions frequently also exhibit a lower ability to regulate anger, a facet at the intersection of high neuroticism and low agreeableness [24]. Opioid mortality monitoring and prevention programs in areas with conspicuously low levels of agreeableness can benefit from developing psychological treatments focused on problem-solving techniques, self-expression, and anger management [24].

Finally, we observed a significantly positive impact of neuroticism on fatal opioid overdose ($\beta_{Neuroticism}$=.248, *P*<.001). Approximately for a 4-unit increase (percent) in the relative standing of a county on neuroticism, the expected number of overdoses increases by 1 death. This result further corroborates a substantial body of empirical evidence in the psychology and medical literature demonstrating a positive relationship between neuroticism and substance use disorders [4,70,72], opioid abuse [73], nonmedical prescription drug use [47,74], and longitudinal pain and prescription opioid medication use [10]. A possible explanation for the robust positive association between high neuroticism and opioid mortality could be the composition of the dimensions comprising this construct, including impulsivity [6], a known risk factor for substance use that is stable across different types of substances [97]. Neurotic individuals tend to be more negativistic, avoidant, and emotionally labile, and exhibit negative affectivity [6,24]. High neuroticism is also related to low agreeableness through the facet of anger regulation, which was recently found to have a positive impact on opioid overdose deaths [24]. It can thus be beneficial for clinicians to closely monitor areas with this personality trait combination (high neuroticism and low agreeableness), as it may amplify the risk for opioid mortality. In terms of possible therapeutic interventions, it might be advantageous to emphasize the strengthening of coping skills and emotion regulation as part of opioid therapy.

Discussion

Theoretical and Practical Implications

Our study is part of a nascent stream of research in health informatics that combines geospatial information, medical data, and unstructured user-generated content used to infer community characteristics. In the context of the relationship between personality and opioid mortality specifically, our study demonstrates the relevance and usefulness of examining personality at the community level, also referred to as geo-personality [24]. This approach allows our personality trait predictor variables to more closely approximate the idiosyncratic nature of opioid deaths, which are known to cluster geographically, with the Midwest, Appalachia, and Northeast of the United States being particularly affected [24]. Personality traits have also been found to cluster geographically, which adds more face validity to our geospatial methodology [24]. The community-level geo-personality infoveillance technique used in this paper has several important implications for the theory and practice of health informatics.

Our model and findings address a gap in the literature, which has hitherto not considered the explanatory power of personality in opioid-related outcomes. Specifically, building on the theoretical foundations of the FFM, we provide a more nuanced understanding of how and to what extent openness, conscientiousness, extraversion, agreeableness, and neuroticism contribute to fatal overdose. This knowledge is important because the relative consistency of the five personality dimensions across individuals and groups (eg, communities or counties) provides a stable and detailed framework for the establishing of relationships and, consequently, prevention of such complex behaviors as opioid overdose. Interestingly, contrary to existing findings [70,71,74], agreeableness was shown to have a positive impact on fatal opioid overdose. This contradiction suggests a need for further examining the complex constructs of the Big Five personality factors in the context of health behaviors; although their underlying constituents show remarkable uniformity along other behavioral aspects, in health choices, these monolithic structures may exhibit internal divisions. Furthermore, although personality assessment has long been an important factor in the recruitment of medical personnel by medical schools and health care facilities, our study points to the importance of assessing personality tendencies among patients as well.

In light of the record-high budget allocations for opioid addiction countermeasures, our findings also contribute to practice and can be used for the purpose of developing actionable intervention plans on the part of local municipalities and health providers alike to prompt assessments of at-risk individuals in real time (and prior to prescription) as opposed to implementing impersonal *en masse* Naloxone programs; guidelines for design and implementation of psychometric segmentation strategies, a form of market segmentation that divides consumers into subgroups based on shared psychological characteristics, which can identify personality profiles and pivot to those most closely associated with drug use disorders; IT artifact creation to support health care providers' decision making related to opioid

prescribing; or cognitive psychological programs that complement treatment with medication. To ensure the practical value of our study, we contacted a medical practitioner, who proposed concrete ways in which the insights from our findings could directly benefit the health care field. In addition to the aforementioned applications, the expert suggested the use of our Big Five population assessment mechanism to potentially predict rates of neonatal abstinence (withdrawal) and to plan for county resources for rehabilitation of individuals with opioid use disorder. For instance, if a county exhibits high rates of "agreeableness" as reflected in Twitter data and the use of a validated screening tool, allocating resources for rehabilitation in that county prior to an overdose event could significantly impact the number of overdoses within it.

Implications for Health Informatics

From a health informatics perspective, our research represents a novel approach in three ways. First, we demonstrate the feasibility of intelligently mining unstructured (Twitter) data for epidemiologic discoveries, eliminating the potential ethical dangers of privacy and confidentiality breaches by aggregating personality scores at the communal (county) level—a research technique with proven value in the epidemiology literature [92]. Second, we show that language used by Twitter users can provide cues associated with the Big Five personality traits at the county level. This addresses the limitations of assessment of such data using traditional approaches, which often have limited spatial and temporal precision [99]. Moreover, the use of a psycholinguistic approach for Big Five personality trait assessment allows for a level of model explainability, transparency, and replicability, which are not always possible with more complicated or proprietary "black-box" open-dictionary approaches based on deep learning techniques. Finally, given the fact that major opioid-related statistics are reported by counties and states with a time lag, analysis of readily available Twitter data allows us to overcome this limitation and provide up-to-date estimates of opioid-related outcomes.

Conclusion and Limitations

We studied the impact of personality traits at the county level on fatal opioid overdose, a nationwide crisis. In particular, we used a FFM that included openness, conscientiousness, extraversion, agreeableness, and neuroticism dimensions. We used publicly available multisource data and operationalized our focal predictors using a robust lexicon-based implementation well established in the information systems literature. We tested our model using robust econometric modeling, accounting for endogeneity caused by omitted variable bias using an instrumental variable approach. Overall, our results obtained by means of Twitter mining are consistent with the prior literature, yet they suggest several surprising insights.

The study is not without limitations. First, given that we merged multiple data sets from different sources, some information was lacking for a number of counties due to missing values. Consequently, some descriptive statistics might differ from those in other published studies. Second, because of the "suppressed value" limitation on the outcomes, our results are an approximation, although they still provide reasonable estimations and useful inferences. Third, although one might prefer analysis that handles interval-censored count outcomes, we are not aware of any such analysis (including longitudinal data considerations). Fourth, admittedly, only a small fraction (less than 3%) of Twitter users report locations of their residence as well as the origin of the tweets, thereby limiting the representativeness of our sample. Fifth, we note that counties differ significantly in terms of area and population size, rurality, education, household income, power of county governments, and poverty rates, leading us to assume differences in the personality traits of the population in different counties. Yet, although we observed evidence showing that the personality scores of different counties vary, it only reflects the personality traits of the Twitter users who report their locations, thus leading to some selection bias. Finally, despite the fact that we aggregated individual tweets to capture personality traits of the population at the county level, individual tweets allow a maximum of 140 characters, which might erect barriers to understanding the personality traits of a person from such a short piece of text.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary material.
[DOCX File , 50 KB - mental_v8i3e24939_app1.docx]

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Abbreviations

CDC: Centers for Disease Control and Prevention
CHRR: County Health Rankings and Roadmaps
FFM: five-factor model

FIPS: Federal Information Processing System
ICD-10: International Statistical Classification of Diseases and Related Health Problems, 10th revision
JSON: JavaScript Object Notation
LIWC: Linguistic Inquiry and Word Count
OCEAN: openness, conscientiousness, extraversion, agreeableness, and neuroticism
WONDER: Wide-Ranging Online Data for Epidemiologic Research

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Original Paper

Using a Tablet-Based App to Deliver Evidence-Based Practices for Suicidal Patients in the Emergency Department: Pilot Randomized Controlled Trial

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Abstract

Background: Emergency departments (EDs) have the potential to provide evidence-based practices for suicide prevention to patients who are acutely suicidal. However, few EDs have adequate time and personnel resources to deliver recommended evidence-based assessment and interventions. To raise the clinical standard of care for patients who are suicidal and seeking psychiatric crisis services in the ED, we developed Jaspr Health, a tablet-based app for direct use by such patients, which enables the delivery of 4 evidence-based practices.

Objective: This study aims to evaluate the feasibility, acceptability, and effectiveness of Jaspr Health among suicidal adults in EDs.

Methods: Patients who were acutely suicidal and seeking psychiatric crisis services participated in an unblinded pilot randomized controlled trial while in the ED. Participants were randomly assigned to Jaspr Health (n=14) or care as usual (control; n=17) groups. Participants were assessed at baseline, and a 2-hour posttest using self-report measures and a semistructured interview were conducted.

Results: Conditions differed significantly at baseline with regard to age but not other demographic variables or baseline measures. On average, participants had been in the ED for 17 hours before enrolling in the study. Over their lifetime, 84% (26/31) of the sample had made a suicide attempt (mean 3.4, SD 6.4) and 61% (19/31) had engaged in nonsuicidal self-injurious behaviors, with an average rate of 8.8 times in the past 3 months. All established feasibility and acceptability criteria were met: no adverse events occurred, participants' app use was high, Jaspr Health app user satisfaction ratings were high, and all participants using Jaspr Health recommended its use for other suicidal ED patients. Comparisons between study conditions provide preliminary support for the effectiveness of the app: participants using Jaspr Health reported a statistically significant increase in receiving 4 evidence-based suicide prevention interventions and overall satisfaction ratings with their ED experience. In addition, significant decreases in distress and agitation, along with significant increases in learning to cope more effectively with current and future suicidal thoughts, were observed among participants using Jaspr Health compared with those receiving care as usual.

Conclusions: Even with limited statistical power, the results showed that Jaspr Health is feasible, acceptable, and clinically effective for use by ED patients who are acutely suicidal and seeking ED-based psychiatric crisis services.

Trial Registration: ClinicalTrials.gov NCT03584386; https://clinicaltrials.gov/ct2/show/NCT03584386

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KEYWORDS

suicide; emergency department; digital technology; suicide prevention

Introduction

Background

With 48,344 suicides reported in 2018 (1 every 11 min and 132 per day) [1], suicide remains the 10th leading cause of death across all age groups [2] and the second leading cause of death among people aged 10-44 years [3] in the United States. Moreover, suicide rates have significantly increased over the past two decades, making suicide one of the few health outcomes proving difficult to impact [2,4]. Specifically, the annual suicide rate increased by 33% between 1999 and 2017 [5], from 10.5 to 14.8 per 100,000. From 2009 to 2018, the rate increased from 19.23 to 22.79 per 100,000 for males and from 4.88 to 6.18 per 100,000 for females [6]. Nearly 16 million people worldwide make a suicide attempt on an annual basis [7,8], with approximately 1.4 million adults in the United States making attempts in 2018 [7,9]. In addition, a staggering 12 million American adults thought seriously about trying to kill themselves [10]. Although death by firearms remains the most common method of suicide in the United States, intentional self-poisoning with substances, including opioids, accounts for more than 5000 suicides annually [11].

These staggering increases have led to soaring numbers of emergency department (ED) visits for suicide attempts and ideation in recent years [12]. Approximately 575,000 people are treated annually in US EDs for injuries because of self-harm [13], and 1% of all ED visits involve suicidal ideation [12]. Between 2006 and 2013, ED visits for suicidal ideation increased by 12% annually. During this same period, costs of ED visits because of suicidal ideation increased by over 20% annually—from US $600 million to US $2.2 billion.

Suicidal patients pose special and difficult challenges for EDs [14]. On average, these patients wait for care more than 3 times longer than those with medical emergencies [14,15], which leads to the problem of *boarding*, where the patient is waiting (and still under observational status) in the ED for an inpatient or residential bed to become available [16-18]. Factors contributing to extended wait times include a lack of available inpatient beds (72% of patients who are suicidal are referred to inpatient hospitalization) [12] and inadequate access to hospital-based mental health providers to provide suicide risk assessments, stabilize crises, and help safely transition patients home [19]. Boarding then leads to crowding, poor patient experience, lower quality care [20], delays in treatment, and morbidity and mortality [21] as beds that might otherwise be used to treat patients with life-threatening medical conditions [19] are used for patients who are suicidal while they await treatment or transfer to an inpatient unit or a residential facility. Suicide crises also have a tremendous financial impact on EDs. One study found that every behavioral health ED visit prevented 2.2 beds from turning over, costing EDs an average of US $2264 in lost revenue per visit [15].

ED-Based Interventions to Reduce Suicidal Deaths

EDs can also play a consequential role in reducing suicides by providing evidence-based care for a population at high risk for suicide [22]. For example, studies have shown that up to 25% of patients who seek ED services following a suicide attempt will make another attempt and up to 10% will die by suicide. Of those who do, a substantial proportion will have visited the ED for suicidality the year before they die [23-25]. ED-based interventions thus offer a unique opportunity [26] to intervene for this high-risk population where delivery of evidence-based interventions in the ED could reduce annual deaths from suicide by as much as 20% [27]. For these reasons, a number of public health policy initiatives have recommended increased delivery of suicide prevention efforts during ED visits [28]. Accordingly, in recent years, The Joint Commission has required improved screening for suicidality. By July 2021, The Joint Commission will also require EDs to create suicide crisis safety plans for all patients who are acutely suicidal [29]. The reality, however, is that few EDs have the time and personnel resources to perform these best practices [30].

The use of electronic tablets in health care by providers and patients has exponentially increased over the past decade because of their portability, efficiency, and range of functionality. For patients who are suicidal in the ED, a tablet encased in a strong protective case could easily be brought to the patient's bedside, play psychoeducational videos, and allow users to generate text content to complete a comprehensive, evidence-based suicide risk assessment. Such an app could replace hours of unstructured waiting that characterizes the typical ED experience with robust suicide prevention interventions.

Study Purpose

We sought to create a digital technology for use in EDs to increase the delivery of suicide prevention evidence-based practices without adding to personnel needs in an effort to reduce suicidal behavior with an ultimate goal of saving lives while also improving the quality of ED care delivered to those who are suicidal. Jaspr Health was developed over a span of several years using an iterative process of development and best practices in user-centered design [31-34]. Extensive feedback was sought from ED patients who were suicidal (n=89) and their ED-based care team (n=105) from 4 large health care systems across the United States. At its core is the Collaborative Assessment and Management of Suicidality (CAMS), a highly adaptable evidence-based suicide prevention intervention developed by Jobes [35], for use by clinicians in engaging, assessing, and treating patients who are suicidal. CAMS uses a chart-ready documentation tool, the Suicide Status Form, to

serve as a clinical roadmap guiding assessment, treatment planning, and ongoing tracking of risk and care disposition. Developed two decades earlier, CAMS contains many recommended practices, including a comprehensive suicide risk assessment, stabilization planning, and lethal means safety counseling [36]. It has been used as a brief intervention, an add-on to an existing treatment, and a short-term suicide-focused treatment. Beyond suicide risk factors and warning signs, CAMS identifies and treats patient-articulated *drivers* of suicide, as defined as those problems and other issues that compel a person to consider suicide, for example, trauma, romantic breakup, or financial issues. To date, 5 published randomized controlled trials (RCTs) support CAMS efficacy as a clinical suicide prevention intervention [37-41]. CAMS was integrated into Jaspr Health.

We conducted this preliminary RCT in EDs to examine the feasibility, acceptability, and effectiveness of Jaspr Health for adults who were acutely suicidal in the ED. We sought to determine if patients in the midst of a profound suicide crisis would be able and willing to use a tablet-based app to complete a comprehensive suicide risk assessment, build a crisis stability plan, undergo lethal means counseling, and learn behavioral skills to improve their capacity to tolerate future crises. Would patients feel as if using an app diminished or compromised their overall ED satisfaction and experience? In addition, would providers and health care systems allow their patients who are suicidal to interact with a tablet? And would Jaspr Health produce outcomes that might justify its continued use—in the ED and other care pathways? Results from this pilot can assess the promise of this app's approach for patients who are acutely suicidal and inform our and others' development of digital innovations used for behavioral and medical interventions, including telehealth delivery. We predicted that, compared with care as usual (CAU) control participants, Jaspr Health participants would receive more evidence-based suicide prevention interventions, report greater reductions in their agitation and distress, indicate superior capacity for coping with their suicidal ideation over time, and exhibit higher patient satisfaction with their overall ED experience.

Methods

Design and Recruitment

We recruited individuals who were acutely suicidal and seeking ED-based psychiatric crisis services from 2 EDs located in the Midwest. Although a number of large health care systems in geographically diverse regions of the United States had intended to participate in the research, only 2 systems had completed the necessary contractual procedures at the start of the study; efforts to complete contracting with other systems ceased with COVID-19. Both health care systems identified their participating EDs. In both cases, EDs were selected on the basis of serving a large number of patients who are suicidal and the ED staff's willingness to incorporate the research into their workflow. Each ED offered 24/7 psychiatric care offered by behavioral health providers. One site used master's level social workers to perform an initial clinical assessment and recommended discharge disposition for later review by an ED physician. The other site had a psychiatrist and psychiatric nurse practitioner embedded in the ED to perform the initial suicide assessment and clinical intervention, with the psychiatrist determining the discharge disposition. All study procedures took place in the patient's ED room.

An advisory group of people with lived experience (PLE) with suicide assisted in developing research procedures to ensure the acceptability of the research method. Before finalizing the research protocol (measures, scripts, and methods), a timed ED protocol simulation test was conducted individually with 4 PLE advisors that fully mirrored the ED research experience. Advisors provided their impressions on a number of issues such as the overall length and relevance of the research measures, including whether they were acceptable given the cognitive load experienced by suicidal persons while in the ED and ensuring the researcher script was clear, easy to understand, and in plain speech (rather than scientific or clinical language that may be confusing or off-putting). Concerns expressed by one PLE were treated as hypotheses to verify with another. By applying a user-centered design method commonly used when developing software, modifications were made until the protocol was deemed acceptable (content, process, and time required to complete) by investigators, the Director of Lived Experience Integration, and PLE advisors. All procedures were approved by a full board review by the Sterling Institutional Review Board and the Institutional Review Board at the Catholic University of America. External monitoring was provided by an independent Data Safety Monitoring Board comprising recognized suicide experts. The trial was registered at ClinicalTrials.gov NCT03584386.

Eligible participants were English-speaking adults, 18 years or older, and acutely suicidal in the ED. Patients who were actively psychotic, severely agitated, and/or significantly impaired by alcohol or drugs were excluded from participating because they would be unable to provide informed consent and participate meaningfully in a behavioral intervention and/or because of safety concerns involving access to a tablet that could be weaponized.

Potentially eligible participants were identified by a member of the medical team or behavioral health specialists who initially approached each patient to briefly describe the study and assess their interest in participating. A researcher then met with the patient, provided a high-level summary of the project to determine the patient's interest, and conducted an eligibility screen to verify that the patient met the study criteria. As patients who are suicidal are a vulnerable population, great care was taken to ensure that before providing consent, eligible participants had a thorough understanding of the study procedure, including its risks and benefits. To standardize the informed consent process and ensure that all information was reliably, simply, and succinctly delivered, all eligible participants watched a brief 5-min video in which the study's Director of Lived Experience Integration walked through all study procedures aided by a simple PowerPoint illustrating the key points. Eligible participants were offered the opportunity to review the written informed consent form and/or to have the researcher review other specific sections. To minimize enrollment bias, randomization to either Jaspr Health or the

CAU condition occurred after the process of informed consent was performed. A minimization randomization procedure was used to match participants to condition based on suicide severity and earlier history of ED visits for suicidal behavior. To guard against bias or possible disappointment caused by not being randomly assigned to the Jaspr Health condition, specific details about Jaspr Health were contained in a separate supplemental 2-min video, and consent was provided to those assigned to Jaspr Health following the randomization procedure.

Following the completion of the informed consent and randomization process, participants completed a baseline assessment using a tablet. In the CAU condition, participants completed the posttest assessment 2 hours after the baseline assessment. In the Jaspr Health condition, participants were given up to 2 hours to use the app and then administered the posttest assessment. The 2-hour study time and app use were paused when Jaspr Health participants met with a member of their care team and then resumed when done. To ensure safety while using the tablet-based app, the researcher remained in the patient's room during their use and sat on a chair in the corner of the room. Researchers told patients that they would be focusing on their own work to minimize the impact of their presence. Researchers were allowed to answer specific questions asked by the patient about Jaspr Health use but did not speak to the patient during the study session. Jaspr Health participants also received access to usual care.

Measurements

Study data were collected using SurveyMonkey, a Health Insurance Portability and Accountability Act of 1996 (HIPAA)–compliant secure web-based assessment tool and were stored in a HIPAA-compliant cloud-based server. Participants completed self-report questionnaires on an Apple iPad tablet. Researchers entered additional data (eg, time spent using Jaspr Health and answers to semistructured interview questions) onto laptops where content was saved and stored on the cloud-based server.

Key domains assessed among those in the Jaspr Health group included feasibility and acceptability. Feasibility was measured by the absence of negative or adverse events, the premature *stopping* of a test session by medical personnel concerned about the patient's welfare, or the premature disengagement of use (requesting to stop after 20 min, the average length of an ED-based clinical interview). Acceptability was measured by the total number of minutes used, whether the patient would recommend Jaspr Health to others in their situation, and satisfaction.

RCT measures were developed in collaboration with the Emergency Department Safety Assessment and Follow-up Evaluation [42] principal investigator and Jaspr Health consultant (Dr Boudreaux), reviewed with PLEs, and selected for their brevity and simplicity for use with individuals who are suicidal and seeking psychiatric crisis services in an ED. The *Safety and Imminent Distress Questionnaire* is a 4-item, face-valid self-report survey based on Dr Boudreaux's Keeping Myself Safe Subject Usability Survey [43]. Participants rated their feelings in the present moment using a 10-point scale. The following items were included: intensity of emotional distress (1=no distress; 10=highest distress ever felt), the extent to which they felt calm or agitated (1=very calm; 10=very frustrated or agitated), their ability to cope with thoughts of killing themselves (1=no ability to cope; 10=strong ability to cope), and their ability to go home safely (1=not able; 10=very able). The *Suicide-Related Coping Scale* (SRCS) [44] is a 17-item psychometrically sound self-report measure of coping with suicidal thoughts, urges, and crises. The SRCS uses a 5-point rating scale (0=strongly disagree; 4=strongly agree). The Emergency Room-Patient Satisfaction Survey (ER-PSS) is a 7-item measure used to assess patient experience in the ED. The measure was developed in consultation with the patient experience division of a large reputable health care organization. The initial 6 items used a 5-point rating scale (1=poor; 5=excellent). Items included the helpfulness of ED visit, the degree to which the patient felt listened to and cared about by their care team, the likelihood that they would recommend the ED to others in their situation, and their overall rating of care they received. A final item involves rating their overall ED experience from 1 (worst) to 100 (best). The *Jaspr Health Patient Satisfaction Questionnaire* is an 8-item survey that adapts the ER-PSS to evaluate Jaspr Health, including its ease of use and helpfulness to patients. Patients also rate Jaspr Health on a 100-point scale and indicate whether they would recommend Jaspr Health to others in their situation. A *brief semistructured interview* was conducted at the end of the posttest session and sought to identify what, if any, suicide prevention best practices the participant received while in the ED. When they positively affirmed receiving an intervention, patients were asked to subjectively rate the thoroughness with which they received best practices using a 5-point Likert scale (1=not very thorough; 5=very thorough). They were also asked who delivered the best practice (a member of their care team, Jaspr Health, or both). On average, baseline and posttest measures took less than 10 min to complete, and the semistructured interview took approximately 3 min to administer.

Intervention

All clinical interventions contained in Jaspr Health draw upon well-established evidence-based practices for suicide prevention that are recommended for adults in the ED who are suicidal [45]. Guided by the CAMS Suicide Status Interview, an adaptation of the Suicide Status Form, Jaspr Health includes an artificial intelligence–powered virtual guide chatbot that gathers patient self-report: the guide *conducts* the comprehensive suicide assessment, *discusses* the importance of lethal means safety management and collaboratively generates a plan to reduce or eliminate access during the high-risk period, and generates a crisis stabilization plan with the patient. Content from these chatbot-driven *discussions* are then summarized in a clinical decision support guide for use by the care team in deriving an evidence-based discharge disposition.

In light of the increased awareness of the power of imparting messages of hope and insights by PLEs [46-50], Jaspr Health also includes psychoeducation videos delivered by PLEs on what to expect in the ED, how to survive the first days after returning home from the hospital, coping with shame, strategies for staying well, and inspiring messages to generate hope (eg, *My Wish for You*). Efficacious behavioral skills from Dialectical

Behavior Therapy [51-63], a recognized gold standard in the treatment of suicidal behavior, are also included to teach users how to tolerate distress, change unwanted negative emotions, distract from painful cues, better manage their thoughts with mindfulness, and radically accept that which cannot be changed. If used as intended, Jaspr Health may significantly increase the routine delivery of evidence-based suicide prevention interventions compared with usual care while decreasing potential exposure to malpractice liability through improved suicide-focused practice and extensive documentation.

Statistical Analysis

We used descriptive statistics, chi-square tests, and generalized linear model (GLM). Descriptive statistics (means and percentages) described the sample, satisfaction with Jaspr Health, and number of evidence-based interventions received. GLM compared Jaspr Health and CAU on satisfaction with their ED experience and the amount of change from baseline to posttest (using GLM's generalized estimating equations [GEEs]). These GLM analyses controlled for which ED patients were in and for age (which we found differed between conditions). Chi-square tests compared conditions on what intervention they received. Power was low for comparing means and proportions between conditions, with a very large effect size (Cohen d=1.05) needed to detect a statistically significant (P=.048) difference (power of 0.80, two-tailed test). Power was higher for detecting a statistically significant time×condition effect in GEE analysis, with the ability to detect a medium effect size (f=0.27).

Results

Enrollment and Participant Characteristics

For approximately 2 months (January through February 2020), 41 patients who were suicidal in the ED were approached, screened, and informed of the study. Of these, 33 consented to being randomized to Jaspr Health (n=16) or CAU (n=17). Two Jaspr Health participants were excluded from participation after randomization (one was transferred to an inpatient unit before beginning the intervention and the other had previously participated in an earlier usability study), resulting in a Jaspr Health sample size of 14. Unfortunately, the rapid spread of COVID-19 required the suspension of recruitment efforts at participating health care organizations, thus ending this phase of research earlier than planned and with a significantly smaller sample size than originally planned (N=90). Figure 1 provides a consort flowchart of the enrollment.

Of the sample, 65% (20/31) were identified as female and 87% as White (27/35). Participants' ages ranged from 18 to 68 years, and the average age was 34.4 years (SD 15.17). A total of 32% (10/31) of the sample graduated from high school, 23% (7/31) obtained a 2-year college degree, 13% (4/31) earned a 4-year college degree, and 10% (3/31) had earned a graduate degree. Of the 31 participants, 25 (82%) had made a suicide attempt in their lifetime and 16 (64%) had made 2 or more attempts in their lifetime. In addition, 61% (19/31) of participants reported a lifetime history of engaging in nonsuicidal self-injurious behaviors and at an average rate of 8.8 times (median=2.0) during the past 3 months. Moreover, 55% (17/31) of participants indicated that they had visited the ED for suicidal behaviors 3 or more times in their lifetime; of this subsample, 77% (23/31) of participants had been to the ED before the index ED visit 1 to 2 times in the past 3 months for suicidal behaviors. Overall, 48% (15/31) of participants had sought psychiatric crisis services in the ED on 3 to 7 occasions in their lifetime. Participants had already been in the ED for an average of 17 hours before enrolling in the research study. With the exception of age, no differences were detected between conditions at baseline on demographics and baseline measures. Furthermore, no differences between sites were detected for gender, race, education, use of emergency services, or suicidal-related variables (eg, suicide severity and history of attempts and nonsuicidal self-injury). Table 1 shows participants' characteristics by condition.

Figure 1. Participant enrollment CONSORT (Consolidated Standards of Reporting Trials) flow chart. ED: emergency department.

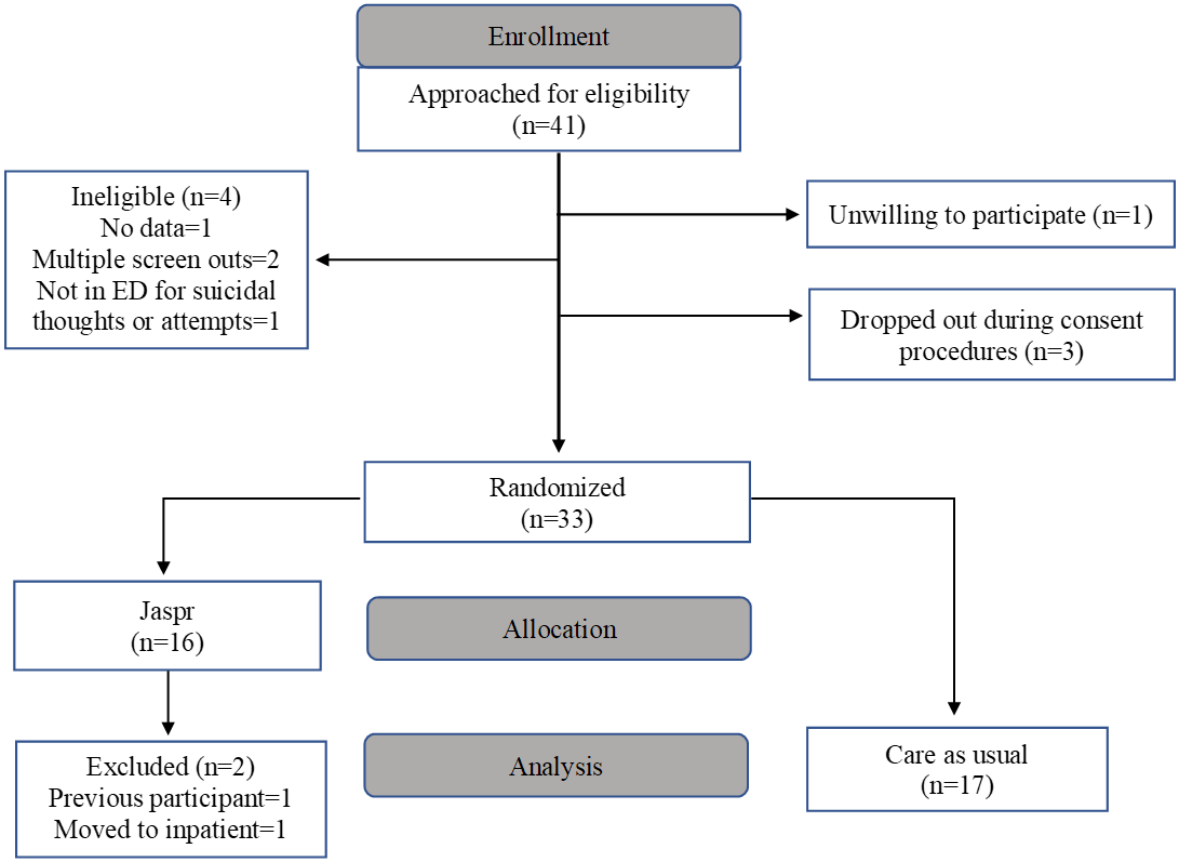

Table 1. Participants' characteristics by study group (enrollment).

Participant characteristic[a]	Jaspr Health (n=14)	CAU[b] (n=17)
Age (years), mean (range, SD)	29 (19-49, 10.76)	39 (18-68, 16.92)
Gender,[c] n (%)		
Female	8 (57)	12 (71)
Male	6 (43)	5 (29)
Race,[d] n (%)		
Black or African American	0 (0)	1 (6)
White	12 (86)	15 (88)
More than one race or other	2 (14)	1 (6)
Education, n (%)		
Less than high school	1 (7)	1 (6)
High school graduate	3 (21)	7 (41)
Some college	3 (21)	2 (12)
2-year college degree or trade school	4 (29)	3 (18)
4-year college degree	2 (14)	2 (12)
4-year degree+masters	1 (7)	2 (12)
Suicide severity and history, n (%)		
No attempt	3 (21)	3 (18)
1 attempt	5 (36)	4 (24)
2 or more attempts	6 (43)	10 (59)
Emergency services' use history, n (%)		
No previous ED[e] visits	2 (14)	3 (18)
1 or 2 ED visits	6 (43)	3 (18)
3 or more ED visits	6 (43)	11 (64)
Emergency services used in the past 3 months, n (%)		
1-2 times	11 (79)	13 (77)
3-4 times	2 (14)	1 (6)
5-7 times	0 (0)	0 (0)
7-10 times	1 (7)	1 (6)
More than 10 times	0 (0)	1 (6)
Emergency services used across lifespan, n (%)		
1-2 times	7 (50)	4 (24)
3-4 times	5 (36)	5 (29)
5-7 times	2 (14)	3 (18)
7-10 times	0 (0)	2 (12)
More than 10 times	0 (0)	2 (12)
Nonsuicidal self-injury, n (%)		
Yes	7 (50)	12 (71)
No	7 (50)	5 (29)

[a]Numbers and percentages may not sum to total because of missing data.

[b]CAU: care as usual.

[c]One sex assignment was different from birth.

[d]One participant identified as Hispanic.

[e]ED: emergency department.

Feasibility and Acceptability of Digital Technology

Factors representative of the feasibility and acceptability of Jaspr Health showed strong, positive results. All Jaspr Health participants completed the use of digital technology without any adverse events or premature stopping of the test session either by medical personnel or participants. Jaspr Health participants used Jaspr Health for an average of 80 min (SD 33 min; median 85 min). All Jaspr Health participants indicated that they would recommend the digital tool to other suicidal individuals in their situation. In addition, participants gave Jaspr Health high satisfaction ratings. As shown in Table 2, the average satisfaction rating for Jaspr Health was 4.4 (SD 0.63) using a 5-point Likert scale, where 1=poor and 5=excellent.

Table 2. Satisfaction ratings among Jaspr Health participants[a].

Item	Mean (SD)
Jaspr was easy to use and understand	4.5 (0.76)
Helpfulness or Jaspr	4.1 (0.77)
Felt cared about Jaspr	3.9 (0.92)
Helpfulness of information	4.1 (1.00)
Overall rating of care by Jaspr	4.4 (0.63)

[a]Response categories for Jaspr satisfaction items coded from 1 to 5: 1=poor; 2=fair, 3=good, 4=very good, and 5=excellent.

Feasibility and Effectiveness

Key findings favored the Jaspr Health over the CAU condition. As shown in Table 3, Jaspr Health participants reported receiving significantly more of the best practice interventions recommended for suicidal individuals while in the ED. In addition, Jaspr Health participants indicated robust exposure to these interventions. As shown in Table 4, they reported learning an average of 3 new behavioral skills (SD 1.3) and *engaged* with 4 PLEs (SD 2.63). The degree of thoroughness with which Jaspr Health participants received best practices ranged from an average of 3.4 (SD 1.1; crisis plan) to 4.1 (SD 0.86; PLE) on the 5-point scale.

Table 3. Participants responding yes to receiving interventions.

Variable	CAU[a] (n=17), n (%)	Jaspr (n=14), n (%)	χ^2 (*df*)	*P* value
Crisis stabilization plan	2 (12)	14 (100)	23.9 (1)	<.001
Lethal means counseling	1 (6)	12 (85)	19.0 (1)	<.001
Skills	2 (12)	13 (93)	20.2 (1)	<.001
PLE[b]	1 (6)	13 (93)	23.4 (1)	<.001

[a]CAU: care as usual.

[b]PLE: people with lived experience with suicide.

Table 4. Interventions received across conditions: number received and rating of thoroughness (n=31).

Intervention	Number received, mean (SD)	Thoroughness[a], mean (SD)
Crisis stabilization plan	__[b]	3.4 (1.08)
Lethal means counseling	__[b]	3.5 (1.31)
Skills	2.7 (1.30)	3.7 (1.38)
PLE[c]	3.7 (2.63)	4.1 (0.86)

[a]Response categories for thoroughness coded from 1 to 5: 1=not very thorough and 5=very thorough.

[b]Participants did not receive a quantifiable number of interventions for crisis planning or lethal means counseling.

[c]PLE: people with lived experience.

Table 5 shows that Jaspr Health participants had greater improvement than CAU participants from baseline to posttest in suicide-related coping, capacity to cope with distress, and agitation and distress using GEE analysis. Statistically significant time×condition effects show that during the 2-hour experimental procedure, compared with CAU patients, Jaspr Health patients reported greater decreases in intensity of agitation and distress and greater increases in their ability to cope with thoughts of killing themselves. Within-condition effect sizes were large to very large for Jaspr Health participants'

decreases in agitation and distress (Cohen *d*=0.61 and 1.00, respectively) and increases in coping ability (Cohen *d*=0.90). In contrast, effect sizes for CAU participants were small. Specifically, a decrease in distress (Cohen *d*=0.33), a small increase in agitation (*d*=0.11), and an increase in coping ability (Cohen *d*=0.32) were observed in CAU. Although the time×condition effect for readiness to go home safely was not statistically significant, effects sizes were small for CAU but larger (though still small in magnitude) for Jaspr Health. Finally, compared with CAU, Jaspr Health participants reported a significant time×condition effect, reflecting a greater increase in their SRCS-measured suicide-related coping capability than CAU participants, with a very large effect size for Jaspr Health (Cohen *d*=1.11) compared with a small effect for CAU (Cohen *d*=0.26).

Table 5. Repeated measures analysis comparing Jaspr and care as usual on pre- and postintervention outcomes.

Scales or items	Baseline, mean (SD)	Postintervention, mean (SD)	Time		Time×condition		Cohen *d*[a]: within-condition change
			χ^2 (*df*)	*P* value	χ^2 (*df*)	*P* value	
SRCS[b]			17.3 (1)	<.001	8.1 (1)	.004	
Jaspr[c]	34.8[d] (11.00)	44.8 (11.69)					1.11
CAU[e,f]	37.6 (13.28)	39.5 (14.16)					0.26
SIDQ[g]—Distress			15.8 (1)	<.001	5.5 (1)	.02	
Jaspr	6.7[h] (2.02)	4.4 (2.38)					1.00
CAU	7.3 (2.71)	6.7 (2.49)					0.33
SIDQ—Agitation			3.6 (1)	.06	5.5 (1)	.02	
Jaspr	5.9[i] (2.61)	4.23 (2.24)					0.61
CAU	6.1 (2.76)	6.3 (2.14)					0.11
SIDQ—Coping ability			13.2 (1)	<.001	5.8 (1)	.02	
Jaspr	4.6[j] (2.28)	6.6 (2.71)					0.90
CAU	4.8 (2.41)	5.2 (2.28)					0.32
SIDQ—Readiness to go home			1.2 (1)	.27	0.5 (1)	.49	
Jaspr	7.0[k] (3.32)	7.8 (2.26)					0.28
CAU	4.0 (3.33)	4.4 (2.95)					0.05

[a]Interpretation of Cohen *d* is 0.20 small, 0.50 medium, and 0.80 large.

[b]SRCS: Suicide-Related Coping Scale.

[c]Analysis sample size of Jaspr, n=14.

[d]Response categories for suicide-related coping coded from 0 to 4: 0=strongly disagree and 4=strongly agree.

[e]Analysis sample size of care as usual, n=17.

[f]CAU: care as usual.

[g]SIDQ: Safety and Imminent Distress Questionnaire.

[h]Response categories, for distress coded from 1 to 10: 1=no distress and 10=highest distress ever felt.

[i]Response categories for agitation coded from 1 to 10: 1=very calm and 10=very frustrated or agitated.

[j]Response categories, for coping ability coded from 1 to 10: 1=no ability to cope and 10=strong ability to cope.

[k]Response categories, for readiness to go home coded from 1 to 10: 1=not able and 10=very able.

Although not generally statistically significant, Table 6 shows that effect sizes comparing Jaspr Health and CAU conditions on ED patient satisfaction favored Jaspr Health and ranged from medium to large in magnitude. A large effect size (Cohen *d*=0.80) and a nearly statistically significant difference (*P*=.06) was observed on arguably the most important ED patient satisfaction item *Overall Rating of Care*, again favoring Jaspr Health.

Table 6. *t* tests comparing Jaspr and care as usual on emergency department satisfaction measures.

Items[a]	Jaspr (n=14), mean (SD)	CAU[b] (n=17), mean (SD)	Between condition		
			χ^2 (*df*)	*P* value	Cohen *d*[c]
Helpfulness of ER[d] visit	3.8 (0.98)	3.2 (1.19)	2.2 (1)	.14	0.56
Felt listened to	4.2 (0.98)	3.5 (1.23)	2.0 (1)	.15	0.63
Felt cared about	4.1 (1.23)	3.7 (1.12)	1.1 (1)	.29	0.42
Ready to return home	3.4 (1.50)	2.8 (1.44)	0.6 (1)	.43	0.41
Recommend ER	4.3 (1.20)	3.5 (1.23)	2.6 (1)	.11	0.65
Overall rating of care	4.2 (0.98)	3.4 (1.17)	3.7 (1)	.06	0.80

[a]Response categories for ED satisfaction items coded from 1 to 5: 1=poor, 2=fair, 3=good, 4=very good, and 5=excellent.

[b]CAU: care as usual.

[c]Interpretation of Cohen *d* is 0.20 small, 0.50 medium, and 0.80 large.

[d]ER: emergency room.

Discussion

Relevance and Findings

We wondered whether patients who are acutely suicidal would tolerate interacting with an artificial intelligence–powered chatbot designed to deliver evidence-based suicide-focused interventions. Would they also choose to virtually hear from PLE and learn behavioral skills to increase their capacity to cope with distress? If they did, would it produce positive clinical outcomes and improve their overall ED visit experience?

Preliminary findings strongly supported Jaspr Health's feasibility and acceptability, while also appearing promising as an effective clinical intervention. With respect to feasibility and acceptability, patients who are suicidal in the ED tolerated Jaspr Health and opted to use the app on their own for a median of 85 min. Of 14 Jaspr Health patients, all completed a comprehensive suicide assessment and created a crisis stabilization plan, and 12 (85%) patients engaged in lethal means counseling. Jaspr Health participants also opted to learn 3 behavioral skills and hear from 4 PLEs and gave Jaspr Health high satisfaction ratings—100% recommended it for use by others in their situation. In addition, no adverse events occurred during its use. Jaspr Health appeared clinically effective. In comparison with CAU participants, those receiving Jaspr Health reported statistically significant reductions in agitation and distress over time and improved capacity to cope with current and future suicidal thoughts. They also felt more positively about their overall ED experience. These findings are not surprising, given that those who received Jaspr Health received the evidence-based interventions recommended by experts at a much higher and statistically significant rate compared with CAU patients. Only 12% (2/17) of CAU patients had developed a crisis stabilization plan while in the ED, and only 6% (1/17) of CAU patients discussed the lethal means with his or her care team. The findings are particularly noteworthy, given that the study was underpowered because of the sudden need to stop the study because of COVID-19.

Although still in the early stages, the implications of this study are substantial. First, this study demonstrates that digital technologies can be used to fulfill the mandate and vision of aiding the delivery of evidence-based suicide prevention care to patients who are acutely suicidal while in the ED. Powerful interventions supported by decades of suicide prevention clinical research can reach *and impact* those they are designed to help without significant demands on personnel or extensive training. Indeed, care teams may actually *save* time, as tools such as Jaspr Health reliably and compassionately gather relevant information from the patient that can be used by the provider to deepen their own clinical interview. Second, delivering state-of-the-art evidence-based care for people who are in an acute suicide crisis can be performed anytime and anywhere there is internet access and a tablet computer, including rural and frontier communities with unusually high rates of suicide and limited access to psychiatric care. By extension, digital technologies such as Jaspr Health may be blended with other crisis stabilization services and delivered via telehealth, which reduces the need for some to go to the ED altogether. They can also be used to support the standardized delivery of evidence-based care to patients who are suicidal or admitted to a medical or surgery unit for injuries resulting from a suicide attempt or in a primary care context. When integrated into a health care system's electronic health record, such tools may augment (not replace) a trained medical personnel's interventions and improve the overall quality of care. They may also help mitigate malpractice claims by ensuring thorough documentation of specific evidence-based care received by a patient, including ongoing assessment of their suicidality while in the ED [64].

Limitations

This preliminary study is the first of its kind that we are aware of where digital technology was used to intervene with a highly vulnerable suicidal population seeking psychiatric crisis services in an ED. The study contained a number of inherent methodological limitations, as a feasibility- and acceptability-oriented RCT. Although developmentally appropriate for a study at this early phase, the threats to internal validity are notable. First, researchers were only in the room for Jaspr Health, but not CAU, to ensure safe use of the app during initial testing. Although the researchers were instructed to not engage in conversation with the participants (in fact, they

were instructed to appear busy on their laptops), their presence alone may have been a factor that accounted for a reduction in distress and agitation compared with CAU. Furthermore, their presence may have also positively affected study outcomes via a social desirability bias. Second, a placebo device was not used for the CAU participants. Without controlling for the tablet itself and engagement with it, we cannot know for certain whether the effect achieved was because of Jaspr Health's content or simply the outcome of having access to a tablet. (It is worth noting, however, that all rooms were equipped with a television for patient use). Third, the assessors were not blinded to the patients' study condition. Finally, limitations of budget and project scope, complicated further by reducing study length because of COVID-19, resulted in our inability to expand to other ED research sites located in more ethnically and racially diverse regions of the United States. This resulted in another significant study limitation, namely, a predominantly White sample that significantly limits the study's external validity. Future research should focus specifically on ED sites in ethnically and racially diverse regions of the United States to ensure greater sample diversity to address this considerable limitation.

Conclusions

This pilot study provides preliminary support for an approach that may reduce suicide by delivering powerful evidence-based suicide prevention assessments and interventions for suicidal ED patients at particularly high risk for death by suicide. It also paves the way for digital innovations to solve complex behavioral health problems by improving reliable delivery of evidence-based practices, enhancing patient experiences, and producing compelling clinical outcomes while aiding and not taxing busy care providers. It also highlights the need to accelerate efforts to improve the delivery of evidence-based suicide prevention practices in EDs. Despite the study's limitations, which include threats to internal validity in the RCT and the small sample size, the use of digital technologies appears feasible and acceptable to both patients *and* their care teams, even for a highly vulnerable population in a complex and fast-paced environment. In addition to a statistically significant reduction in distress and agitation compared with CAU and increased capacity to cope with current and future suicidal thoughts, perhaps the most notable finding is that those using the digital solution actually *received* evidence-based suicide-focused interventions. Digital solutions such as Jaspr Health also allow hospital-based care teams to improve their own clinical impact by using a chatbot to gather important information that can then be used in subsequent clinical discussions with the patient. Future studies should seek to reduce threats to internal validity by building in greater experimental controls while also recruiting participants from more ethnically and racially diverse regions of the country to extend opportunities for ethnic and racial minorities to participate and increase external validity, thereby saving the lives of people in need.

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Conflicts of Interest

LD and KK co-own the Evidence-Based Practice Institute, Inc, a for-profit company that owns Jaspr Health. DJ is the treatment developer of CAMS and receives royalties for his books from the American Psychological Association Press and Guilford Press. He is a founder and co-owner of CAMS-care, a limited liability corporation, a for-profit training and consultation organization. Both DJ and PG have equity shares in Jaspr Health. To manage investigators' potential conflicts of interest, statistical consultant BB, independently oversaw all data management, data analyses, and written interpretation of all results and verified the accuracy and validity of all study data before any data have been publicly presented.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1194 KB - mental_v8i3e23022_app1.pdf]

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Abbreviations

CAMS: Collaborative Assessment and Management of Suicidality
CAU: care as usual
ED: emergency department
ER-PSS: Emergency Room-Patient Satisfaction Survey
GLM: generalized linear model
GEE: generalized estimating equations
HIPAA: Health Insurance Portability and Accountability Act of 1996
PLE: people with lived experience
RCT: randomized controlled trial
SRCS: Suicide-Related Coping Scale

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Original Paper

Mental Health Specialist Video Consultations Versus Treatment-as-Usual for Patients With Depression or Anxiety Disorders in Primary Care: Randomized Controlled Feasibility Trial

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Abstract

Background: Most people affected by depression or anxiety disorders are treated solely by their primary care physician. Access to specialized mental health care is impeded by patients' comorbidity and immobility in aging societies and long waiting times at the providers' end. Video-based integrated care models may leverage limited resources more efficiently and provide timely specialized care in primary care settings.

Objective: The study aims to evaluate the feasibility of mental health specialist video consultations with primary care patients with depression or anxiety disorders.

Methods: Participants were recruited by their primary care physicians during regular practice visits. Patients who had experienced at least moderate symptoms of depression and/or anxiety disorders were considered eligible for the study. Patients were randomized into 2 groups receiving either treatment-as-usual as provided by their general practitioner or up to 5 video consultations conducted by a mental health specialist. Video consultations focused on systematic diagnosis and proactive monitoring using validated clinical rating scales, the establishment of an effective working alliance, and a stepped-care algorithm within integrated care adjusting treatments based on clinical outcomes. Feasibility outcomes were recruitment, rate of loss to follow-up, acceptability of treatment, and attendance at sessions. Effectiveness outcomes included depression (Patient Health Questionnaire-9), anxiety (Generalized Anxiety Disorder-7), burden of specific somatic complaints (Somatic Symptom Disorder-B Criteria Scale-12), recovery (Recovery Assessment Scale-German [RAS-G]), and perception of chronic illness care (Patient Assessment of Chronic Illness Care), which were measured at baseline and 16 weeks postallocation by assessors blinded to the group allocation.

Results: A total of 50 patients with depression and/or anxiety disorders were randomized, 23 in the intervention group and 27 in the treatment-as-usual group. The recruitment yield (number randomized per number screened) and the consent rate (number randomized per number eligible) were 69% (50/73) and 86% (50/58), respectively. Regarding acceptability, 87% (20/23) of the participants in the intervention group completed the intervention. Of the 108 planned video consultations, 102 (94.4%) were delivered. Follow-up rates were 96% (22/23) and 85% (23/27) for the intervention and control groups, respectively. The change from baseline scores at postmeasurement for the No Domination by Symptoms domain of recovery (RAS-G) was somewhat higher in the intervention group than in the control group (Mann-Whitney *U* test: rank-biserial r=0.19; 95% CI −0.09 to 0.46;

P=.18). We did not detect any notable differences between the intervention and control groups in terms of other effectiveness outcomes. We did not observe any serious adverse events related to the trial.

Conclusions: The intervention and study procedures were found to be feasible for patients, primary care practice staff, and mental health specialists. A sufficiently powered pragmatic trial on mental health specialist video consultations should be conducted to investigate their effectiveness in routine care.

Trial Registration: German Clinical Trials Register DRKS00015812; https://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00015812.

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KEYWORDS

primary care; integrated care; telepsychiatry; videoconferencing; depression; anxiety; recovery; randomized controlled trial

Introduction

Primary Care Mental Health

Depression and anxiety disorders are two of the three most prevalent mental disorders and cause substantial global and individual disease burden [1]. Patients with depression or anxiety disorders are often treated exclusively in primary care, which brings the primary care physician in a crucial position for mental health care [2-4]. Most primary care physicians provide comprehensive care to their patients. However, a substantial proportion of patients with severe conditions and somatic comorbidities are not adequately treated. They need more specialized care; however, their access is often impeded by (1) long waiting times at the provider's end, (2) older patients' immobility because of increasing multimorbidity in an aging society, and (3) an emphasis on assessment and treatment of somatic symptoms because of guideline recommendations [5,6]. To resolve these challenges, it is essential to develop health care models that combine the easily accessible environment of primary care and the expertise in timely diagnostics and therapy of a mental health specialist.

Health care models, which may provide a tailored treatment for patients initially presenting to their primary care physician, have been developed. In some of these models (eg, collaborative care), the primary care physician is supported by a care manager, who tracks patients per telephone, conducts psychological assessments, and presents the data to a mental health specialist, often a psychiatrist [7,8]. The mental health specialist monitors the patients by scanning the case reports and can intervene, if necessary, by prescribing drugs or scheduling face-to-face consultations. In other models, the primary care team and mental health specialist are colocated [9-11]. The mental health specialist provides team-based specialized treatment as a routine part of primary care, such as goal setting together with patients, patient activation, and psychosocial care. In the practice, direct cooperation allows patients to be referred by warm handoffs instead of conventional referral forms. Regardless of whether a mental health specialist is locally present, these health care models provide more direct access to specialized care for mental health patients and foster cooperation between primary and specialized mental health care.

These integrated care models are promising and have been successfully implemented, particularly in the US health care system. However, small and remote primary care practices struggle with the implementation of these care models. In European countries, such as the United Kingdom, France, and Germany, where the mean number of physicians per practice is lower than that in the United States, practices with 1 or 2 doctors often do not have the financial resources to employ an additional mental health specialist [12]. Especially in the German health care system, integrated mental health care models have rarely been implemented so far. Therefore, it is essential to develop and evaluate innovative modes to put these integrated care approaches into practice.

Mental Health Specialist Video Consultations

Real-time video consultations conducted by mental health specialists have been shown to be a promising approach to integrated care. This technology-supported mode of delivery is increasingly considered as an alternative to face-to-face settings. We conducted a thorough literature review and identified 315 records. A total of 11 records were relevant, and among these, 6 systematic reviews show that, in general, telemedicine interventions for mental health conditions seem to be effective [13-18]. Concerning the integration of telepsychiatry services in primary care, several observational and interventional studies have demonstrated that mental health specialist video consultations contribute to overcoming geographical barriers and treating the increasing number of multimorbid patients often cut off from specialized care [19-24]. Randomized trials evaluating video consultations have been conducted either in the unique setting of the US Veterans Health Care Administration in Rural Federally Qualified Health Centers [19,20] or included patients from inpatient health care settings [23,24]. The implementation of telemedical approaches within mental health care has generally been promoted more in the United States than in Europe through passing guidelines by the American Telemedicine Association [25]. In particular, for European primary health care settings, the results of those settings can therefore only be generalized to a limited extent.

Purpose of the Study

Consequently, the aim of this study is to evaluate if and how mental health specialist video consultations and primary care can be integrated into a European health care system. Therefore, we conducted a randomized controlled feasibility trial in Germany by implementing mental health specialist video consultations in 5 primary care practices. If the intervention proves to be feasible, the results of this trial will inform the

planning and setup of a subsequent larger randomized controlled prospective trial to evaluate efficacy.

Methods

Trial Design and Participants

We conducted an assessor-blinded, randomized, prospective, parallel group feasibility PROVIDE-B (improving cross-sectoral collaboration between primary and psychosocial care: an implementation study on video consultations-B) trial between March 1 and October 7, 2019, in 5 primary care practices in the State of Baden-Wuerttemberg in Southern Germany [26]. Primary care physicians were either recruited during a preceding qualitative preimplementation study [27] or through a network of collaborating academic research practices affiliated with the Department of General Practice and Health Services Research at Heidelberg University. We sent an invitation letter and visited interested practices to inform the practice teams about the study, including the concomitant process evaluation and the assessments involved. We also tested the quality of the internet connection to evaluate eligibility. We recruited 4 mental health specialists at the Institute for Psychotherapy, Heidelberg, which is a state-approved psychotherapeutic training facility at Heidelberg University. Mental health specialists were clinical psychologists with a diploma or master's degree in psychotherapy training or resident doctor training for board certification in psychosomatic medicine and psychotherapy, which is an independent specialty in Germany. All participating specialists had at least 2 years of training. Although specialists were not allowed to prescribe medication because of regulatory reasons, they had the possibility to suggest starting the patient on medication or changing their medication.

Eligible patients (1) exceeded cutoffs of 9 points for the Patient Health Questionnaire-9 (PHQ-9) and/or for the Generalized Anxiety Disorder-7 (GAD-7), respectively [28], which represents at least moderately severe symptom burden by either disorder; (2) did not yet have mental health treatment or, until the date of commencement of the study, insufficient treatment (psychotherapy, psychopharmacotherapy, or both) or difficulty with adherence to treatment; (3) agreed to participate in the study by written informed consent; (4) were capable of giving consent; and (5) were aged 18 years or older. Exclusion criteria for patients were (1) substance abuse/dependence that is likely to compromise intervention adherence; (2) risk of endangerment to others and/or risk of self-endangerment; (3) need for emergency medical treatment, for example, admission; (4) acute psychotic symptoms, for example, persecutory delusions and/or thought insertion; (5) severe cognitive impairment or dementia; (6) significant hearing and/or visual impairment; (7) pregnancy in the second trimester or later; and (8) insufficient German language proficiency. To ensure maximum generalizability, general practitioners as experts for their patients decided whether treatment was insufficient or whether there were difficulties with adherence. All other inclusion and exclusion criteria were assessed through standardized computer-assisted telephone interviews conducted by a study team member. The PROVIDE-B trial protocol was approved by the Medical Faculty of the University of Heidelberg Ethics Committee (S-634/2018) and was subsequently published [26].

Randomization and Masking

The participants were recruited via their primary care physicians during regular visits in the practice. On the basis of their clinical judgment, GPs prospectively selected individuals suspected to be affected by depression or anxiety and presented the study to them by offering information material. After providing written informed consent, eligible participants were randomly assigned (1:1) to the video consultation model versus treatment-as-usual via a secure, web-based randomization system (Randomizer V.2.0.2) operated by a data manager at the Institute of Medical Biometry and Informatics, Heidelberg University. We used block randomization stratified by primary care practice, with a block size of 4. Randomization at the individual level was independent and concealed. Allocation was subsequently made known to the principal investigator (M Haun), trial coordinator (JT), and mental health specialists. Participants, mental health specialists, and primary care practice staff were informed of the allocation by phone or email. Telephone interviews were used to assess the baseline data before randomization. Two research assistants, masked to group allocation, conducted the postmeasurement in telephone interviews with the participants.

Procedures

Participants allocated to the mental health specialist video consultations were offered up to 5 sessions with a mental health specialist during a 3-month treatment window. If patients and mental health specialists agreed that no further treatment was required, they were allowed to end the consultations as early as after the third session. The intervention featured web-based, real-time video consultations involving a 2-way interactive video to a primary care practice between mental health specialists and patients. Apart from that, the intervention was fairly similar to conventional consultation-liaison models in mental health primary care [29] and the collaborative care model [30,31], which both constitute a trade-off between increasing involvement of the primary care clinician on the one hand and increasing involvement of the mental health specialist on the other hand [32]. Both models, such as the PROVIDE-B intervention, target well-defined disorders that are associated with some degree of disability but for which effective treatments are available. Nevertheless, in contrast to consultation-liaison and collaborative care services where mental health specialists act as advisors to primary care physicians (eg, care managers in collaborative care), our intervention included more therapeutic aspects. Specifically, the intervention included 3 core intervention elements (*active ingredients*) for effective primary care–based mental health care, namely (1) systematic diagnosis plus proactive monitoring using validated clinical rating scales, (2) the establishment of an effective working alliance, and (3) a stepped-care algorithm within integrated care adjusting treatments based on clinical outcomes. If indicated, the intervention also included brief psychological therapy that worked with interpersonal dynamics, which has been shown to confer additional benefits [8]. When the patient had a more chronic condition that demanded long-term treatment, the mental health specialists and the patients mutually developed a care

plan that, if indicated, included transition to secondary specialist care. Furthermore, the mental health specialist discussed cases with primary care physicians. The intervention followed a transdiagnostic treatment approach for emotional disorders (depression and anxiety), for which various meta-analyses have shown efficacy compared with control conditions on measures of overall anxiety, disorder-specific anxiety, and depression [33,34]. In addition, the intervention entailed elements from problem-solving therapy, which has been shown to yield moderate effects in alleviating depression and anxiety in primary care [35]. Psychodynamic elements following a relationship focus and interpersonal understanding were added to foster the working alliance, which has been promoted as a crucial element of manuals achieving high acceptability in both patients and clinicians. At the end of the consultations, the mental health specialist proceeded as laid out in the care plan, providing a treatment summary and tailored recommendations to both the patient and the primary care physician. The intervention was conducted in line with the *Best Practices in Videoconferencing-Based Telemental Health* issued by the American Psychiatric Association and the American Telemedicine Association [25]. In line with the stage model of psychotherapy manual development, we compiled a stage I intervention manual delineating treatment techniques, goals, and format (the manual is available in the study by *Tönnies* et al [26]). For the description of the intervention, we followed the template for intervention description and replication guidance [26,36]. A structured description of the intervention is presented in Multimedia Appendix 1.

Patients received their first video consultation shortly after randomization and were scheduled for up to 5 sessions, lasting 50 minutes each, at biweekly intervals. The video consultations were conducted on a secure (ie, encrypted), web-based videoconferencing platform on a subscription basis (arztkonsultation ak GmbH;) at the fixed time slots set by the primary care practice staff. The patients were in a designated room in the general practice and the mental health specialists in either their office/private practice or another suitable, designated room at home. For every video consultation, patients received a transaction authentication number to log on to the encrypted, web-based videoconferencing platform for clinical video consultations. As the platform was easy to access, patients who had different levels of experience with videoconferencing had no major difficulties with logging in. Each mental health specialist was permanently assigned to one primary care practice. After the third session, we conducted an interim evaluation of the symptoms (using the PHQ-9 and GAD-7) and sent the results to the mental health specialist to tailor the treatment accordingly. After the last consultation with the patient, the mental health specialist sent a written case summary to the primary care practice, which was then attached to the medical record and on which, if needed, further decisions on follow-up procedures were based. Parallel to the study, mental health specialists received weekly group supervision led by a senior consultant in psychiatry and psychosomatic medicine from the Department of General Practice and Psychosomatics, Heidelberg University. Patients allocated to the control group were informed that they would receive the usual care provided by their primary care physicians. This might or might not have included a referral to a mental health specialist or other psychosocial treatment outside the study. The respective primary care physician was also informed about the group to which the patient was allocated. There were no restrictions on the usual treatment by primary care physicians.

Outcomes

The main outcome was the feasibility of a mental health care model integrating mental health specialist video consultations and primary care, which we operationalized by applying early stage implementation outcomes [37]:

- Recruitment strategy and recruitment rate (efficiency of recruitment strategies).
- Intervention acceptability in patients (attendance of sessions for the intervention arm).
- Acceptability of outcome measurements (rate of loss to follow-up and feedback after assessments).
- Intervention safety in patients (Inventory for the Assessment of Negative Effects of Psychotherapy [INEP]).
- Feasibility of study procedures, including the intervention (qualitative process evaluation will be published elsewhere).

In addition to feasibility, the measurements of effectiveness were also included. Effectiveness outcomes were depressive (PHQ-9) and anxiety (GAD-7) symptom severity, burden of specific somatic complaints (Somatic Symptom Disorder-B Criteria Scale [SSD-12]) [38], and recovery (Recovery Assessment Scale [RAS-G]), defined as “the personal process of adaptation and development through which the individual overcomes the negative personal and social consequences of [a] mental disorder and regains a self-determined and meaningful life” [39] consisting of 5 subdomains (more details on the domains are given in Multimedia Appendix 2 [40]) and “the quality and patient-centeredness of chronic illness care” (Patient Assessment of Chronic Illness Care [PACIC]) [41]. Health-related quality of life was measured using the European Quality of Life 5 Dimensions [42]. This also included a visual analog scale ranging from 0 to 100, on which the patients rated their quality of life with 0 for the lowest quality and 100 for the highest quality. Intervention-related costs and health care usage, including use of service and medication prescribing, were measured using the Questionnaire for the Assessment of Medical and Nonmedical Resource Utilization in Mental Disorders [43]. All these outcomes were assessed at baseline and 16 weeks postallocation. By choosing this period, we sought to (1) ensure that the intervention was completed despite possible delays (eg, because of time-consuming appointment management, patients’ and providers’ vacations) and (2) be able to assess not only immediate but also long-term effects. For the intervention group, intervention safety (unintended consequences and adverse effects) was assessed during close-out measurement by applying INEP [44]. INEP comprises 21 items asking the participant how they assess the effects of a psychosocial intervention.

Statistical Analysis

We based the sample size on recommendations for obtaining reliable sample size estimates in feasibility studies, which indicated that 50 patients would be needed (ie, 25 in each group)

[45]. The primary analysis followed the intention-to-treat principle.

First, as part of the data preparation, we applied an available-item strategy to calculate the total scale scores [46]. In this feasibility trial, we used pairwise deletion as a missing data strategy and did not adjust for multiple testing in the analyses. Second, we computed descriptive statistics for the feasibility outcomes, summarizing results for discrete variables in absolute and relative frequencies, and for continuous variables in means, SDs, medians, and IQRs. Third, we conducted assumption checks (screening for normality and equality of variances) for all variables of effectiveness outcomes. To investigate differences in effectiveness outcomes, we compared the change between baseline assessment and postassessment of PHQ-9, GAD-7, RAS-G, SSD-12, and PACIC in both groups using Mann-Whitney *U* tests [47,48]. We applied the screening values for computing the PHQ-9 and GAD-7 change scores if the baseline assessment had been performed no later than 28 days after screening. To increase interpretability, change scores were calculated by taking the difference between baseline assessment and postassessment scores or between postassessment and baseline assessment scores, depending on the respective scale. Therefore, a positive change indicates an improvement between the baseline assessment and postassessment. For the effect size *r* (rank-biserial correlation coefficient), the following interpretation applies: if $r>0$ in the baseline or follow-up scores, the health status in the intervention group was better than that in the control group. If $r>0$ for the change score, the improvement in the intervention group was larger than that in the control group.

We used R (version 4.0.2), JASP (version 0.12.2) [49,50], and Stata (version 15.1) for all analyses. This trial was prospectively registered with the German Clinical Trials Register (registration no. DRKS00015812). We did not implement any changes to the methods after trial commencement. We have reported this trial in accordance with the CONSORT (Consolidated Standards of Reporting Trials) extension for randomized pilot and feasibility trials (see the checklist given in Multimedia Appendices 3 and 4) [51].

Results

Sample Description

Of the 70 approached primary care practices, 12 were interested in participation. This relatively low rate may be explained by the fact that the provision of a designated room for a fixed time slot of 4 hours per week and a stable internet connection were mentioned as obligatory inclusion criteria. Outside the fixed time slot, the practice could use the room for routine clinical care. Some practices might not have been able to meet these requirements; therefore, they did not reply in the first place. Supporting this assumption, a preimplementation survey among primary care practitioners showed that more than half of them had no designated room available for video consultations [52]. After screening, we included 5 practices. Reasons for exclusion were a lack of designated rooms and/or internet connectivity. We recruited 50 participants—23 were randomized to mental health specialist video consultations and 27 to treatment-as-usual (Figure 1; Table 1). A total of 96% (48/50) participants had at least moderate levels of both depressive (PHQ-9≥10) and anxiety (GAD-7≥10) symptom severity, whereas 4% (2/50) participants were affected by moderate levels of depressive symptom severity only.

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

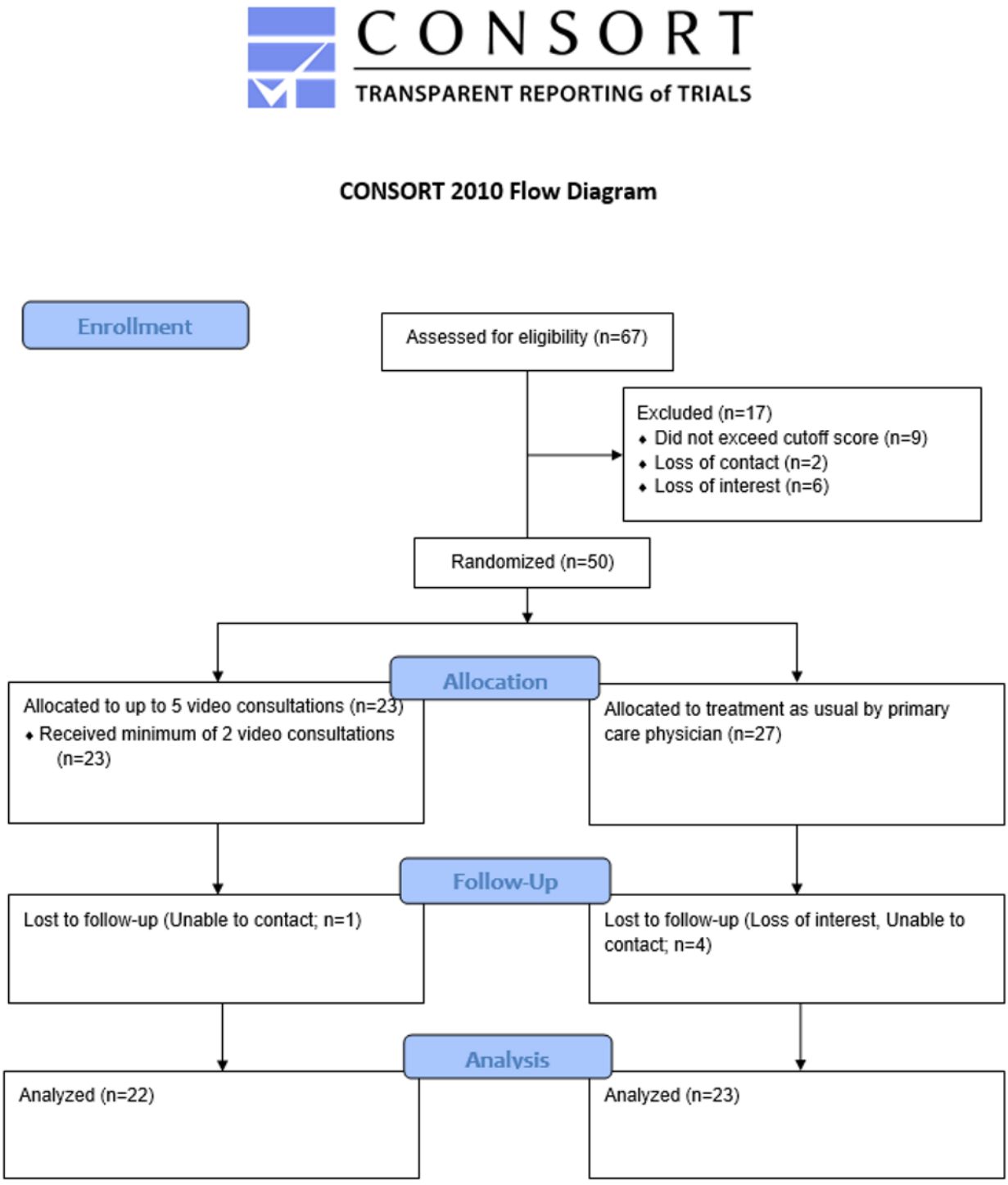

Table 1. Baseline characteristics (N=50).

Variable	Intervention group (n=23)	Control group (n=27)	Overall (N=50)
Age (years)			
Mean (SD)	45.9 (15.86)	51.2 (15.46)	48.8 (15.71)
Median (range)	48 (22-72)	56 (18-72)	54 (18-72)
Gender, n (%)			
Female	16 (69.6)	19 (70.4)	35 (70)
Male	7 (30.4)	8 (29.6)	15 (30)
Marital status, n (%)			
Single	5 (21.7)	5 (18.5)	10 (20)
In partnership	18 (78.3)	22 (81.5)	40 (80)
Education level, n (%)			
9 years or less	6 (26.1)	14 (51.9)	20 (40)
More than 9 years	15 (65.2)	13 (48.1)	28 (56)
Missing	2 (8.7)	0 (0)	2 (4)
Employment status, n (%)			
Employed	13 (56.5)	9 (33.3)	22 (44)
On sick leave	3 (13)	5 (18.5)	8 (16)
Retired	4 (17.4)	5 (18.5)	9 (18)
Unemployed	2 (8.7)	2 (7.4)	4 (8)
Missing	1 (4.3)	6 (22.2)	7 (14)
Number of chronic diseases			
Mean (SD)	0.9 (1.06)	1.4 (1.33)	1.1 (1.22)
Median (range)	1 (0-3)	1 (0-4)	1 (0-4)
Missing	0 (0)	1 (3.7)	1 (2)
Current psychiatric treatment or psychotherapy, n (%)			
No	20 (87)	21 (77.8)	41 (82)
Yes	3 (13)	6 (22.2)	9 (18)
Past psychiatric treatment or psychotherapy, n (%)			
No	7 (30.4)	9 (33.3)	16 (32)
Yes	13 (56.5)	12 (44.4)	25 (50)
Declined to answer	2 (8.7)	3 (11.1)	5 (10)
Missing	1 (4.3)	3 (11.1)	4 (8)
Current psychopharmacological treatment, n (%)			
No	15 (65.2)	14 (51.9)	29 (58)
Yes	8 (34.8)	12 (44.4)	20 (40)
Missing	0 (0)	1 (3.7)	1 (2)
Past psychopharmacological treatment, n (%)			
No	9 (39.1)	12 (44.4)	21 (42)
Yes	5 (21.7)	4 (14.8)	9 (18)
Declined to answer	5 (21.7)	5 (18.5)	10 (20)
Missing	4 (17.4)	6 (22.2)	10 (20)
Willingness to accept psychotherapy, n (%)			
Disagree	1 (4.3)	1 (3.7)	2 (4)

Variable	Intervention group (n=23)	Control group (n=27)	Overall (N=50)
Agree	4 (17.4)	3 (11.1)	7 (14)
Strongly agree	17 (73.9)	20 (74.1)	37 (74)
Missing	1 (4.3)	3 (11.1)	4 (8)
Willingness to accept psychopharmacological treatment, n (%)			
Strongly disagree	5 (21.7)	4 (14.8)	9 (18)
Disagree	6 (26.1)	5 (18.5)	11 (22)
Agree	5 (21.7)	3 (11.1)	8 (16)
Strongly agree	6 (26.1)	9 (33.3)	15 (30)
Missing	1 (4.3)	6 (22.2)	7 (14)
Level of depressive symptoms (PHQ-9[a]), n (%)			
Blank	1 (4.3)	0 (0)	1 (2)
Mild	1 (4.3)	4 (14.8)	5 (10)
Moderate	17 (73.9)	10 (37)	27 (54)
Severe	3 (13)	11 (40.7)	14 (28)
Highly severe	1 (4.3)	2 (7.4)	3 (6)
Level of anxiety (GAD-7[b]), n (%)			
Blank	2 (8.7)	2 (7.4)	4 (8)
Mild	8 (34.8)	5 (18.5)	13 (26)
Moderate	10 (43.5)	12 (44.4)	22 (44)
Severe	3 (13)	8 (29.6)	11 (22)

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

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

Recruitment, Rate of Loss to Follow-Up, and Success of Blinded Assessment

The overall recruitment yield (number randomized per number screened) was 69% (50/73), the recruitment rate (number recruited and randomized per primary care practice per month) was 50/(4×7+1×5)=1.52. The consent rate (number randomized per number eligible) was 86% (50/58). We did not have to employ any additional recruitment routes in addition to direct recruitment by primary care physicians. With 1 dropout in the intervention group (1/23, 4% could not be reached/reason unknown) and 4 dropouts in the control group (4/27, 15%; reasons: 3 lost interest and 1 could not be reached/reasons unknown), follow-up rates were 95.7% and 85.2% for the intervention and control groups, respectively. The overall follow-up rate was 90%. Unintentional unblinding of the actual randomly assigned group during postmeasurement occurred in 13% (4/45) of retained cases. Of these, 5 blind breaks were in the video consultation group and 1 was in the control group. The period of recruitment and intervention was between March 1 and October 7, 2019. The last follow-up measurement was conducted on February 10, 2020.

Acceptability of Treatment, Attendance at Sessions, and Reasons for Dropout

Retention in the video consultation group was reasonable, with 87.0% (20/23) of the participants completing the intervention as planned (regardless of availability of follow-up data). In total, 8.7% (2/23) participants attended only the first 2 sessions (1 experienced persistent connectivity failures; 1 expected long-term therapy and was dissatisfied with the length of the intervention). Of the 23 participants, 1 (4.3%) stopped after the third session for unknown reasons. Participants who were allocated to the 50-minute video consultation received an average of 4.4 sessions (SD 0.9; range 2-5 consultations). Of the 108 planned video consultations, 102 (94.4%) were successfully delivered. For completers, the median interval between the initial and final video consultation amounted to 49.5 days (range 21-70 days). In the intervention group, 35% (8/23) of the patients received some form of specialist mental health care (defined as at least one visit to a psychiatrist or psychotherapist as measured on the Questionnaire for the Assessment of Medical and Nonmedical Resource Utilization in Mental Disorders) outside the study. Of the 27 participants in the control group, 12 (44%) received some form of specialist mental health care. The patients had no major difficulties in responding to the questionnaires applied as part of the outcome measurement. They evaluated the assessments as feasible and appropriate. Considering all data for the change from baseline scores at follow-up, the highest fraction of missing information was found for the *No Domination by Symptoms* domain of recovery (RAS-G), amounting to 7% (3/45) of cases.

Effectiveness and Health Economic Outcomes

The findings for the effectiveness outcomes and health economics are presented in Multimedia Appendices 5 and 6 [43,53], respectively. Change from baseline scores for the "No Domination by Symptoms" domain of recovery (RAS-G) were somewhat higher at postmeasurement for the video consultation group (mean change score 1.8, SD 2.56) compared with the control group (mean change score: 0.9, SD: 2.30; Mann-Whitney *U* test: rank-biserial *r*=0.19; 95% CI −0.09 to 0.46, 75% CI 0.02-0.35, *P*=.18). We did not detect any notable differences between the intervention group and the control group for the other effectiveness outcomes. Regarding the use of services outside the trial, the number of psychiatric outpatient clinic contacts seems to be larger at follow-up than at baseline for both groups. However, only 3 individuals in the intervention group had 21 contacts. The 7 contacts in the control group were induced by 2 individuals. The sum of provided specialist mental health care by psychotherapists, specialists in psychosomatic medicine, and psychiatrists is larger in the control group (baseline: 29; follow-up: 61) than in the intervention group (baseline: 7; follow-up: 38), which is again driven by few individuals (individuals of the control group with at least one specialist mental health care contact at baseline [n=6] and at follow-up [n=12]; individuals of the intervention group with at least one specialist mental health care contact at baseline [n=6] and at follow-up [n=8]).

Unintended Consequences and Adverse Effects

Self-report data for unintended consequences and adverse effects, as measured on the INEP at 16 weeks postallocation, were available for 96% (22/23) of the participants assigned to video consultations. Considering all 21 INEP items, 18% (4/22) of these participants reported at least one unintended consequence or adverse effect attributed to the intervention instead of their life circumstances (average number of adverse effects per patient 0.3, SD 0.7). One participant reported that she or he "feels worse" at the end of the intervention and that they were depending too much on their mental health specialist. A second participant stated that they "felt hurt" by the mental health specialist's statements and that they experienced longer periods of feeling down during or after the intervention. A third participant indicated that they feared that colleagues could find out about them being in treatment and that they experienced longer periods of feeling down during or after the intervention. A fourth participant reported being affected "from events in her/his past more than in the time before the intervention." Of the 22 participants in the intervention group for whom data were available, 18 (81%) did not report any unintended consequences or adverse effects attributed to the intervention. Notably, we did not observe any serious adverse events (ie, sexual harassment by mental health specialists, self-endangerment, and/or endangerment to others).

Discussion

Principal Findings

In this assessor-blinded, randomized controlled feasibility trial, we found that a study comparing mental health specialist video consultations and treatment-as-usual by primary care physicians is feasible in people presenting with depression and/or anxiety in primary care. The feasibility of a subsequent definitive randomized controlled trial providing robust information on effectiveness is underscored by a reasonable recruitment yield, the high level of consent among eligible patients, and most importantly high levels of intervention acceptability and a low rate of loss to follow-up, which was slightly more pronounced in the control group. We attribute this to the integration of mental health specialists and primary care physicians, which accounted for seamless referrals from primary care to specialized care. Mental health specialist video consultations were generally safe and well accepted by both patients and health professionals. Although this feasibility trial was not formally powered to assess the evidence of a clinical response, the preliminary outcome data point to the benefits of being empowered to cope with symptoms. For the remaining outcomes, we did not find notable differences between the intervention and control groups, which may be explained by the fact that more patients in the control group had already been receiving psychiatric treatment, psychotherapy, and/or psychopharmacological treatment at enrollment compared with the intervention group. Even if we have found significant differences in our feasibility trial, it would have been inappropriate to interpret them as such because of the small and not formally calculated sample size in pilot or feasibility trials [54]. As our feasibility study covered several aspects of a full-scale randomized controlled trial and we present different outcomes, it is similar to a pilot trial. However, because our main objective was to test the feasibility of a mental health care model and to find aspects that may improve the implementation in the upcoming main trial, this study meets the characteristics of a feasibility trial. In addition, the fact that we conducted a parallel qualitative process evaluation indicates a feasibility trial [55].

Limitations

This feasibility trial had several limitations. First, with respect to generalizability, we had to draw on a nonprobability sample for all participants, including practices and mental health specialists. In this regard, we cannot fully rule out volunteer bias, that is, participating stakeholders exhibiting a higher openness toward web-based delivery of care compared with the respective underlying population. However, at this stage, our main goal is to evaluate feasibility, which usually builds on the motivation and engagement of innovators who are less reluctant to depart from the conventional paradigm of face-to-face clinical encounters. Some authors have explicitly encouraged trialists to focus on innovators as opposed to losing time on so-called laggards in the pilot phase of telepsychiatry programs [56]. Second, we did not systemically observe or measure fidelity to the intervention as laid out in the intervention manual to prevent implementation failure because we regarded video and/or audio recording of the sessions as too disruptive for the therapeutic process [57,58]. Although we cannot fully rule out inadequate implementation, together with the supervisor, the principal investigator (M Haun) did assess the content of the sessions in the weekly supervision. However, in the sufficiently powered effectiveness trial, we will implement a systematic self-report fidelity assessment for mental health specialists at the end of each video consultation, enabling us to determine the extent to

which the results will be because of the study intervention and to further increase statistical power [59]. Most importantly, we will monitor and foster continuous adherence to the fidelity plan throughout the trial. Third, patients' intervention acceptability was measured by the number of sessions attended. However, patients might have attended mental health video consultations despite finding them not useful. As this was the only measure of patients' acceptability, more detailed statements on how the patients evaluate the consultations will not be available until the results of the qualitative process evaluation are published. Fourth, it is not clear to which degree participants in the intervention group received more attention than those in the control group. A potential clinical improvement in the intervention group therefore does not necessarily have to be caused by the intervention but may be because of greater attention. However, following the recommendation for pragmatic trials in mental health services research, the definition of the control condition as treatment-as-usual was deliberately broad and was supposed to be as equal as possible to routine care [60]. Therefore, we tried not to interact with the patients at all and did not assess more information about the potential attention they might have received, for example, by using other health services during the trial. Nevertheless, in the sufficiently powered main trial, we will include health care service use in subgroup analyses with respect to attention received by control group subjects. Fifth, during the trial, some patients in both groups received other psychosocial care. As the intervention aimed to provide triage and, if indicated, facilitate the transition to specialist mental health care and the control condition was defined as treatment-as-usual, the use of treatment outside the trial was not excluded. As described, we did not collect data on the use of services in great detail and therefore did not include those in the analysis of clinical outcomes. However, we will include these data in subgroup analyses in a sufficiently powered main trial to investigate the potential clinical impact of psychosocial services use.

Comparison With Previous Work

The findings of this trial concur with results on feasibility from previous trials and synthesized findings from reviews. A large systematic review on telehealth interventions in mental health analyzed 5 full-scale randomized controlled trials using video consultations for various mental health conditions in settings other than primary care. In all of these trials, video consultations were reported as well accepted by different populations and under different conditions [61-64]. The few trials that specifically integrated mental health specialist video consultations in primary care also yielded substantial acceptance of and satisfaction with this new form of technology-based care [19,20,65,66]. Nevertheless, all these trials were conducted in the United States and/or drew on samples from specific, in part, high-structured contexts (eg, military, including veterans). It is very likely that the patient population in primary care and the contextual factors of how primary care is organized (eg, single-practitioner models in Europe) differ in many other Western countries [12,67]. Specifically, neither collaborative care nor integrated care models are commonly used in Germany or other European health care systems. Thus, our intervention comprising the integration of specialized and primary care combined with the video-based mode of delivery can be considered relatively innovative. In this regard, the findings of our trial, that is, high retention, no major adverse effects, and high satisfaction, show that video-based integrated care models are feasible more broadly, even in health care systems with a low level of experience in integrated care. Against the background of the debate on which patient populations video consultations might be suitable for, particularly pertaining to older aged and/or severely burdened patients [68], our sample proved to be quite heterogeneous (eg, in terms of age and socioeconomic status). Overall, the findings of this feasibility trial indicate that even severely burdened patients can be reached through mental health specialist video consultations in primary care. In this regard, our intervention involved patients from difficult-to-reach populations who might have never been engaged in specialized treatment following conventional care pathways [69,70]. Indeed, 1 in 3 of the participants in our study had never sought specialized mental health treatment before enrollment in our trial. An additional strength of this feasibility trial was the innovative, systematic assessment of adverse and negative effects and harms and their potential attribution to the intervention itself using a validated self-report instrument. Although calls for such an assessment in clinical trials are continuously put forward, there is some evidence that in the field of psychotherapy, only a small proportion of studies actually report unintended consequences or adverse effects [71]. We found that 18.2% of all participants (average number of adverse effects per patient 0.3, SD 0.7) reported at least one unintended consequence or adverse effect attributed to the intervention, which is (1) much less than the prevalence of 70.5% for INEP in a clinical sample (average number of adverse effects per patient 2.1, SD 2.2) [72] and (2) well within the range of 0% to 25% reported for intervention groups in psychotherapy trials [71]. However, in digital health interventions, the impact of the patient-clinician relationship has scarcely been investigated [73]. Therefore, it is not clear whether unintended consequences or adverse effects are caused by the mode of delivery through videoconferencing or by failed rapport between the patient and clinician. At any rate, technology-supported interventions are challenging for the patient-clinician relationship, and this requires investigation regarding the negative or adverse effects of psychotherapy. Notwithstanding, interpreting unintended consequences or adverse effects remains to be a unique challenge in psychotherapy interventions, where the sound delivery of treatment may nevertheless be linked to patients reporting such effects [74].

Conclusions

A study comparing mental health specialist video consultations and treatment-as-usual by primary care physicians in patients with depressive and anxiety disorders is feasible. The main implication of this trial is that a sufficiently powered effectiveness trial is needed to provide evidence about the relative efficacy of mental health video consultations in primary care. In our trial, the intervention proved to be unobtrusive and compatible with normal practice. Participants from various socioeconomic and cultural backgrounds could be enrolled so that a definitive trial should aim more broadly at the primary care patient population by applying pragmatic eligibility criteria.

Indeed, we have embarked on a full-scale effectiveness trial in which 320 patients will be enrolled (NCT04316572), which will also include a health economic evaluation. Having applied a conservative sample size calculation, we accounted for loss to follow-up by inflating the recruitment by 20%. From a clinical perspective, at present, it seems reasonable and safe to offer video consultations to patients who cannot assess specialist services using conventional pathways.

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Authors' Contributions

All authors contributed substantially to the conception, design, and analyses of this study. RB, DW, JT, MW, MH, AI, MV, and M Haun contributed to the data analysis plan. JT and M Haun collected and prepared data for analysis. RB, DW, and MV conducted all data analyses regarding feasibility and clinical and health economic outcomes. JT, RB, DW, MV, MH, and M Haun drafted the manuscript. All authors critically revised the manuscript for important intellectual content. All authors approved the version of the manuscript to be published and agreed to be accountable for all aspects of the work.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Structured description of the intervention.
[DOCX File , 19 KB - mental_v8i3e22569_app1.docx]

Multimedia Appendix 2
Structured description of the domains of the Recovery Assessment Scale, German Version.
[DOCX File , 29 KB - mental_v8i3e22569_app2.docx]

Multimedia Appendix 3
CONSORT (Consolidated Standards of Reporting Trials) checklist, an extension for randomized pilot and feasibility trials.
[DOCX File , 32 KB - mental_v8i3e22569_app3.docx]

Multimedia Appendix 4
CONSORT (Consolidated Standards of Reporting Trials) eHealth checklist (V.1.6.1).
[PDF File (Adobe PDF File), 10077 KB - mental_v8i3e22569_app4.pdf]

Multimedia Appendix 5
Results on effectiveness outcomes.
[DOCX File , 36 KB - mental_v8i3e22569_app5.docx]

Multimedia Appendix 6
Detailed health economic results (European Quality of Life 5 Dimensions and the Questionnaire for the Assessment of Medical and Nonmedical Resource Utilization in Mental Disorders).
[DOCX File , 47 KB - mental_v8i3e22569_app6.docx]

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Abbreviations

GAD-7: Generalized Anxiety Disorder-7
INEP: Inventory for the Assessment of Negative Effects of Psychotherapy
PACIC: Patient Assessment of Chronic Illness Care
PHQ-9: Patient Health Questionnaire-9
PROVIDE-B: improving cross-sectoral collaboration between primary and psychosocial care: an implementation study on video consultations-B
RAS-G: Recovery Assessment Scale-German
SSD-12: Somatic Symptom Disorder-B Criteria Scale

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Short Paper

Understanding Side Effects of Antidepressants: Large-scale Longitudinal Study on Social Media Data

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Abstract

Background: Antidepressants are known to show heterogeneous effects across individuals and conditions, posing challenges to understanding their efficacy in mental health treatment. Social media platforms enable individuals to share their day-to-day concerns with others and thereby can function as unobtrusive, large-scale, and naturalistic data sources to study the longitudinal behavior of individuals taking antidepressants.

Objective: We aim to understand the side effects of antidepressants from naturalistic expressions of individuals on social media.

Methods: On a large-scale Twitter data set of individuals who self-reported using antidepressants, a quasi-experimental study using unsupervised language analysis was conducted to extract keywords that distinguish individuals who improved and who did not improve following the use of antidepressants. The net data set consists of over 8 million Twitter posts made by over 300,000 users in a 4-year period between January 1, 2014, and February 15, 2018.

Results: Five major side effects of antidepressants were studied: sleep, weight, eating, pain, and sexual issues. Social media language revealed keywords related to these side effects. In particular, antidepressants were found to show a spectrum of effects from decrease to increase in each of these side effects.

Conclusions: This work enhances the understanding of the side effects of antidepressants by identifying distinct linguistic markers in the longitudinal social media data of individuals showing the most and least improvement following the self-reported intake of antidepressants. One implication of this work concerns the potential of social media data as an effective means to support digital pharmacovigilance and digital therapeutics. These results can inform clinicians in tailoring their discussion and assessment of side effects and inform patients about what to potentially expect and what may or may not be within the realm of normal aftereffects of antidepressants.

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KEYWORDS

antidepressants; symptoms; side effects; digital pharmacovigilance; social media; mental health; linguistic markers; digital health

Introduction

As mental health concerns continue to surge as an epidemic, arguably exacerbated in the present and the near future due to the ongoing COVID-19 pandemic [1], there is a growing need to better understand the impact of antidepressants on individuals with mental illnesses. Typically, the effects of these drugs are measured using randomized controlled trials and databases maintaining adverse event reports [2,3]. However, these trials are susceptible to biases [4]. Importantly, antidepressants are known to show varying effects across individuals and conditions [5]. Despite several meta-analyses [6], existing evaluations of the benefits and harms of antidepressants are based on group data and can only serve as advisories for individual patients.

Due to clinical heterogeneity, an individual's subjective experience is crucially important to consider but is difficult to be incorporated. Understanding the effects of a particular antidepressant on a particular individual is nontrivial, as emphasized in precision psychiatry and Research Domain Criteria–informed treatment research [7]. Common side effects related to antidepressants may include those related to gastrointestinal problems, weight gain or appetite, dry mouth, sleep, and sexual issues among others [8]. Side effects remain a common reason people discontinue these medications [9], yet it remains difficult to anticipate in which patients they will occur. Larger sample sizes are often necessary to uncover new findings about antidepressants [10], and social media offers a new tool to understand side effects that may otherwise remain undetected.

This short paper targets the above gap by adopting an observational study approach using natural language and machine learning methodologies on large-scale social media data. Our work draws motivation from the success of using social media as an effective source of unobtrusive, real-time, low-cost, and naturalistic data to infer wellbeing. Social media platforms enable individuals to share and express their day-to-day psychosocial concerns; therefore, this is a form of longitudinal verbal and behavioral data, and computational linguistic approaches have helped reveal naturalistic patterns of mood, behavior, cognition, psychological state, and social milieu of individuals and collectives [11-15].

Linguistic cues and social interactions on social media have enabled the inference of psychopathologies including depression, anxiety, stress, suicidal ideation, and loneliness [11,12,16-19]. In particular, the public-facing and microblogging-based design of Twitter (which is also the primary data set of our study) is known to enable candid self-disclosure and self-expressions of individuals, including on sensitive topics such as mental health and behavioral symptoms [20,21]. Twitter data were also recently leveraged to measure the psychosocial effects of COVID-19 [20]. Recent data and meta-reviews suggest that people are often more honest and may self-disclose more about mental health concerns and medications on social media than on other mediums [22].

This work uses natural language and causal inference analytic techniques on self-initiated social media expressions of antidepressant users to study the heterogeneity of individual and drug-specific outcomes. Our rationale is situated in the emergent body of empirical evidence in "digital pharmacovigilance" [23]. Digital pharmacovigilance has enabled understanding effects (and side effects) of prescription drugs by employing data mining techniques on large-scale social media data [24]. In recent studies leveraging publicly available Twitter data, Nikfarjam et al studied the mentions of side effects of 81 drugs [25], and Saha et al conducted a quasi-experimental study to explore the effects of 49 generic psychiatric medications [26]. These works revealed that Twitter data are an effective source to study digital pharmacovigilance, including that of antidepressants. This work extends the existing body of work by examining a set of clinically grounded side effects of antidepressants through identifying distinct linguistic markers in the longitudinal Twitter data; these data comprise 112,025,496 posts from 34,518 individuals showing the most and the least improvement in symptoms following the self-reported intake of antidepressants.

Methods

Data

To begin with, a list of Food and Drug Administration–approved antidepressants and antidepressant augmentation drugs was developed in consultation with the psychiatrist coauthor (JT). This list included 297 brand names mapped to 49 generic names across the four major drug families: serotonin-norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants, and tetracylic antidepressants. Next, the Twitter application programming interface was queried for public English posts containing the brand name or generic name of these drugs between January 1, 2015, and December 21, 2016, to obtain 601,134 posts by 230,573 unique users. Because a mention of a drug does not necessarily indicate a self-intake, a personal medication intake classifier built in prior work [27] was used to identify self-intakes of these medications. This classifier used a support vector machine model and could distinguish if a Twitter post corresponded to a self-report about a personal medication intake with an accuracy and F1 score of 0.82 [26]. The personal medication intake classifier identified 93,275 posts from our initial data set to indicate a personal intake. After pruning the data to only typical Twitter users, the entire longitudinal Twitter data sets of 23,191 users were collected, amounting to 112,052,496 Twitter posts made in the 4-year period between January 1, 2014, and February 15, 2018. These users self-disclosed the personal intake of 297 brand names (mapping to 49 generic names) of psychiatric medications (Textbox 1). A control data set was also built including 707,475,862 Twitter posts from the same period in the longitudinal timelines of 283,374 random users who did not disclose any medicine intake (also referred to as the control users).

Textbox 1. List of antidepressants considered in this work.

agomelatine, amineptine, amitriptyline, amoxapine, bupropion, butriptyline, citalopram, clomipramine, desipramine, desvenlafaxine, dibenzepin, dosulepin, doxepin, duloxetine, escitalopram, etoperidone, fluoxetine, fluvoxamine, hydroxynefazodone, imipramine, iprindole, levomilnacipran, lofepramine, maprotiline, mazindol, meta-chlorophenylpiperazine, mianserin, mirtazapine, nefazodone, nisoxetine, nomifensine, norclomipramine, northiaden, nortriptyline, opipramol, oxaprotiline, paroxetine, protriptyline, reboxetine, sertraline, setiptiline, trazodone, triazoledione, trimipramine, venlafaxine, vilazodone, viloxazine, vortioxetine, zimelidine

Study Design

This work aimed to obtain individuals who most and least improved in mental health symptomatic outcomes after the use of antidepressants. Replicating prior work [26], the study was designed by adopting a quasi-experimental approach to measure the relative treatment effect (RTE) of antidepressants of self-disclosed users of these drugs on social media. This approach draws motivation from the potential outcomes framework [28], where counterfactual outcomes are estimated based on the outcomes of similar (matched) individuals. A stratified propensity score analysis was conducted to match treatment and control, conditioned on a set of covariates. These covariates were computed on the pretreatment data of each user and included social media structural features (number of followers and Twitter posts, duration on platform) and linguistic features such as psycholinguistic use [2], 2000 raw unigrams, and baseline mental health symptomatic outcomes [26]. A logistic regression model predicting a user's treatment status based on the covariates estimated the propensity scores, and then the propensity scores were stratified into 100 strata of equal length. Thereby, each stratum contained matched treatment and control users who exhibited similar propensity scores. Then, the RTE was quantified for each drug in each strata of matched individuals as the ratio of the likelihood of an outcome measure in the treatment group to that in the control group. The outcome measures consisted of mental health symptomatic expressions of depression, anxiety, stress, suicidal ideation, and psychosis, as quantified via binary transfer learning classifiers of these expressions [26]. Accordingly, for each drug, after sorting the strata in descending order of RTEs, the top 10 strata contained users with the most improvement, and the bottom 10 strata contained users with the least improvement.

To drill into the posttreatment linguistic markers associated with the symptomatic changes per medication, an unsupervised language modeling approach, the Sparse Additive Generative (SAGE) model [29], was employed on the posttreatment Twitter posts of the most and least improved users. Given any two data sets, SAGE selects distinctive keywords from each data set by comparing the parameters of two logistically parameterized multinomial models, using a self-tuned regularization parameter to control the trade-off between frequent and rare terms. SAGE identified the salient *n*-grams in the posttreatment data sets of treatment users who showed contrasting changes in symptomatic outcome measures of depression, anxiety, stress, suicidal ideation, and psychosis. A detailed approach is included in the supplementary information in Multimedia Appendix 1 [2,26,28-30]. This paper compares and reports the analysis for 4 major antidepressants and qualitatively dives deep into the linguistic markers.

Results

Overview

To understand drug-specific effects, first, the posttreatment linguistic markers associated with the symptomatic outcomes of individuals who used antidepressants were compared (Figure 1). Table 1 shows the linguistic markers from the data sets of those individuals who showed the most improved RTE and those who showed the least improved RTE in outcomes. Table 2 presents the excerpts of five side effects known to be clinically significant for antidepressants, which are explained below.

Figure 1. Top n-grams (n=1,2,3) with normalized prevalence that co-occur with the named side effects. Blue and red bars represent magnitude of normalized occurrence in the social media data of individuals showing the most and least improved symptomatic outcomes, respectively.

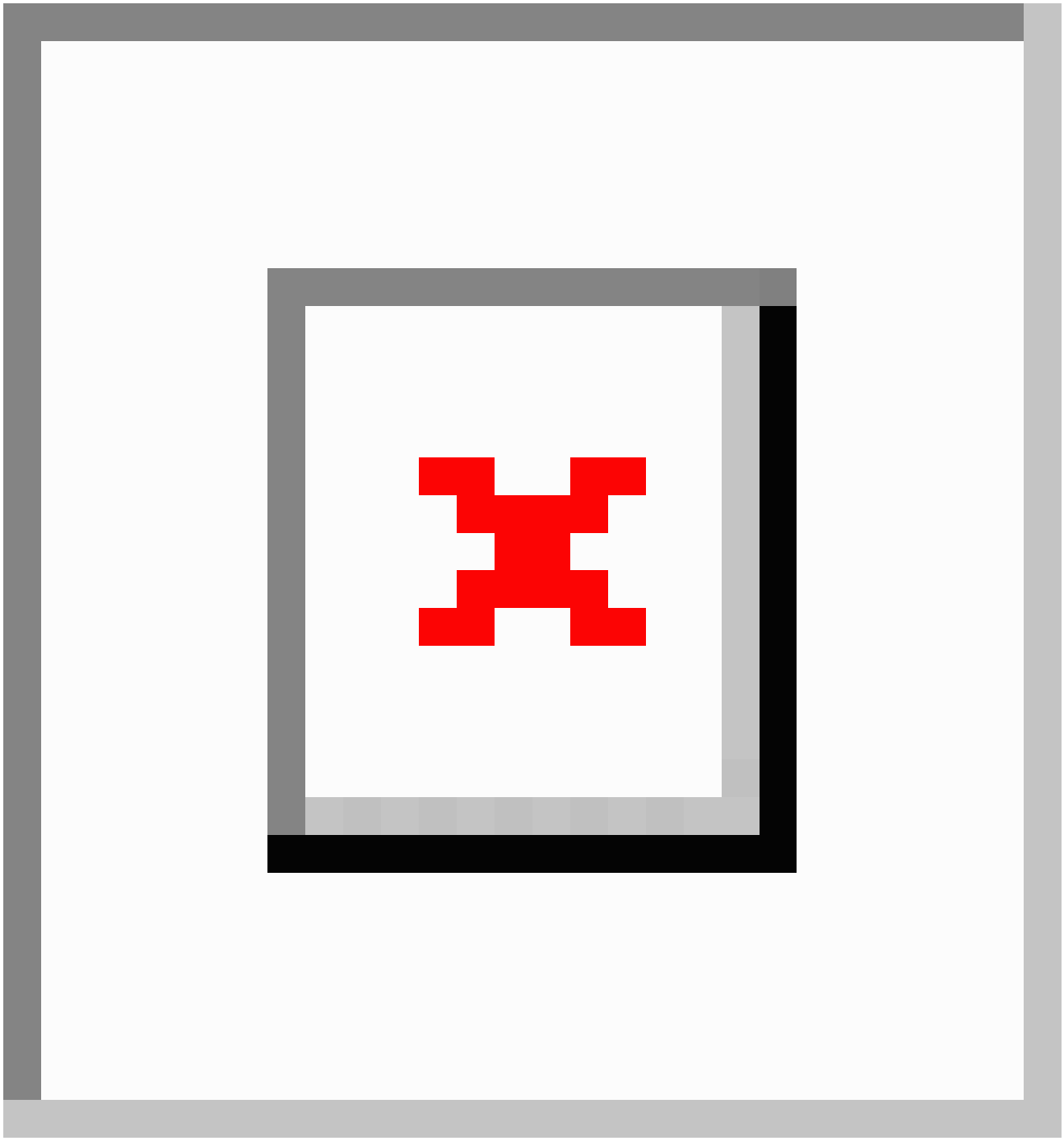

Table 1. Top keywords extracted by SAGE [29] in the most and least improved strata of the 4 most popular antidepressants. Improvement is measured in terms of relative treatment effect on strata of similar users based on changes in mental health symptomatic outcomes of depression, anxiety, stress, suicidal ideation, and psychosis.

Antidepressant	Most improved in symptomatic outcomes	Least improved in symptomatic outcomes
Sertraline	fell asleep, fall asleep, good night, hours sleep, makes sad, asexual, kissing, lips, sex, daddy, honest, fear, love, hair, tonight, makeup, excited, kid, conversation, doctor, wanna talk	fucking kidding, stop listening, conspiracy theory, green tea, math class, times bed, want eat, want sleep, freedom speech, want die, dark souls, dental plan, hell drug, family problems
Escitalopram	weight loss, fall asleep, feeling better, stay safe, want eat, swear god, thank love, making feel, spend time, hours sleep, sleep night, want sleep, lose weight, dreams, want die, best friend	grad school, parents, health care, health insurance, viagra, pre scription, patient, eye, alcohol, 20 mg, weight gain, cancer, weed, sexual, married, anxiety attack, dont want, sex pills
Fluoxetine	eating disorder, mental illness, feel good, mental health, fall asleep, hungry, hair, scared, smell, lose weight, just feel, anxiety, hate people, need help, sleeping, asking friend	work today, really hope, big deal, wanna know, health care, research, girlfriend, husband, work tomorrow, middle class, read book, great day, really bad, trying make, old man
Duloxetine	lives matter, chronic pain, pain meds, weight loss, heart attack, im crying, best friend, hours sleep, mental health, going sleep, sexual, im excited, self care, lose weight, healthy	today cancer, let play, better soon, good night, awake, hope feel better, panic attack, chronic illness, feel sick, pharmacy, weed, brother, hair, smoke, wake, food, bed, tired, beer, married

Table 2. Excerpts from individuals who improved the most and least.

Side effect	Excerpt from most improved (antidepressant used)	Excerpt from least improved (antidepressant used)
Sleep	I'm worried I fall asleep literally anywhere. (sertraline)	Badly just want some sleep. It is not happening! (sertraline)
Weight	This drug may cause weight loss and hypomania cool! (duloxetine)	My body is absolutely starting weight gain. It's terrible (escitalopram)
Eating behavior	I deal with depression, social anxiety, obsessional OCD, and eating disorders, and that's pretty damn cool (fluoxetine)	i want to eat my body weight in food (duloxetine)
Pain	Come to join others dealing with the daily challenges of chronic illness and chronic pain from the comfort of your life (duloxetine)	I suck at sleeping always, a common chronic pain thing (duloxetine)
Sexual issues	Come at me brother. I could have anyone but I choose to be with who I want so I'm technically asexual until I want intimacy (sertraline)	Even my viagra did not work! (escitalopram)

Sleep

Antidepressants are known to affect the circadian rhythms [31]. Sleep-related keywords distinctly occurred in the data sets of the most and least improved antidepressant users. For instance, for sertraline, the most improved users distinctly used "fall asleep," whereas the least improved users used "sleep paralysis" and "want sleep." Similar contrasting patterns were found in duloxetine, where the most improved users distinctly used "going sleep," whereas the least improved users used "wake" and "awake." The contrasting effects are also evident in Table 2.

Weight

Change in weight is a prominent behavioral side effect of many psychiatric medications [9]. The keywords of "weight loss" and "lose weight" dominated in the data set of the improved users of escitalopram, fluoxetine, and duloxetine, whereas "weight gain" dominated in the least improved users of escitalopram.

Eating Behavior

Keywords related to eating occurred saliently in both the most and least improved users. For instance, keywords such as "eating disorder" and "hungry" dominated in the posts by the improved users of fluoxetine, whereas "want eat" dominated in the least improved users of sertraline, and "food" dominated in the least improved users of duloxetine.

Pain

Neuropathic pain is a symptom in depression [32] and is also often comorbid with many depressive disorders. Additionally, antidepressants such as duloxetine are prescribed for chronic pain–related complications [32,33]. These factors could explain the salience in related keywords such as "chronic pain" and "chronic illness" in response to reactions to duloxetine.

Sexual Issues

Antidepressants are likely to affect sexual issues [34]. In this regard, our data set reveals varying findings; keywords such as "sex," "love," "kissing," and "asexual" dominate in the most improved users of sertraline, whereas "viagra" and "sexual" dominate in the least improved users of escitalopram.

Discussion

Summarily, our linguistic analysis reveals many keywords potentially related to prominent side effects of the antidepressants. There is a lack of simple and systematic means to understand side effects of antidepressants [4,5]. It is known that many side effects remain underreported in clinical care, and this study offers a new means to better assess what the actual burden and lived experience of patients may be. A major takeaway of our work is that examining social media data corresponding to self-reported medication use and symptomatic outcomes, can enable the discovery of drug-specific effects and

adverse effects, including personal accounts of how these effects can impact the lives of individuals. For instance, mentions of sleep were found to be largely associated with improvements following reported use of certain medications. In the context of weight, self-experiences of gaining weight following medication intake, as well as using antidepressants to target weight loss, were found. These potential effects of antidepressants are known in the literature [35], especially a recent finding related to the last observation, which is that certain antidepressants contain glucose-lowering agents that lead to weight loss [35,36]. However, in some cases, the same keyword appeared in both most and least improved outcomes, such as "sleep" for sertraline and "pain" for duloxetine. This observation also aligns with clinical studies that report many psychiatric medications to have both sleep-disturbing and sleep-promoting effects [37].

Our knowledge about the etiopathogenesis of mental diseases continues to be "top to bottom" instead of being "bottom up" [7]. Considering that the efficacy of all antidepressants is roughly the same and that prescribing is often done based on the side effect profiles of these medications [5], there is an urgent need to better understand the common effects of antidepressants. These observations of effects are able to produce observable data reflecting an individual's perceived effect and, at the same time, provide scalable population level insights. While there remain many concerns in using social media data in clinical care, recognizing value in social media data and how they may help inform decision making is an important step. Consequently, translating the potential promised by this brief research into impacting real world outcomes and decisions needs engaging conversations between computational and clinical researchers and practitioners, as well as policymakers. This work can be used to inform algorithms in the clinical decision support modules of medical records to help ensure that prescribing is more tailored to actual side effects of antidepressants. This study can also help inform patients about the full range of side effects and be used as a tool for more standard decision making around medication selection. In addition, this work bears implications toward drug repurposing and in developing new drugs that target treatments with fewer side effects.

Finally, this study adopts a quasi-experimental study design, which cannot establish a "true causality." However, it is more robust than more simple correlational analysis because of minimizing the confounders. This work motivates future computational study designs that combine the power of complementary digital data sources, including social media, and other ubiquitous data streams to obtain a more holistic understanding of an individual's behavior with respect to the use of antidepressants.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary information.
[DOCX File , 14 KB - mental_v8i3e26589_app1.docx]

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Abbreviations

RTE: relative treatment effect
SAGE: Sparse Additive Generative
SNRI: serotonin-norepinephrine reuptake inhibitor
SSRI: selective serotonin reuptake inhibitor

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Original Paper

Optimizing Engagement in an Online Dietary Intervention for Depression (My Food & Mood Version 3.0): Cohort Study

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Abstract

Background: Online interventions can be a cost-effective and efficient way to deliver programs to large numbers of people regardless of geographic location. However, attrition in web-based interventions is often an issue. Developing ways to keep participants engaged is important for ensuring validity and limiting potential biases. We developed a web-based dietary intervention as part of The My Food & Mood study which aimed to optimize ways to engage participants with low mood or depressive symptoms to promote dietary behavior change. Different versions of the My Food & Mood program were tested during optimization. Iterations were developed based on user feedback and usage analysis.

Objective: The purpose of this study was to compare engagement and nonusage attrition across 4 program iterations—which differed by platform format, delivery mode, and activity type—to create an optimized version.

Methods: Each program version contained modular videos with key activities with respect to implementing behavior change techniques of equivalent levels of required participation and length: version 1.0, desktop program and smartphone app; version 2.1, desktop or smartphone program; version 2.2, desktop program; and version 3.0, smartphone app. Adults with PHQ-8 scores of 5 or greater were recruited online and assigned to 1 of the 4 versions. Participants were asked to use the program for 8 weeks and complete measures at weeks 4 and 8. Engagement data were collected from the web-based platform system logs and customized reports. Cox regression survival analysis examined nonusage attrition and Kruskal-Wallis tests compared engagement across each cohort.

Results: A total of 614 adults participated. Kruskal-Wallis tests showed significant differences across the 4 cohorts in all engagement measures. The smartphone app (version 3.0) had the greatest engagement as measured by weeks engaged, total usage time, total time key activities, number of active sessions, percentage of activities completed against protocol, goals completed, and percentage of videos watched. Cox regression multivariate survival analysis showed referral from a health practitioner (hazard ratio [HR] 0.344, *P*=.001) and greater proficiency with computers (HR 0.796, *P*=.049) reduced the risk of nonusage attrition. Computer confidence was associated with an increased risk of nonusage attrition.

Conclusions: My Food & Mood version 3.0, a dietary intervention delivered via smartphone app with self-monitoring tools for diet quality and mood monitoring, was the version with greatest engagement in a population with low mood or depression. The iterative design techniques employed and analysis of feedback from participants resulted in a program that achieved lower rates of nonusage attrition and higher rates of intensity of use.

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KEYWORDS

online intervention; nutritional psychiatry; depression; low mood; dietary intervention; eHealth; mHealth; dietary intervention; engagement; nonusage attrition

Introduction

Background

Depression is a common and debilitating mental illness that is estimated to affect 4.4% of the world's population [1]. There is a well-documented and significant treatment gap attributable to lack of knowledge, stigma [2], and poor access [3]. Even with full provision of established psychological and pharmacological treatments, it has been estimated that only 50% of the burden of the disease is addressed [4]. The symptomatology of depression impairs function in daily life and may also impair an individual's ability to adhere to psychological and pharmacological treatment. Subsyndromal depression is also common and causes similar impairment and impact [5]. Individuals with subsyndromal depression are at increased risk of developing clinical depression. These findings highlight an urgent need for novel and accessible treatment and prevention strategies at the population level.

Nutritional psychiatry is an emerging field of research that could potentially provide such strategies. This field investigates the relationship between diet and mental health [6] and has produced substantial observational evidence that diet quality is associated with the risk of depression [7-9]. This evidence is now supported by intervention studies [10-12] showing that intervening to improve diet quality can improve depressive symptoms. Two systematic reviews, one with meta-analysis [13,14], reported that dietary interventions are efficacious adjunctive treatments for reducing depressive symptoms. It is thought that diet quality mediates the systematic inflammation characteristic of depression by influencing the immune system response through the gut microbiota [15]; however, in order to determine if these findings can translate into accessible population-level treatment and prevention strategies, further large-scale trials are required, using platforms capable of widespread and cost-effective translation.

A digital dietary intervention for people experiencing depressive symptoms has the potential to be large scale and attract people who may not seek treatment through traditional channels. There is a substantial body of evidence supporting digital delivery of psychological interventions for depression as an accessible and feasible way to reach this population [16-18]. Digital interventions have the potential to reach isolated or resource-poor populations, can be used at a time and place convenient to the user, and provide anonymity to overcome stigma; they are likely to appeal to the segment of the population experiencing depressive symptoms that is reluctant to or unable to seek help through traditional channels. As such, a web-based dietary intervention—eHealth or mobile health (mHealth)—could be a cost-effective and scalable way to further test dietary interventions in depression. Both eHealth and mHealth dietary interventions have been shown to be comparable in effectiveness, with low to medium effect sizes [19]; however, it is important that these interventions are developed with the target population to ensure barriers to use and change are addressed in intervention design. It is also important that potential disparities to access (eg, eHealth literacy, access to technology) are addressed in dissemination strategies.

However, despite the promise of these technologies, literature suggests that they have not yet been successfully harnessed to achieve meaningful and sustained health behavior change [20,21]. In order to reach their potential, digital interventions need to address the issues of limited uptake, engagement, adherence, and high attrition rates [22,23]. Attrition rates greater than 50% are not uncommon in both eHealth and mHealth programs [24-27]. In addition, there are inconsistent approaches to the conceptualization of engagement and its measurement in the literature [28,29]. A paper reporting a recent study [28] into understanding and promoting effective engagement with digital behavior change interventions notes conceptualization should account for user experiences of the technology as well as social and therapeutic contexts and proposes that measurement of engagement should include qualitative feedback, self-report questionnaires, and logs of system usage data.

Traditionally, engagement in web-based interventions has been measured by content access measures, such as how many times a user logs into the intervention site or how many pages of intervention content are accessed [30,31]. While these are useful indicators of activity, they are not able to detail if the user has had sufficient exposure to the program or if exposure has been in a manner appropriate to digest the materials presented or adequately complete assigned tasks. If a user accesses all the content but does not complete the required assessments for the intervention and is therefore considered a dropout, there are few conclusions that can be drawn as to why. However, if analytics highlight that the user simply clicked through the content and did not spend sufficient time on the site to properly consume the intervention content, then their experience of the intervention and actual level of engagement can be better understood. These types of measurements (examining time versus access or analysis of interaction with intervention features such as time spent watching video content, drop-off points for video content, time spent on forums, or messaging within the system) are defined as intensity-of-use measures [31]. The e-CONSORT

guidelines [31] recommend reporting both usage measures and intensity-of-use measures for all web-based interventions, in order to improve both the quality of publications and analysis of engagement and user interaction with these types of interventions. In addition, analyzing these types of data against intervention outcomes will enable robust estimates of effective engagement [21].

Understanding how participants use digital interventions has been identified as key to understanding the issues of limited uptake, engagement, adherence, and high attrition rates [20]. Analyzing nonusage attrition, as defined by Eysenbach [30], is also important for understanding these issues. This has prompted more research into understanding usage and nonusage attrition in digital interventions [32,33]. Understanding how users interact (usage and nonusage) with a digital intervention can help to better measure adherence and intervention effectiveness [23]. In addition, the trajectory of symptoms and the experience of depression itself may impede participants' abilities to adhere to or engage with a digital intervention. Understanding usage patterns and nonusage attrition might help guide future intervention designs that are more accommodating of the impact of symptoms or more engaging for the target population.

The My Food and Mood study aimed to develop and optimize a digital (eHealth and mHealth) dietary intervention for people experiencing depressive (including subclinical) symptoms. From 2017 to 2019, the My Food & Mood study developed an initial version of the program (My Food & Mood Program version 1.0) guided by evidence from nutritional psychiatry, behavior change, expert input, and consumer input. Using principles of user-centered design, this study iteratively optimized the program based on qualitative feedback, self-report questionnaires, and analysis of both usage and intensity of use engagement measures. Each version of the program was trialed by a separate cohort of the target population. During the course of the optimization phase, 3 subsequent versions of the program (My Food & Mood Program version 2.1, version 2.2, and version 3.0) were produced and trialed. This study is an analysis of the quantitative engagement data collected during the My Food and Mood study.

Objectives

The primary aim was to analyze patterns of usage across all 4 cohorts of the My Food and Mood study to understand quantitative differences in engagement across each version and to determine which version of the program had the highest rates of user engagement and lowest rates of nonusage attrition. The secondary aim was to identify factors that predicted active usage and nonusage attrition across all cohorts.

Methods

Study Design: My Food & Mood Study

The My Food & Mood study was conducted from 2017 to 2019. The study design was guided by the Information Systems in Research framework [34]. The study initially involved the development and testing of a web-based dietary intervention program for people with depressive (including subclinical) symptoms. This resulted in the first version of the program (My Food & Mood version 1.0) which was trialed by cohort 1 from October 2018 to March 2019 (recruitment round 1). Subsequent phases of optimization were run with the second (version 2.1), third (version 2.2), and fourth (version 3.0) versions of the programs from June 2019 to January 2020 (recruitment round 2) and trialed by separate cohorts (2.1, 2.2, and 3.0, respectively). Design iterations informed by feedback and analysis of engagement from preceding cohorts aimed to optimize the program. Standard software development version control methods were employed to manage each iteration. Participants in each cohort had access to their respective version of the program for an 8-week period. Feasibility analysis for the optimized version has been published elsewhere [35]. This analysis examined the quantitative engagement measures collected during the My Food & Mood study to look at usage and nonusage attrition across each version of the program.

Participants

Participants were recruited by targeted email campaigns, online advertising, and social media posts. Campaign emails were sent to members of the Food & Mood Centre's potential participants database and to members of the Community and Research Network run by Innovation in Mental and Physical Health and Clinical Treatment Strategic Research Centre Strategic Research Centre. The program was also advertised by Beyond Blue to members of Blue Voices, a community with lived experience who contribute to the development of mental health services, policy, and programs [36]. Targeted advertisements were placed on Facebook ads, and social media posts were disseminated through the Food & Mood Centre's channels. Printed flyers were distributed at Barwon Health's acute mental health inpatient clinic, and the program was advertised during community presentations conducted by the Food & Mood Centre researchers.

Screening was performed online via the recruitment website [37]. Recruitment material and the recruitment website were branded with the Food & Mood Centre, Innovation in Mental and Physical Health and Clinical Treatment Strategic Research Centre, and Deakin University logos. Participation was voluntary, and all participants provided digital consent prior to commencement. The study was conducted in accordance with the National Statement on the Ethical Conduct of Research and the protocol was approved by Deakin University Faculty of Health's Ethics Committee (reference 14/SW/1127).

Inclusion and Exclusion Criteria

The screening survey included demographic questions, questions about access and use of technology, and questions about dietary autonomy. Computer proficiency was evaluated using the Computer Proficiency Questionnaire (CPQ-12) [38], and screening for possible eating disorders was conducted using the Sick, Control, One, Fat, and Food (SCOFF) questionnaire [39]. The 8-item Patient Health Questionnaire (PHQ-8) was used to screen for depressive symptoms. [40] In recruitment round 1, eligible participants completed the Simple Dietary Questionnaire (SDQ) as part of the baseline questionnaires. In recruitment round 2, the Mediterranean Diet Adherence Screener (MEDAS) assessed level of adherence to a Mediterranean diet [41].

Individuals were eligible for the study if they were aged over 18 years and reported current depressive symptoms (PHQ-8 score ≥5). Individuals were excluded if they did not have access to the internet, a computer, or smartphone; had low computer literacy (CPQ-12 score <10); had limited English literacy; were not able to follow a different diet (no diet autonomy); and if there was risk of eating disorder (SCOFF score ≥2). In recruitment round 1, participants were excluded if they were not located in Australia or the United States. This additional criterion was due to the available versions of the diet recall tool that was used in this part of the trial. In recruitment round 2, individuals were also excluded if they already followed a high-quality diet (MEDAS score >11).

Interventions

Overview

All 4 versions of the program addressed the relationship between diet and mental health. Advice provided in version 1.0 was for a diet for good gut health; this focused on increasing fiber intake and decreasing discretionary food intake and was aligned to the Australian Dietary Guidelines [42]. It included food recommendations based on traditional dietary patterns such as the Mediterranean diet. The dietary advice was updated for versions 2.1, 2.2, and 3.0 based on user feedback and expert analysis of the outcomes from cohort 1. The advice for these versions was for a modified Mediterranean style diet that aligned to the Australian Dietary Guidelines [42]. The dietary advice was delivered via video, in question and answer format, and filmed using Food & Mood Centre researchers. All versions implemented the same behavior change techniques. The key behavior change techniques and their implementation are summarized in Multimedia Appendix 1. Each of the programs required equivalent levels of participation for the key behavior change activities (key activities). Key activities for each program and the expected duration required are listed in Multimedia Appendix 2. The versions differed in delivery platforms and formats (version 2.1: web-based or smartphone program; version 2.2: web-based–only program; version 3.0: smartphone app only). The web-based programs were built in Moodle 3.6 (developed by Martin Dougiamas) and were accessed via personal computer through a supported browser. Version 2.1 could also be accessed through the Moodle app. The smartphone apps were custom developed using Corona Labs (graphics depicting the user interfaces for each version are shown in Multimedia Appendix 3).

My Food & Mood Version 1

Version 1 was a 6-module web-based program and accompanying smartphone monitoring app. Each module contained an educational video and 6 reinforcement activities (game, quiz, additional reading, shopping list, recipe, and goal setting). The smartphone app enabled self-monitoring of diet and mood with simple graphical inputs and produced a graph of daily food and mood scores. Participants had 8 weeks to complete the 6 modules. Participants were advised to use the smartphone app daily from week 1.

My Food & Mood Version 2.1

Version 2.1 was a web-based program that delivered the intervention content as 16 discrete short modules. The program was optimized for use on a desktop but could also be accessed on a smartphone. Each module contained a video explaining an aspect of the Mediterranean diet and an activity or a short quiz about the video content. The program also included a web-based activity to self-monitor diet. The videos were between 1.5 to 3 minutes in length. Participants could work through the videos and activities at their own pace over the 8-week period.

My Food & Mood Version 2.2

My Food & Mood version 2.2 was a web-based–only program that delivered the intervention content in a week-by-week format. The program also included a web-based activity to self-monitor diet. The first 2 weeks presented the intervention video content as compiled modules. Modules 1 to 8 were presented in week 1 and modules 9 to 16 in week 2. The subsequent 6 weeks of the intervention presented recipes and goal setting activities.

My Food & Mood Version 3.0

My Food & Mood Version 3.0 was a custom-built smartphone app. The intervention content was presented as links with the content divided as per version 2.2 (Modules 1-8, Modules 9-16). The app also contained self-monitoring tools for diet, mood, and lifestyle as well as tools for goal setting and food shopping. Participants could see their progress against the ModiMed Diet score [43] on the progress page, which reflected improvement needed (with respect to food groups) to achieve higher diet quality.

Measures

Sample Characteristics

Participant characteristics were derived from the screening survey. BMI was calculated from self-reported height and weight. Socioeconomic index and remoteness area classification were coded from Australian Bureau of Statistics datasets [44,45] for Australians who supplied postcodes. Computer confidence was self-rated on a Likert scale between not *confident at all* to *confident* and computer skill level was also self-rated on a Likert scale between *never used* to *highly skilled*.

Diet Quality

Diet quality was measured at baseline, week 4, and week 8 using the validated MEDAS [46,47] and the SDQ (Parletta N, unpublished). The MEDAS is a 14-item scale with a maximum score of 14. It has acceptable accuracy and reliability for assessing adherence to a Mediterranean diet [41]. The SDQ is a 27-item food frequency questionnaire, based on the Australian Dietary Guidelines, that is suitable for self-report and simple to complete. Its score range is 0 to 100 and it has been validated against 24-hour recall and demonstrated moderate validity correlations (r=0.42 to 0.57; Parletta N, unpublished data). A combined baseline diet quality score (MEDAS Rescored) was calculated for both the MEDAS and SDQ responses; this included responses to overlapping questions from the 2 instruments. Diet quality question mapping and scoring is shown in Multimedia Appendix 4.

Depressive Symptoms

Depressive symptoms were measured at baseline, week 4, and week 8 using the PHQ-8. PHQ-8 is reliable and valid 8-item assessment of depressive symptoms with a score ranging from 0 to 24. PHQ-8 has been shown to be suited to self-reporting [48]. Baseline depressive symptom severity was calculated from PHQ-8 scores (mild, score 5-9; moderate, score, 10-14; moderately severe, score 15-19; and severe, score >20) [49].

Engagement

Engagement was represented by duration, frequency, and intensity-of-use measures; 8 engagement measures were calculated from database entries, timestamped event logging from active sessions, and a custom script tracking the duration of videos watched. An active session was recorded any time the participant logged into the desktop app or opened the smartphone app and accessed content or made data entries. The measures were (1) *weeks engaged*: duration of program use in weeks calculated by subtracting the date and time of the last active session from the date and time of the first active session; (2) *total usage time*: calculated from the sum total time for all active sessions; (3) *total time key activities*: calculated from the sum total time of active sessions for key activities; (4) *number of active sessions*: total count of active sessions; (5) *average time per session*: mean total time of active sessions; (6) *per protocol percentage*: total number of completed key activities divided by total number of key activities; (7) *goals completed*: number of goals set and marked as complete; and (8) *percentage videos watched*: maximum duration watched for each video divided by video duration.

Nonusage Attrition

Weeks engaged, per protocol percentage, and number of active sessions were used as indicators of nonusage attrition. Participants were coded as *nonusage attrition observed* if there were less than 4 active sessions recorded over the 8-week period and if they had completed less than 90% of the key activities (per protocol percentage) for their program by their last active session. (These requirements were based on the optimization protocol and the number of sessions required to complete the key activities.) Participants who recorded more active sessions and had completed more than 90% of the key activities (per protocol percentage) were coded as *nonusage attrition not observed*.

An active participant was defined as a participant who used their allocated program. Use was determined as those who logged in to the desktop program at least once (version 1.0, 2.1, and 2.2) or downloaded and logged into the smartphone app (version 1.0 and 3.0).

Statistical Analysis

The sample size required to detect an improvement in engagement, calculated from time required per activity, was based on the initial program design (My Food & Mood version 1.0). In this program, the 6 modules required 15 to 20 minutes engagement time. Assuming mean 90 (SD 25) minutes for engagement time, a sample size of 100 participants per cohort, and type I error of .05, the study had 80% power to detect 10 minutes or greater improvement in mean engagement time across each version of the program. This is equivalent to a moderate effect size of 0.4.

Nonusage attrition rate across weeks engaged was analyzed using Cox regression multivariate survival analysis, with weeks engaged and the coded survival variable. Univariate analyses were conducted on baseline characteristic variables of interest to select covariates for the model. Selected characteristic variables were age, gender, recruitment source, BMI, education, employment, computer skills, computer confidence, baseline mood, and diet quality. Cox regression multivariate survival analysis was repeated including only active participants. Intervention engagement was evaluated by comparing median engagement time and intensity of use outcomes (weeks engaged, total usage time, total time key activities, number of log-ins, average time per log-in, per protocol percentage, goals completed, percentage videos watched) between the 4 cohorts using Kruskal-Wallis *H* tests.

Results

General

A total of 614 adults were recruited online into the 4 cohorts at the 2 time points. Participants were predominantly female (536/614, 87.3%) and from Australia (443/614, 70.5%). Of those who supplied a valid Australian postcode (304/614, 49.5%), 79.3% (241/304) were from major cities, 20.1% (61/304) were from regional areas, and 0.7% (2/304) from remote areas. Most participants had a university education and lived in higher-ranked socioeconomic index areas. Table 1 presents the demographic characteristics of each cohort. There was a significant difference in age (χ^2=12.295, *P*=.006) baseline PHQ-8 (χ^2=11.323, *P*=.01), and baseline MEDAS Rescored (χ^2=26.093, *P*<.001) across cohorts. Consort diagrams for each recruitment round are provided in Multimedia Appendix 5.

Table 1. Characteristics of participants from each of the cohorts.

Variable	Cohort 1 (n=156)	Cohort 2.1 (n=154)	Cohort 2.2 (n=151)	Cohort 3 (n=153)
Gender, n (%)				
Male	34 (21.8)	14 (9.1)	19 (12.6)	28 (18.3)
Female	122 (78.2)	140 (90.9)	132 (87.4)	125 (81.7)
Age, median (quartile 1, quartile 3)	40 (32, 49)	37 (30, 45)	41 (34, 49)	42.5 (33, 50)
BMI, mean (SD)	26.41 (5.68)	25.85 (7.19)	26.09 (6.05)	26.28 (6.11)
Depressive symptoms (Mood PHQ-8[a]), median (quartile 1, quartile 3)	8 (6, 12)	10 (6, 12)	10 (7, 15)	10 (7, 14)
Taking antidepressants, n (%)	50 (23.4)	49 (22.9)	59 (27.6)	56 (26.2)
Diet quality, MEDAS[b] (Rescored), median (quartile 1, quartile 3)	3 (2, 4)	2 (1, 3)	2 (1, 3)	2 (2,3)
Socioeconomic index, median (quartile 1, quartile 3)	8 (6, 9)	9 (6, 9)	8 (5, 9)	7 (5, 9)
Recruitment referral source, n (%)				
Facebook	67 (43.1)	64 (41.5)	65 (42.9)	66 (43.0)
Instagram	11 (7.0)	11 (6.9)	10 (6.3)	11 (7.1)
Twitter	19 (12.0)	20 (13.1)	18 (11.6)	19 (12.2)
The Food & Mood Centre	12 (7.9)	12 (8.1)	13 (8.3)	12 (7.8)
Health Practitioner	29 (18.3)	26 (17.2)	26 (16.9)	26 (17.3)
Family	9 (6.0)	11 (7.1)	10 (6.7)	9 (6.1)
Friend	7 (4.5)	8 (5.1)	8 (5.2)	7 (4.3)
Other	2 (1.2)	2 (1.0)	3 (2.1)	3 (2.2)
Education, n (%)				
Less than high school	2 (1.5)	2 (1.3)	3 (2.0)	4 (2.6)
High school graduate	9 (6.8)	7 (4.5)	9 (6.0)	11 (7.3)
Some college	18 (13.5)	20 (13.0)	17 (11.4)	23 (15.3)
2-year degree	8 (6.0)	12 (7.8)	13 (8.7)	7 (4.7)
4-year degree	41 (30.8)	36 (23.4)	23 (15.4)	30 (20.0)
Professional degree	47 (35.3)	48 (31.2)	45 (30.2)	38 (25.3)
Doctorate	8 (6.9)	7 (4.5)	5 (3.4)	7 (4.7)
Employment, n (%)				
Employed full time	69 (44.5)	66 (42.9)	52 (34.9)	65 (43.3)
Employed part time	50 (32.2)	46 (29.9)	55 (36.9)	45 (30.0)
Unemployed (looking)	5 (3.2)	6 (3.9)	8 (5.4)	5 (3.3)
Unemployed (not looking)	6 (3.9)	6 (3.9)	9 (6.0)	13 (8.7)
Retired	2 (1.3)	3 (1.9)	4 (2.7)	6 (4.0)
Student	6 (3.9)	4 (2.6)	5 (3.4)	6 (4.0)
Disabled	17 (11.0)	23 (14.9)	16 (10.7)	10 (6.7)
Computer skill level, n (%)				
Never used	0 (0)	0 (0)	0 (0)	0 (0)
Beginner	1 (0.7)	4 (2.6)	0 (0.0)	2 (1.3)
Competent	144 (97.3)	74 (48.1)	84 (56.4)	75 (50.0)
Highly skilled	3 (2.0)	76 (49.4)	65 (43.4)	73 (48.7)
Computer confidence, n (%)				
Not confident at all	0 (0)	0 (0)	0 (0)	0 (0)

Variable	Cohort 1 (n=156)	Cohort 2.1 (n=154)	Cohort 2.2 (n=151)	Cohort 3 (n=153)
I usually need help	0 (0)	1 (0.6)	0 (0)	2 (1.3)
It depends on the task	22 (14.9)	18 (11.7)	17 (11.4)	16 (10.7)
Confident	126 (85.1)	135 (87.7)	132 (88.6)	132 (88.0)

[a]PHQ-8: Patient Health Questionnaire.

[b]MEDAS: Mediterranean Diet Adherence Screener.

Engagement

Table 2 presents the comparisons for engagement measures across cohorts. Cohort 3 received the highest mean rank score for a majority of the engagement measures, including weeks engaged, total usage time, total time key activities, number of sessions, percentage of activities completed against protocol, goals completed, and percentage videos watched (Figures 1-4).

Table 2. Engagement metric comparisons across cohorts.

Measures	Kruskal Wallis test statistics			Cohorts, median (95% CI)			
	n (*df*)	*H*	*P* value	Cohort 1	Cohort 2.1	Cohort 2.2	Cohort 3
Usage measures							
Weeks engaged	424 (3)	12.573	.006	1.1 (0.6, 2.2)	1.4 (0.7, 2.1)	2.7 (1.2, 3.7)	3.6 (2.1, 4.1)
Total usage (hours:minutes:seconds)	424 (3)	22.077	<.001	1:15:20 (0:48:29, 1:43:59)	1:28:30 (1:06:23, 1:55:00)	1:35:16 (1:22:21, 1:50:12)	1:52:15 (1:28:32, 2:22:55)
Total time key activities (hours:minutes:seconds)	424 (3)	48.392	<.001	0:42:51 (0:40:23, 0:49:19)	0:51:24 (0:45:00, 0:59:09)	1:10:12 (0:58:49, 1:22:05)	1:30:01 (0:52:00, 1:48:00)
Goals completed, n	424 (3)	30.426	<.001	1 (0, 2)	1 (1, 2)	2 (0, 3)	3 (2, 4)
Active sessions, n	424 (3)	61.208	<.001	15 (6, 20)	3 (1, 4)	3 (3, 4)	30 (17, 24)
Intensity of use measures							
Average duration per session (hours:minutes:seconds)	424 (3)	77.057	<.001	0:02:25 (0:01:28, 0:05:06)	0:21:41 (0:05:01, 0:30:00)	0:27:27 (0:24:58, 0:31:11)	0:04:55 (0:03:25, 0:08:22)
Per protocol percentage	424 (3)	28.527	<.001	12.7 (11.4, 16.9)	25.3 (14.4, 34.4)	33.5 (27.7, 43.0)	38.4 (25.5, 65.6)
Percentage videos watched	424 (3)	39.164	<.001	22.0 (13.0, 26.0)	35.5 (23.0, 48.0)	55.0 (46.0, 70.0)	70.00 (47.5, 83.5)

Figure 1. Total time key activities.

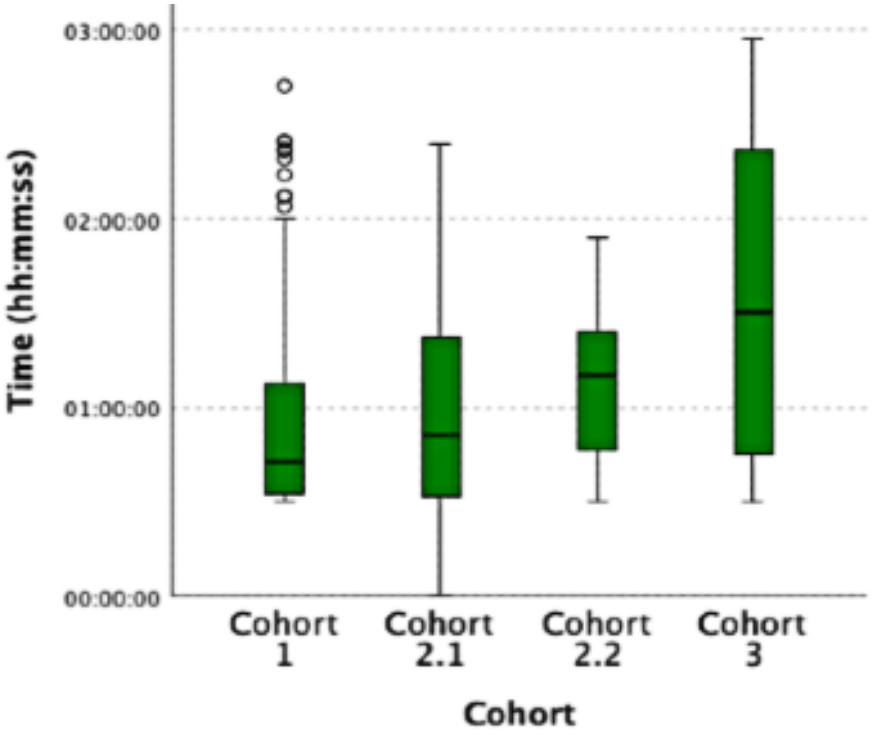


Figure 2. Average duration per session.

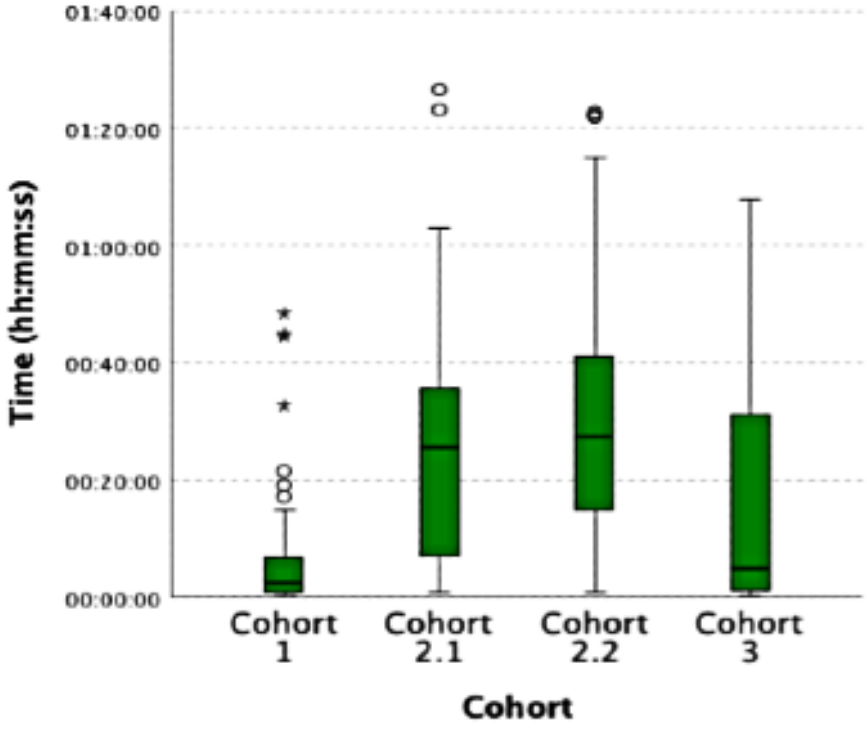


Figure 3. Percentage watched videos.

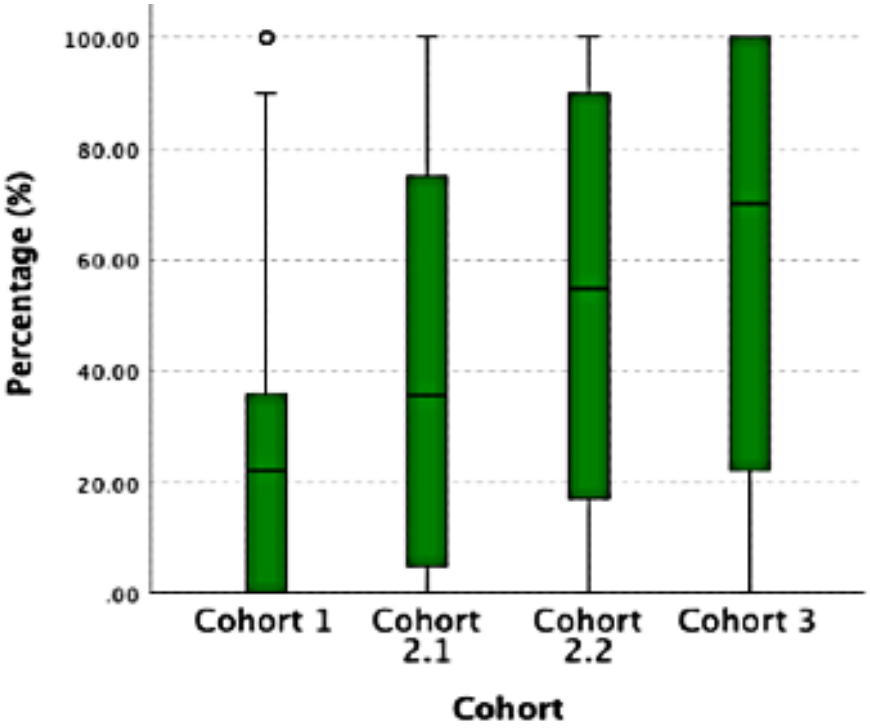
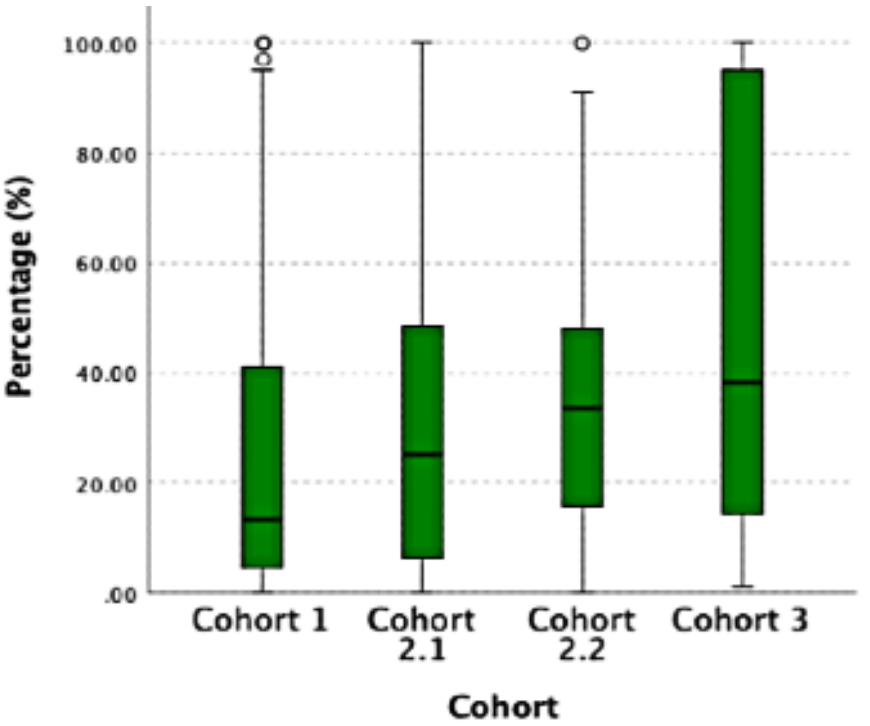


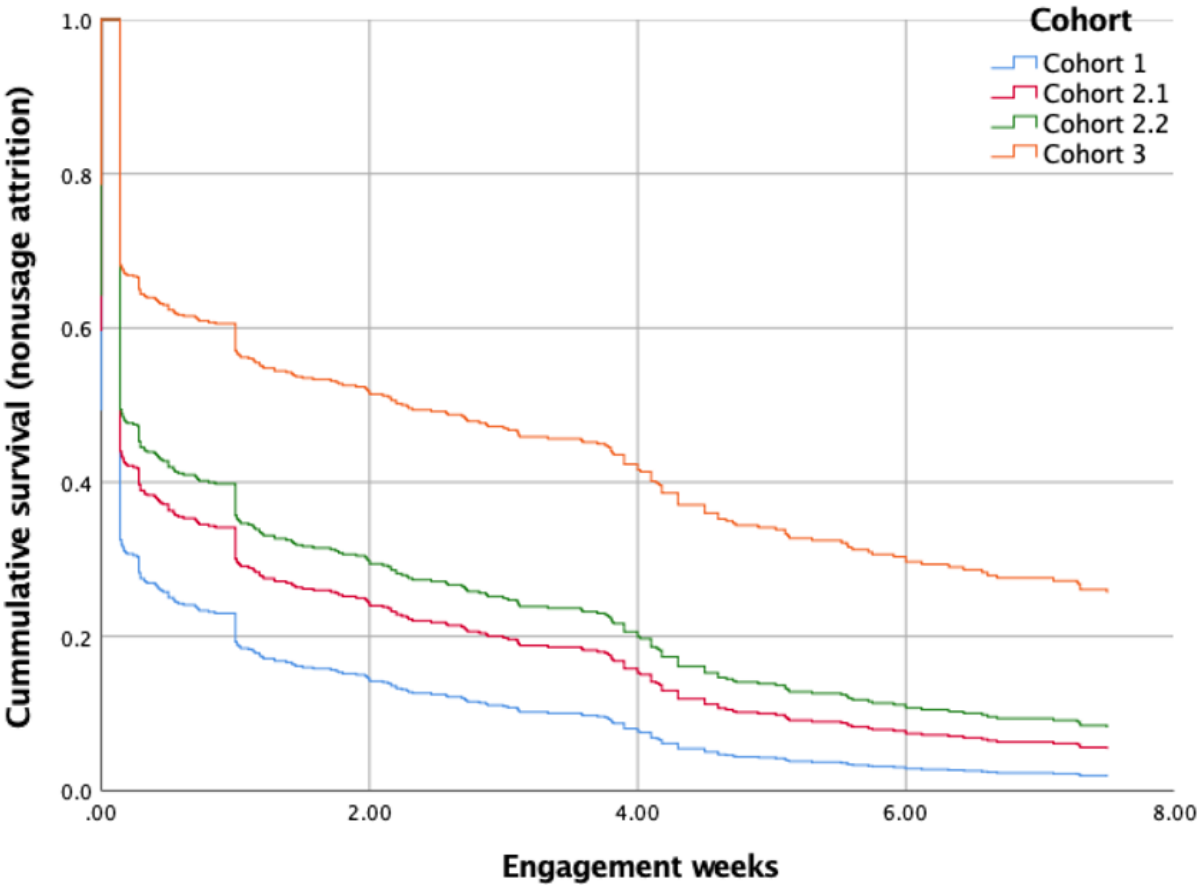
Figure 4. Per protocol percentage.



Nonusage Attrition

Survival curves for each cohort from the Cox regression survival analysis are shown in Figure 5. Cohort 3 (My Food & Mood Program version 3.0) had the lowest rates of nonusage attrition versus weeks engaged. All survival curves show a drop in cumulative survival (the percentage of participants still using the intervention) after 1 week. Significant predictors of active usage were referral from a health practitioner (hazard ratio [HR] 0.344, 95% CI 0.179-0.660, *P*=.001) and high computer skills (HR 0.796, 95% CI 0.634-0.999, *P*=.049). High computer confidence was a significant predictor of nonusage attrition (HR 1.511, 95% CI 1.111-2.056, *P*=.009). No other variables were significant predictors of nonusage attrition.

Figure 5. Survival curve (Cox regression) for nonusage attrition versus weeks engaged across all cohorts of the My Food & Mood Program.



When including only active participants, referral from a health practitioner remained a significant predictor of active usage across all versions of the intervention (HR 0.277, 95% CI 0.123-0.626, *P*=.002); however; computer skills rated as highly skilled did not (HR 0.799, 95% CI 0.597-1.068, *P*=.13). In this model, age was also a significant predictor of active usage (HR 0.987, 95% CI 0.974-1.00, *P*=.047). Computer confidence rated as confident remained a significant predictor of nonusage attrition (HR 1.604, 95% CI 1.065-2.437, *P*=.03).

Discussion

Principal Findings

Of 4 versions of a digital-based dietary program in individuals with low mood or depression, a smartphone app version was associated with greatest engagement and the lowest levels of nonusage attrition. These results indicate that the optimization process led to the development of a program that had improved uptake in the target population. The analysis also showed that nonusage attrition was minimized if participants were referred to the program by a health practitioner or if they rated their computer skills high. Somewhat paradoxically, however, high computer confidence was a significant predictor of nonusage attrition. In active users (those who recorded duration using the programs), we found that older adults were more likely to continue to use their allocated program. There were no relationships found between nonusage attrition and baseline depression symptoms or diet quality.

Analysis of quantitative engagement measures showed that the optimization of the program resulted in the latest version of the program (ie, the smartphone app) being a more acceptable version compared to all other versions. Participants who used this version of the program completed more activities, spent more time using the app, completed more goals and watched more of the intervention video content. Version 3.0 required that participants log daily food and mood entries and also prompted them to do so. This more regular interaction did not increase participant burden but appeared to improve usage and engagement. This is contrary to evidence from the field that suggests continually requiring data entry from participants introduces burden that may gradually erode the intervention's effectiveness [50]. Literature also suggests that participants find it difficult to maintain routine self-monitoring over time [51]. It is possible that the consistent prompts and ability to reflect on their daily diet quality and mood may have had a reinforcing effect in this population.

The versions that directed intervention participation over the course of the 8 weeks (versions 2.2 and 3.0) had higher rates of engagement and completion of activities. These versions directed the users to complete the videos in the first 2 weeks and perform a series of behavior change activities in the following 6 weeks. This structured approach seemed to be preferred by participants. Even though this required all videos to be watched in the first 2 weeks, participants in cohorts 2.2 and 3.0 watched a greater percentage of the intervention videos compared to cohorts 1.0 and 2.1. The videos in version 1.0 were

also of a longer format than and with different content to those in subsequent versions; however, the videos in version 2.1 were the same as those in version 2.2 and version 3.0. These results suggest that the structure and direction was more important for prompting engagement and completion than the length of the videos.

There were also more active participants (ie, participants who accessed the program at least once) for the version 3.0 program. This was despite the additional step required to access this version. Participants allocated to this version had to install the app to their smartphone prior to logging in, whereas participants using the desktop programs only needed to click a link to access their version. With ubiquitous use of mobile phones across the globe, this is a promising finding for the design and dissemination of dietary interventions.

While many researchers have investigated predictors of adherence and attrition, there is little consensus as to which defining characteristics might predict active engagement with a digital intervention [26,32]. Analysis into predictors of nonusage attrition from psychological web-based interventions for depression have reported lower baseline rates of depression, younger and older age, low levels of education, and poorer knowledge of psychological treatments as predictors [52,53]. Our results only concur with theirs for age as a significant predictor of active usage (HR 0.987, 95% CI 0.974-1.00, *P*=.047) when analysis nonusage attrition for active users. This result may be counterintuitive as there is a common assumption that younger users are more likely to engage with technology due to their higher levels of technology use [54]; however, there is a growing body of literature indicating older adults are more likely to remain engaged with digital interventions.

We found no relationship between baseline depressive symptoms and nonusage attrition and our subsequent feasibility analysis [35] showed that participants were able to complete the program independent of the severity of their baseline symptoms. This is concordant with findings from clinical intervention trials in nutritional psychiatry that have found dietary change was possible independent of the level of baseline depression severity. The evidence to date supports dietary improvement as a feasible and acceptable treatment strategy for people experiencing depressive symptoms.

In addition, there was also no relationship between nonusage and baseline diet quality, the primary outcome measure for the feasibility study. This finding shows participants with low diet quality and more opportunity for improvement could engage with the intervention as well as those with higher diet quality and less opportunity for improvement.

One key finding from the analysis of nonusage attrition was that participants referred to the program by a health practitioner were more likely to use the program. There are two reasons why this may have been the case. Referral by health care practitioners may have increased the perceived credibility of the program, thereby encouraging usage. Second, participants referred by health practitioners may have been identified as well-suited to this form of adjunctive treatment. Increased engagement due to these informal referral channels is a positive finding and an important consideration for the design and dissemination of future interventions of this kind. In order to increase participation and reduce the risk on nonusage attrition in future trials and treatment programs, more formal referral and recruitment processes utilizing health practitioners should be employed.

Participant's with higher self-rated computer skills were more likely to remain actively using the program. However, if users rated their computer confidence as high, this was a significant predictor of nonusage attrition. These findings appear contradictory; we would expect confident users to encounter fewer barriers to navigating through or actively using an eHealth intervention. Participant characteristics across all cohorts showed there were much larger proportions of participants rated as confident compared to any other level. Given the common use of technology in modern society, and the limited range of options for this response the majority of participants rating themselves as confident is perhaps not surprising. It may be that additional nontechnical barriers limited progress of participants through the programs. Even if perceived confidence is high and participants are willing to engage, having inadequate skills may be one such barrier. In order to manage this, strategies to improve participants skill-level to improve nonusage attrition rates could be introduced in the initial program stages, especially focusing on the skills required to participate in the intervention.

The nonusage attrition analysis highlights the need to address attrition in the early stage of digital interventions. A large percentage of participants across all cohorts did not use the intervention (pretreatment dropouts) or only used the intervention for a short period of time, with nonusage attrition curves across all cohorts showing significant drop in usage after 1 day or within the first week. Qualitative feedback was collected during the web-based programs and follow-up surveys 4 and 8 weeks after the program [35]; however, for those who never accessed the intervention, we were unable to ascertain why this was the case.

The screening survey ended with links and log-in information to directly access the program or download the required smartphone app. This was designed to be a seamless transition to starting the programs. Analysis of participant behavior at this final screen might aid the design of future interventions. An additional prompt, given prior to closing the browser for participants who do not click on the access links, similar to notifications used by marketing websites, might improve these access numbers. In addition, the access information was also sent to participants via email. Automating follow-up of click through rates on access information emails for those yet to access the program might also be an opportunity to prompt users to log-in.

Strengths and Limitations

The strengths of this study include the quantitative data analysis of engagement across all participants, as these data were available for the entire cohort. Moreover, active engagement of people with lived experience, including members of Beyond Blue's Blue Voices, informed the design of the program and produced an mHealth version that was able to be used by people experiencing differing severities of depression symptoms. The study design allowed multiple internet delivery parameters to

be explored. Lastly, the study met its recruitment targets such that sufficient power to explore endpoints was available.

Despite the strengths of this study, there were also limitations. The dietary advice changed between the first version and the subsequent versions of the program. The change in dietary advice to a more prescriptive Mediterranean diet resulted from relevance and rigor cycles and were defined by the Information Systems Research framework [34] that was undertaken in the optimization phase. User feedback, expert dietitian input, and review of current literature resulted in the decision to modify the dietary advice to be more prescriptive. While the dietary advice delivered in version 1.0 was not a prescriptive Mediterranean diet, as it was in the 3 subsequent versions (version 2.1, version 2.2, and version 3.0), the programs were comparable in the style, content, delivery, and equivalence of key behavior change activities required.

A large proportion of participants were based in Australia, which may limit global generalizability. In addition, we were unable to collect feedback from those who left the study without downloading the app. Without this feedback, it is difficult to address the reasons the different versions of the program were not able to capture their attention.

Conclusions

The optimization study of the My Food & Mood program resulted in an mHealth version of a dietary intervention that had higher levels of usage and engagement than 3 previous versions of the intervention. More participants using this version completed more of the assigned activities and remained engaged, actively using the program for longer. These findings will inform and support the development of future large-scale trials aimed at further testing dietary interventions in depression.

Analysis of nonusage attrition showed that referral by a health practitioner reduced the risk of nonusage attrition. In addition, nonusage was independent of participants' depressive symptoms or diet quality. While several researchers have investigated predictors of adherence and attrition, there is little consensus in the literature of which characteristic might predict participants actively engaging with a digital intervention [26,32]. Our findings contribute further to this discussion.

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Conflicts of Interest

FNJ has received industry support for research from Meat and Livestock Australia, Woolworths Limited, the A2 Milk Company, Be Fit Foods and travel support and speakers' honoraria from Sanofi-Synthelabo, Janssen Cilag, Servier, Pfizer, Health Ed, Network Nutrition, Angelini Farmaceutica, Eli Lilly, and Metagenics. She has written two books on diet and health for commercial publication. MB has received support from Cooperative Research Centre Simons Autism Foundation Cancer Council of Victoria, MBF Rotary Health Meat and Livestock Board, Woolworths, Beyond Blue, Geelong Medical Research Foundation, Bristol Myers Squibb, Eli Lilly, Glaxo SmithKline, Organon, Novartis, Mayne Pharma, and Servier; speaker honoraria from Astra Zeneca, Bristol Myers Squibb, Eli Lilly, Glaxo SmithKline, Lundbeck, Pfizer, Sanofi, Synthelabo, Servier, Solvay, and Wyeth. He has been a consultant for AstraZeneca, Bristol Myers Squibb, Eli Lilly, Bioadvantex, Merck, GlaxoSmithKline, Lundbeck, Janssen, Cilag, and Servier. MB is a co-inventor of two provisional patents regarding the use of n-acetylcysteine and related compounds for psychiatric indications, which, while assigned to the Mental Health Research Institute, could lead to personal remuneration upon commercialization. The other authors have no conflicts to declare.

Multimedia Appendix 1
[PDF File (Adobe PDF File), 107 KB - mental_v8i3e24871_app1.pdf]

Multimedia Appendix 2
[PDF File (Adobe PDF File), 122 KB - mental_v8i3e24871_app2.pdf]

Multimedia Appendix 3
[PDF File (Adobe PDF File), 4828 KB - mental_v8i3e24871_app3.pdf]

Multimedia Appendix 4
Diet quality question mapping and scoring.
[PDF File (Adobe PDF File), 63 KB - mental_v8i3e24871_app4.pdf]

Multimedia Appendix 5
[PDF File (Adobe PDF File), 260 KB - mental_v8i3e24871_app5.pdf]

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Abbreviations

CPQ: Computer Proficiency Questionnaire
HR: hazard ratio
MEDAS: Mediterranean Diet Adherence Screener
mHealth: mobile health
PHQ-8: 8-item Patient Health Questionnaire
SCOFF: Sick, Control, One, Fat, Food
SDQ: Simple Dietary Questionnaire

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Commentary

Digital Mental Health Challenges and the Horizon Ahead for Solutions

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Abstract

The demand outstripping supply of mental health resources during the COVID-19 pandemic presents opportunities for digital technology tools to fill this new gap and, in the process, demonstrate capabilities to increase their effectiveness and efficiency. However, technology-enabled services have faced challenges in being sustainably implemented despite showing promising outcomes in efficacy trials since the early 2000s. The ongoing failure of these implementations has been addressed in reconceptualized models and frameworks, along with various efforts to branch out among disparate developers and clinical researchers to provide them with a key for furthering evaluative research. However, the limitations of traditional research methods in dealing with the complexities of mental health care warrant a diversified approach. The crux of the challenges of digital mental health implementation is the efficacy and evaluation of existing studies. Web-based interventions are increasingly used during the pandemic, allowing for affordable access to psychological therapies. However, a lagging infrastructure and skill base has limited the application of digital solutions in mental health care. Methodologies need to be converged owing to the rapid development of digital technologies that have outpaced the evaluation of rigorous digital mental health interventions and strategies to prevent mental illness. The functions and implications of human-computer interaction require a better understanding to overcome engagement barriers, especially with predictive technologies. Explainable artificial intelligence is being incorporated into digital mental health implementation to obtain positive and responsible outcomes. Investment in digital platforms and associated apps for real-time screening, tracking, and treatment offer the promise of cost-effectiveness in vulnerable populations. Although machine learning has been limited by study conduct and reporting methods, the increasing use of unstructured data has strengthened its potential. Early evidence suggests that the advantages outweigh the disadvantages of incrementing such technology. The limitations of an evidence-based approach require better integration of decision support tools to guide policymakers with digital mental health implementation. There is a complex range of issues with effectiveness, equity, access, and ethics (eg, privacy, confidentiality, fairness, transparency, reproducibility, and accountability), which warrant resolution. Evidence-informed policies, development of eminent digital products and services, and skills to use and maintain these solutions are required. Studies need to focus on developing digital platforms with explainable artificial intelligence–based apps to enhance resilience and guide the treatment decisions of mental health practitioners. Investments in digital mental health should ensure their safety and workability. End users should encourage the use of innovative methods to encourage developers to effectively evaluate their products and services and to render them a worthwhile investment. Technology-enabled services in a hybrid model of care are most likely to be effective (eg, specialists using these services among vulnerable, at-risk populations but not severe cases of mental ill health).

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KEYWORDS

challenges; COVID-19; digital mental health implementation; explainable artificial intelligence; hybrid model of care; human-computer interaction; resilience; technology

Introduction

The uncertainties of the COVID-19 pandemic, overlapping issues, and the long-term impact on population mental health make it difficult to predict the issues that would become prevalent. A preliminary longitudinal study reported an increase in the prevalence and incidence of common mental health disorders (not major psychiatric conditions)—mostly related to loneliness—but with a return to prepandemic levels [1]. Chandola et al [1] predicted that unemployment and resulting financial stressors can potentially contribute to an increase in common mental health disorders in the future. Although the initial impact of this pandemic on mental health has been severe, it has been predicted to exacerbate, resulting in an increased number of suicide cases, with the economic impact probably lasting for years [2]. In response to the predicted impact, Rauch et al [3] proposed a method to address mental health needs through a framework of phased interventions and resources with recommendations for leadership and organization within relevant phases. These include self-assessments and brief interventions focused on ensuring that basic needs are met, being creative with socialization, drawing on previously successful positive coping strategies, creating opportunities to communicate and share stories (although avoiding debriefing of traumatic or morbid experiences), as well as providing information on accessible mental health resources. Evidence-based digital and telehealth services that gained impetus during the COVID-19 pandemic were "strongly preferred by patients and families to emergency and inpatient care" [2]. Patient perceptions of telepsychiatry were overall positive and should be further assessed beyond the context of the current pandemic to account for changes in perception and impact on clinical outcomes [4]. Mental health care services are grappling with demand management strategies owing to an increased vulnerability to mental ill health [5].

The current pandemic has exacerbated the demand for mental health services, providing an opportunity for the supply of digital technologies (eg, videoconferencing-based tele-mental health interventions) and data-driven innovation (eg, predictive technologies), which are emerging to complement traditional in-person and telehealth aspects of psychology and psychiatry [6,7]. New digital technologies and data-driven innovation have been readily applied in radiology and dermatology (diagnostics and predictions with machine learning, robotics, and artificial intelligence [AI] platforms) [8]. However, there has been limited progress in digital mental health treatments, as evident from strong outcomes in efficacy trials since the early 2000s but ongoing failure in implementation owing to exceedingly reductive research models [9]. The Accelerated Creation-to-Sustainment model has addressed the research-to-practice gap; this model builds on existing methodologies, including human-computer interaction (HCI), implementation science, and trial methodology, and aims to develop and sustainably implement technology-enabled services [9].

Delays in progress persist owing to the low quantity and quality of information from evaluated evidence-based studies for digital mental health interventions. This is despite several reviews providing vast support to the potential of technology to improve their effectiveness, efficiency, cost, reach, personalization, and appeal [10]. Scholten and Granic [10] noted that researchers are reconceptualizing the scientific framework, methodology, and implementation strategies for digital mental health implementation and highlighted significant technological challenges including engagement, retention, fidelity, lack of personalization, and cognitive load. They proposed a design thinking solution to social scientists and clinical researchers. However, an impasse resulting from underlying disengagement issues is apparent, which has hindered the progress of evaluative research. Nebeker et al [11] provided a decision-making checklist to guide responsible digital technology selection in research, especially for dealing with technical and ethical considerations [11]. Nonetheless, clinical researchers subsequently called for further evaluation of this tool for its usefulness in technology selection. The pace of change in predictive technologies and other emerging aspects of digital mental health is intensified by the disparities and ineffectiveness of risk assessment in psychology and psychiatry (despite being reliable and valid).

It is difficult to capture the range of global innovation and research in digital mental health. However, Torous et al [12] provided an expert perspective on the depth of studies that contribute to the acceptability, feasibility, and early evaluation of digital mental health technologies. They acknowledged that telehealth is the appropriate solution for meeting the increased demand from the current pandemic, and they further emphasized an unprecedented potential for increased access and quality of digital mental health technologies [12]. Investment was noted as required with funding, research, policy changes, training, and equity, to enhance the progress of such innovations. Further research is required to validate the effectiveness and appropriateness of technology on a larger scale. The failed attempts of digital mental health researchers to engage interest, cooperation, and resolve from developers and their psychological and psychiatric counterparts to address the technical and ethical issues in evaluative research, signal the need to explore how to effectively integrate digital mental health solutions into mental health care service systems, and to apply these technologies among various populations.

Risk Prediction and Predictive Technologies

Risk prediction in mental health has been underestimated as a methodology for counteracting mental ill health and suicidality owing to its confounding effects on clinical decision-making. With respect to the futility of risk assessment in psychiatry, Mulder et al [13] cautioned that suicide rates cannot be reduced through risk categorization from risk prediction in clinical practice by using risk assessment tools. They indicated the rarity of suicide and referred to the study by Chan et al [14], which identified the risk factors of high-risk groups, including individuals who have committed self-harm, and then evaluated risk assessment scales to assess the efficacy of these risk factors [14]. The lack of sufficient specificity and sensitivity of some the scales to be clinically useful was found to be

counterproductive (eg, most of the low-risk categorized patients who completed suicide and high-risk groups of mainly false-positive findings) [14]. Few studies have prospectively examined the effect of risk assessment on patient outcomes [13]. Risk assessment tools may instill false reassurance in clinicians and managers; the unfeasibility of these tools needs to be highlighted, a qualitative understanding of the sequalae of suicidal ideation and attempts in an individual patient is required in a needs-based model of care, and risk assessments should be curtailed to minimize harm to the patient and the therapeutic alliance [13,14]. Redirection from statistical prediction of suicide (albeit valid and reliable in identifying risk factors for death by suicide) to a causal pathway has been recommended [13]. Instead, preventive interventions should focus on "real engagement with the individual patient, their specific problems and circumstances" [13]. This conundrum has been complicated by emerging predictive technologies, associated methodologies, and design systems.

AI approaches are being implemented in digital interventions and social suicide prevention initiatives (eg, web-based and smartphone apps), to enhance user experience and optimize personalized mental health care [15,16]. D'Alfonso [15] reported that data-driven AI methods could be employed to develop prediction and detection models for mental health conditions, gathering insight from digital exhausts (numerous personal digital device and social media interactions mined to obtain behavioral or mental health–related insights). Although limited by a lack of evaluated evidence-based clinical applications, AI has been portrayed as having remarkable accuracy in preliminary studies predicting suicide attempts [16]. Depression with psychosis, schizophrenia, suicidal ideation, and prior suicide attempts have been included as psychological risk factors. In a qualitative narrative review, D'Hotman and Loh [16] noted a significant potential to improve suicide prediction and prevention through novel analytical techniques and tools (eg, leveraging machine learning algorithms and data science) in coordination with the opportunity presented in contact and assessment by health services. They referred to a longitudinal study that reported that most people who die from suicide (83%) will have contacted health services in the year prior to their death, and 45% will have contacted these services in the month prior to their death, which highlights a challenge for more effective screening and tracking.

Although machine learning algorithms may improve existing decision support tools somehow, their usefulness in the clinical setting is limited by an ongoing lack of information on model building and uncertain accuracy [17-19]. Machine learning algorithms can potentially add value to the identification and diagnosis of mental health conditions (eg, depression, suicidal ideation, and cognitive decline), positive mental health outcomes (eg, resilience, identity formation, and personal growth) [17], and the prediction of problems [20]. However, these algorithms are not a replacement for explanations derived from data modeling; hence, hypothesis-based traditional research should not be dismissed. The scarcity of data of sufficient quantity and quality, often required to be able to leverage the potential of machine learning models, has contributed to developmental problems with this approach. There is no robust evidence on the transferability of machine learning models owing to a lack of institutional diversity in applying these models, annotation bottlenecks faced by supervised machine learning algorithms, sensitivity of health data, and privacy concerns [21]. A challenge for machine learning is the advancement of methodologies that integrate with other systems and the clinical validation of these methodologies [22]. Such methodologies are required owing to the rapid development of digital technologies that have outpaced the evaluation of rigorous digital health interventions [23].

Extended Intelligence and Explainable AI

A fundamental problem is associated with the formulation of AI as a machine system distinct from humans, which attempts to control, design, and understand systems [24]. Ito [24] proposed extended intelligence as a design system that integrates humans and machines to constitute responsible, aware, and robust components of complex systems. A key issue is the capacity-to-sense in a manner that benefits humanity, leading to research on *veillance flux* for understanding, mediating, and augmenting the sensory capabilities of machines and humans and their connectedness to larger technological and societal systems [25]. The health care industry has lagged behind in the direct implementation of machine learning algorithms and complex models mostly because of issues with trust, generalizability, and transparency [26,27]. Explainable artificial intelligence (XAI) is an emerging methodology for endowing credibility, accountability, and trust in mission-critical areas of mental health [26]. The main advantage of XAI is that it combines common sense knowledge with semantic reasoning and causality models [26] for implementation in a manner that makes its functioning easy to understand [27]. Other benefits include transferability, informativeness, confidence, fairness, accessibility, interactivity, and privacy awareness [24]. Barredo Arrieta et al [27] proposed XAI as a core concept for responsible AI, which further encapsulates ethics, security, and safety concerns [27].

XAI facilitates a 3-way conversation among the patient, the health care practitioner, and the machine. XAI may help develop a mutually positive understanding and regulate, identify, and control the negative consequences of incorrect predictions or treatments. An issue with the use of existing decision support tools in physical health care (eg, AI-assisted clinical decision support systems) is that recommended treatments are often overridden by health care practitioners [28]. This is problematic if the outcome is ineffective and the decision cannot be adequately explained by the health care practitioner. It is important to consider and balance the differing interests and values in the ethical evaluation of AI-assisted decision-making [28]. The implications of different treatment recommendations may result in discordance (eg, clashing opinions of health care practitioner vs AI). XAI aims for a more complete understanding to potentially facilitate the decision-making process. In the mental health context, XAI is being applied in the conceptual stage of a knowledge-driven evidence-based recommendation system to improve surveillance for adverse childhood experiences as part of an early intervention approach [27]. The enhancement of the explanatory potential of health care practitioners' decisions requires trials and evaluation with

attention to privacy concerns [27]. XAI is worthy of further research, particularly in systems that generate predictions, for effective surveillance of functionality and implications in increasing human interaction with new technology.

Other Emerging Aspects of Digital Mental Health

Accessibility, presentation, and transparency are important aspects of engagement with digital tools (eg, web-based and smartphone mental health apps) [5]. The ability of smartphones or smartwatches to capture the behavior and psychological symptoms of individuals with schizophrenia in real time and to elucidate their utility in early interventions of relapses may serve as a quantifiable method of calculating and managing risk [29]. Henson et al [29] reported that the integration of sensor data and relapse-detecting algorithms has a high potential for prediction and risk modeling. Resources for identifying safe and effective smartphone apps may help understand basic smartphone tools. A challenge for mental health care practitioners is to become familiar with these smartphone tools to fulfil the "next step in incorporating technology use into standard clinical care for relapse prediction and prevention" [29]. The major barriers to the integration of digital tools with other systems and clinical validation include an undeveloped risk-utility data governance framework [30] and an outdated and poorly developed information technology infrastructure (including data gathering and sharing) of many publicly funded health services [31].

The Internet of Things (IoT) refers to human-computer interconnectedness via smart objects or wearable devices, intermediary communication, and processing devices as well as hardware, fog, cloud, server infrastructure, or converged networks. The IoT has benefits in terms of monitoring, welfare interventions, and providing alerts and information services [32]. Digital phenotyping with the assessment of data from smartphones, consumer wearables, and social media has been scoped [33] but is yet to provide evaluated evidence regarding the detection and predictive capabilities of mental health interventions. Should the advantages of digital phenotyping be manifested in the clinical setting (eg, observing presented phenomena, opportunities for self-monitoring, and relapse prevention as well as potential interventions), then so will its disadvantages (eg, privacy in the management of personal data, and potentially not improving causal explanations or psychological understanding) [34].

Immersive virtual therapeutic interventions with virtual reality (VR), have been proposed as a cost-effective aid in treating mental health disorders and symptoms (eg, acrophobia [35], persecutory delusions [36], delusions, hallucinations, or cognitive and social skills associated with the schizophrenia spectrum [37]). A systematic review [37] referred to other studies on the high effectiveness and versatility of VR in the treatment of various pathological conditions (posttraumatic stress disorder, anxiety disorder, and specific phobias) [37]. However, available data on immersive VR are currently limited owing to the paucity of research on this topic. Further studies are required to ascertain transferability to this approach for other mental health conditions. Both VR and augmented reality systems have been recognized as very promising for future research [38], but their current scalability and accessibility inhibit their use in the COVID-19 pandemic [12].

Certain web-based alternatives including guided self-help, chatbots, and other web-based interventions can be used to increase affordable access to psychological therapies (either as an accompaniment or as stand-alone interventions). There is a lack of larger studies and clinical evaluation for evidence-based guided self-help interventions, although positive findings in reducing psychological symptoms in children [39] were expanded upon in the context of neurological illness [40]. The rarity and dissimilarity of evidence-based studies with chatbots limits discussions on their effectiveness. There is a need to develop culture-suitable chatbots and to evaluate software that simulates a conversation via AI with a human on text messaging or voice chat platforms (natural language processing) [41]. A scoping review referred to early evaluation of the feasibility and acceptance of chatbots, and its randomized controlled design yielded effective chatbots with benefits especially directed toward well-being, stress, and depression [42]. However, Bendig et al [42] raised questions regarding the security and acceptance of such new technologies, with issues based on commercial conflict of interests, objective comprehensibility, nonclinical pilots, conceptualization for complex psychotherapeutic understanding (eg, suicidal ideation), and replicability [42]. A range of other web-based interventions is available; for example, TogetherAll, a Canadian anonymous digital mental health service, and Head to Health, an Australian digital mental health gateway providing trusted, evidence-based, peer-reviewed nationwide web-based resources.

No studies have assessed the effectiveness of mental health care facilities with an up-to-date and functional information technology infrastructure and the use of digital tools, digital phenotyping, IoT, and immersive technologies by capable digital mental health practitioners. A current state assessment of the Australian digital mental health ecosystem identified the integration of digital mental health services with the broader health system, software, platforms, and data and evaluation as critical supply issues [43]. The themes of digital inclusion and adoption of services, considerations for vulnerable cohorts, and utilization of lived experience in service design and delivery were identified as significant demand issues [43]. The objectives to improve service access (including workforce considerations) and reduce duplication of effort and investment involved sector consultation to inform the development of a framework [43]. However, a disclaimer for not making generalized representations of the appropriateness of the report [43] highlights transferability issues (for other ecosystems). The quagmire of determining effectiveness, validity, reliability, and reproducibility for digital mental health makes it necessary for engaged consultants to deflect responsibility, duty of care, or liability for other audiences relying on the information. The sense of excitement for integrating digital mental health with the delivery of mental health services to meet the increased demand is countered by the need for a more compelling evidence base for successful implementation and integration. Furthermore, there is no known register for digital mental health products or

services to demonstrate the high quality, safety, security, transparency, and effectiveness of these products.

HCI in Digital Mental Health

The emerging field of HCI is important for the efficacy of a hybrid model of care, especially for psychological screening and tracking with real-time automation and machine learning [5]. There is increasing focus on the digital therapeutic alliance (DTA), which extends from web-based and smartphone apps to digital mental health interventions [44]. Tremain et al [44] explored the DTA with researchers focusing on HCI and introduced psychologists to aspects of HCI. These authors proposed HCI to be conducive in expanding digital mental health, especially with smartphone apps. It remains a challenge to gain a better understanding of the nuances, particularities, and complexities of the psychology underlying the interaction between humans and AI. Furthermore, Tremain et al [44] suggested measuring smartphone interfaces and interactions to determine if there is a relationship between DTA and increased engagement with the adherence to digital interventions. In particular, the DTA was proposed to be measured by a hybrid or renewed version of the mobile Agnew relationship measure, thus accounting for HCI theories to inform affective computing, including the design for personalized responses and an appealing balance of the human characteristics of AI, such as traits, emotions, and intentions. It remains unknown how HCI would impact the efficacy of mental health care because of the limited studies on the DTA. D'Alfonso [15] suggested adapting from purpose-built measures focused on a human client and a computerized therapeutic intervention approach (eg, smartphone or web-based app or sophisticated conversational agent) fostered by AI [15].

Digital Mental Health Implementation in a Hybrid Model of Care

The realization of the availability of digital mental health as a complementary approach is simultaneous with the transition into, and navigation through, the complex digital world. In 2017, a review of emerging digital mental health investigations (especially psychiatric rehabilitation) included web-based tools and smartphone apps and interventions, smartphone audio data analytics, digital self-management strategies, and statistical modeling [45]. Tal and Torous [45] reported that "new knowledge and evidence-based tools to better promote mental health diagnosis, treatment, rehabilitation, and recovery." In aiming for progressive uptake and clinical adoption of digital mental health tools, Torous and Haim [46] detailed the advantages and disadvantages of dichotomous positions on digital solutions to transition a path towards embracing the opposing perspective. Gratzer et al [47] noted the potentially lasting benefits for a hybrid model of care in a review of digital mental health care delivery during the COVID-19 pandemic (eg, access, convenience, and adherence of telepsychiatry, internet-delivered cognitive behavior therapy, and apps) [47]. Potential drawbacks were noted, especially the lack of evidence regarding telepsychiatry for individuals with severe mental health disorders, high dropout rates with internet-delivered cognitive behavioral therapy with nonhuman therapists, and remarkably high dropout rates with apps [47]. It was further noted that standards for patient privacy, confidentiality, equity, and reliability of service delivery will need to be addressed through a thoughtful approach to sustain core services over the long term [47]. The delivery of more secure and stable platforms linked to AI-based apps for real-time screening, tracking, and treatment has been recommended to yield the best investment outcomes [47].

The integration of digital mental health solutions into pathways for delivering mental health services is gaining momentum particularly during the COVID-19 pandemic. For example, a primary youth mental health service has potential to boost care efficiencies in service entry, comprehensive assessment, multidisciplinary care, and routine outcome-based monitoring [48]. Davenport et al [48] referred to extensive co-design and clinical research leading up to the concept of digitally flipping clinics, resulting in a screening and tracking flow chart and operation protocol that includes plans for addressing care needs, categorization in accordance with symptom intensity, and instructions for further assessment and review. A digital platform serves as a customizable digital toolkit in a fee-for-service early intervention system [48]. Previous mental health screening programs in low-prevalence settings have yielded controversial findings owing to a high rate of false-positive results, with a suggestion for screening being more practical in high-prevalence settings [49]. However, an evaluation of the effectiveness of screening in a prison setting was considered as being required in terms of its potential advantages and disadvantages [49]. An evaluation of screening and treatment for depression at the workplace found these approaches to be cost-effective [50]. However, more economic evaluations are required owing to the low rates of treatment uptake, or the lack of effective available interventions could impair the cost-effectiveness of mental health screening.

The inequities in mental health care (eg, the inconvenience of distance and inferior internet connectivity) are a common issue [47,51]. In consideration of demand outstripping supply, the complexities of user experience from clinician and patient perspectives [51] including in-patient care and environmental considerations should be considered with importance (eg, disentangling addiction, psychosis, and serious mental illness from subsyndromal conditions, common mental disorders, or false cases). An advantage of digitalization is that a negative effect of incompatible in-patient care is replaced by unobtrusive solutions which are not as limited (eg, qualification and capabilities related to administration and assessment). The disadvantages of digitalization—in terms of social justice—are compromised accessibility and functionality for individuals with severe mental health disorders [51] and constraints in understanding gestural components (eg, behavioral observation).

Data from the general population and subpopulations are yet to be effectively integrated with algorithms that contribute to a hybrid model of care as part of a general guide [5]. Machine learning and deep learning have until recently only been fed structured data in medical informatics, neglecting invaluable information from unstructured clinical notes [52]. Unstructured data from medical records combined with deep learning tools

hold promise in identifying the most suitable candidates for a study on youth depression, but a reliable recommendation system has not been established [53]. Machine learning has had limited advantages associated with structured data. A study predicting the outcomes of stroke [54] reported that this was because of study conduct and reporting; clinical prediction tools have not made their models available for use or evaluation [54]. The ability of AI to enhance risk prediction in mental health assessment may extend from mining unstructured data (eg, through text or continuous sensor monitoring), such as a study on sepsis, which revealed improved algorithm accuracy (deidentified data made available for review) [55]. The implementation of algorithm prediction systems in predicting the risk of suicide is currently limited to experimental and feasibility studies (with utility) without efficacy evaluation [16,56-58].

The challenges associated with the implementation of digital health solutions (including mental health) are mostly related to their integration with standard clinical care. Various solutions such as apps are available; however, methodologies have not evolved alongside them to perform timely, cost-effective, and robust evaluations [59]. Guo et al [59] recommended innovative approaches, such as simulation-based approaches, for end-users to holistically resolve this dilemma. A main finding is that developers need assurance of a reasonable reward (by means of a valid market) for their time and effort and to not be perturbed by the fallacy of traditional approaches [59]. Further emphasis should be laid on the transparency and reproducibility of machine learning–based prediction models [60]. Researchers can help in generating their code and preferably making their data available. Reporting standards may discourage digital health systems from being commercially available before complete evaluation. The agility of machine learning [17] renders it cumbersome and unfair for a long series of randomized controlled trials. For example, a quasi-experimental design for a model of delivering technology-enabled mental health services revealed relatively strong evidence on model effectiveness before evaluation through randomized controlled trials [61].

Further innovation is required to overcome challenges, increase efficiency, and generate new opportunities to compensate for general human deficiencies, thus helping served, underserved, and unserved individuals [51]. Jurisdictions changed regulatory and compensatory frameworks to allow providers and patients more flexibility in their care options during the COVID-19 pandemic [47]. However, policies regarding the expanded access to treatment are required (eg, protection of privacy and allowing for continued compensation for virtual care) [51]. A hybridized approach with HCI and XAI has the potential for a superior ability to rapidly adapt and effectively recognize, acknowledge, and address marginalized, distorted, acquiesced, and subsyndromal cases, among others. Training for mental health care practitioners in delivering digital mental health interventions [51] should focus on active listening and observation skills to identify prejudice and stigmatization, guilt, fear, shyness, discomfort, shame, detachment, embarrassment, social anxiety, and social isolation among other issues. A reliable and valid understanding of the fundamentals and points of failure is needed to drive innovation. However, we do not see any panacea for dealing with disclosure or dissatisfaction around these issues.

Digital Mental Health Insights and Ethical Considerations

The relatively slow progress in furthering the evaluation of digital mental health has hindered its progress. The connections between stakeholders (patients or end users and physicians or mental health care practitioners) exist within a complex environment. Worldwide changes associated with the COVID-19 pandemic, notably demand outstripping supply, have presented a dilemma for decision-making related to mental health care with regards to digital mental health research and highly efficacious clinical trials. The conflict-theory of decision-making refers to the motivation to reduce tension during essential decision-making with forecasted difficulties regardless of which feasible option is chosen [62]. At the core of the theory is the premise that evasion or suppression of the dilemma is not an effective long-term solution. Psychologists, psychiatrists, and others concerned with mental health care delivery (especially policymakers) could seize the opportunity of digital mental health or dismiss it as euphoria, hype, or a threat without considering the unfavorable consequences of inaction. It is necessary to confront the challenges of digital mental health and determine the weightage of the advantages and disadvantages associated with its implementation.

The call for psychological self-assessments and brief interventions during the COVID-19 pandemic [3] is based on a patient perspective. However, the opposite viewpoint should also be considered. Despite the health-protective attributes of a physician's career, the rates of depression, anxiety, and suicidal ideation are high among them (24.8% of a cohort of Australian physicians prior to a 12-month period—approximately 2-fold that of the general population) [63]. Gerada [63] described the "spiraling of discontent" and increased risk of suicide among physicians, which is associated with the development of psychological defenses that include depersonalization and dissociation [63]. Risk factors such as genetic predisposition and workplace stress contribute to an increased vulnerability to psychological distress and suicidal ideation among junior physicians [64]. The need for early intervention, a lack of discretely accessible and effective interventions, and the mobility of this group led to the development of the smartphone app Shift Health, which is focused on processing co-design and user feedback to engage users and ensure user adherence with increased effectiveness and appropriate screening, tracking, and treatment [64]. The advantages of this app are improved accessibility, cost-effectiveness, usefulness for larger cohort studies, and the ability to inform organizational solutions. The disadvantages of this app include overcoming of the barriers to app usage (eg, personal selection of modules and continuous cohort engagement), attrition rates, and engagement with clinical researchers for evaluation on a larger scale. A strategy for engaging clinical researchers in external evaluation is crucial for its effectiveness beyond strong efficacy in clinical trials.

A digital platform for the management of mental ill health requires innovative design and delivery to provide the capacity for engagement and shared decision-making among users [65]. Torous et al [66] supported the evolution of the therapeutic relationship among users with a freely shared platform code to encourage adaptation and improvement, especially in digital phenotyping. Connectivity to third-party apps using application programming interfaces provides the opportunity to extend the ecosystem of the platform and its capabilities. A knowledge and learning platform should include blueprint skills, inductions, and learning sessions. Dissemination of technical skills with training, weblinks, and support would help others master these skills. Digital innovation requires development along with simultaneous learning in the workflow, with suitable tools and guides available to encourage innovation. It is important for there to be easy access to reports, virtual classrooms, and demonstrations of content and video creation, use of a dashboard, and the creation of course offerings. It is recommended to seek assistance or self-help for creating and setting up of digital content. Furthermore, blogs, podcasts, webinars, and in-person or digital sessions are required to share effective, valid, and reliable data and knowledge.

It is important for strategies to enhance resilience particularly considering the stress of the COVID-19 pandemic [67]. It is also important to address ethical challenges in mental health and suicide prediction tools and models [16,51] with particular attention on privacy, confidentiality, fairness, transparency, and accountability [68]. Private industries should be closely monitored by the scientific community through independent reviews and ethical oversight to confirm the safety, effectiveness, and permissibility of their services [16]. Inputs from patients, service end-users, physicians, and caregivers should be factored in for developing solutions [15] as a first step to consider the consequences of machine learning and AI, including the need to reduce bias and increase efficacy. Different approaches are emerging, including a virtue ethics framework (ie, moral attention and appropriate extension of moral concerns) and micro-ethics (to understand and grasp the grittiness and distinctiveness of each situation) [69]. Impactful actions for using ethics and data security checklists are required with digital capabilities increasing at a rapid rate; for example, IoT-based approaches. Nabi [70] referred to bioethical agility and the need for a “shared conceptual mental map” to address the adverse issues in machine learning applications and to promote “beneficence, justice, patient autonomy, and to prevent maleficence” during the COVID-19 pandemic.

Conclusion

Digital mental health is a debatable issue because of the uncertainty associated with it. The main advantage of this approach is its provision of a complementary system to address the urgent supply for increased demand. Furthermore, mental health care practitioners may be able to prevent mental ill health in some high-prevalence situations through early intervention with predictive systems. Digital platforms and AI-driven apps are currently the most important solutions in this regard. The disadvantages include a lack of evaluated evidenced-based studies. There are difficulties associated with digital mental health services to locate their niche especially during dominant reductivism in mental health research. However, these approaches are limited by a small pool of studies on their reliability, validity, and reproducibility. More generally, scientists have intended to separate machines from humans via AI and replace human decision-making with AI-based decision-making. On such a contentious topic, with continuous advancements in the field, the arguments for and against this topic will undoubtedly persist in the foreseeable future. However, in health care, the patient–health care practitioner relationship is of paramount importance, requiring a level of trust and understanding. XAI as a principal concept is worthy of investigation to help provide future direction. Furthermore, the potential financial implications of digital solutions are astronomical, such that current investment may eventually lead to evaluated scientific breakthroughs that will be largely accessible and affordable to the public.

Digital mental health with real-time screening, tracking, and treatment tools, especially platforms and web-based and smartphone apps, have yet to mature and are therefore not yet cost-effective. Nonetheless, promising developments have been reported, especially for youth mental health services. Digitalization and data science literacy and innovation may extend from resourceful web-based learning journeys. Human-centered outcomes through digital solutions in HCI require extensive consultation, detailed study (eg, DTA), and collaboration to develop and refine methodologies. The COVID-19 pandemic requires the mapping of issues and changes in categorization by systematically examining the uncertainty and impact of ideas, trends, and concepts, such that strategies can be developed in accordance with the relative effort, risk, and reward. The interface between data science and machine learning methods (pattern-based) and traditional research methods (hypothesis-driven) should be based on transparency and inclusiveness, policies, technologies, and education.

Digitalization and data science should instill a culture of quality, security, adaptability, technical excellence, positive empowerment, and motivation. End-users should instigate and simulate innovative research methods to overcome the difficulties of evaluation through traditional research methods. Modeling and prediction, along with future tools and processes, should borrow from existing ones to build new ones for future readiness (explore, interpret, and anticipate). The transparency and reproducibility of machine learning–based prediction models has been emphasized. The technical and ethical challenges, as well as the risk of digital and data-oriented tools, require a balance with opportunities and strategic research and investment. Innovative, safe, and secure digital mental health implementation is needed to improve public health (including equity) and respond to the demand outstripping supply of mental health resources. It is important to engage with eminent digital mental health in a hybrid model of care owing to its positive impact on resilience. Convergence on methodologies is required for expedited evaluation of rigorous preventive strategies and interventions.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
DTA: digital therapeutic alliance
HCI: human-computer interaction
IoT: Internet of Things
VR: virtual reality
XAI: explainable artificial intelligence

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Review

Digital Interventions to Support Population Mental Health in Canada During the COVID-19 Pandemic: Rapid Review

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Abstract

Background: The COVID-19 pandemic has resulted in a number of negative health related consequences, including impacts on mental health. More than 22% of Canadians reported that they had felt depressed in the last week, in response to a December 2020 national survey. Given the need to physically distance during the pandemic, and the increase in demand for mental health services, digital interventions that support mental health and wellness may be beneficial.

Objective: The purpose of this research was to identify digital interventions that could be used to support the mental health of the Canadian general population during the COVID-19 pandemic. The objectives were to identify (1) the populations these interventions were developed for, inclusive of exploring areas of equity such as socioeconomic status, sex/gender, race/ethnicity and culture, and relevance to Indigenous peoples and communities; (2) the effect of the interventions; and (3) any barriers or facilitators to the use of the intervention.

Methods: This study was completed using a Cochrane Rapid Review methodology. A search of Embase, PsycInfo, Medline, and Web of Science, along with Google, Million Short, and popular mobile app libraries, was conducted. Two screeners were involved in applying inclusion criteria using Covidence software. Academic articles and mobile apps identified were screened using the Standard Quality Assessment Criteria for Evaluating Primary Research Papers from a Variety of Fields resource, the American Psychiatric Association App Evaluation Framework, and the Mental Health Commission of Canada's guidance on app assessment and selection.

Results: A total of 31 mobile apps and 114 web-based resources (eg, telemedicine, virtual peer support groups, discussion forums, etc) that could be used to support the mental health of the Canadian population during the pandemic were identified. These resources have been listed on a publicly available website along with search tags that may help an individual make a suitable selection. Variability exists in the populations that the interventions were developed for, and little assessment has been done with regard to areas of equity. The effect of the interventions was not reported for all those identified in this synthesis; however, for those that did report the effect, it was shown that they were effective in the context that they were used. A number of barriers and facilitators to using these interventions were identified, such as access, cost, and connectivity.

Conclusions: A number of digital interventions that could support population mental health in Canada during the global COVID-19 pandemic were identified, indicating that individuals have several options to choose from. These interventions vary in their purpose, approach, design, cost, and targeted user group. While some research and digital interventions addressed equity-related considerations, more research and focused attention should be given to this area.

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KEYWORDS

digital health; psychiatry; mental health; informatics; pandemic; COVID-19; telemedicine; eHealth; public health; virtual care; mobile apps; population health

Introduction

Background

Prior to the onset of the COVID-19 pandemic, 20% of Canadians were estimated to experience a mental illness in any given year [1]. In addition, 1 in 3 Canadians were expected to experience a mental illness during their lifetime [2]. The probability of experiencing mental illness or having suboptimal mental health was found to be significantly more likely for Canadians within socially and economically marginalized populations [3]. As a result of the COVID-19 pandemic, and the uncertainty, fear, and stress created during this unprecedented time, concern has been raised both in the media and academic literature regarding the emerging and concerning mental health crisis within Canada [4]. The economic hardship, isolation, and social distancing measures enacted to slow the virus spread have inadvertently introduced a number of mental health consequences, including increased feelings of anxiety, depression, distress, insomnia, and burnout [5]. The decline in population mental health appears to be a direct result of the worsening public health crisis, which has been detrimental to both Canadian and international populations.

Data from several countries have identified increased risk and burden of mental health distress during COVID-19. A recent survey from the United States found that the prevalence of depression symptoms increased more than 3-fold during the pandemic [6]. Prior to the pandemic, 8.5% of individuals in the United States expressed feelings of depression; this number increased to 27.8% during the COVID-19 pandemic [6]. The study also found that individuals in lower-income brackets were 1.5 times more likely to experience symptoms of depression in comparison to those in higher-income groups [6]. Furthermore, a survey conducted by the Centers for Disease Control and Prevention of US citizens concluded that the adverse mental health impacts created by the COVID-19 pandemic have disproportionately affected marginalized populations, specifically those who identify as persons of color, younger adults, caregivers, and those with pre-existing mental health conditions [7]. Similarly, symptoms of depression, anxiety, and stress increased during the first 4-6 weeks of social distancing and isolation measures in the United Kingdom [8]. The substantial decline in mental well-being in the United Kingdom shows a comparable pattern to the United States, with disproportionate and inequitable impact on marginalized populations. There is a significantly higher prevalence of mental distress among individuals who have pre-existing physical and mental health conditions, those who identify as persons of color, and those in lower-income brackets [9]. The international mental health effects of the COVID-19 pandemic are also evident in the Canadian population [10].

A recent survey conducted by the Centre for Addiction and Mental Health (CAMH), in December 2020, found that 24% of Canadians experienced moderate to severe anxiety, 23% felt lonely, and 22% felt depressed as a result of COVID-19 [11]. Women experienced worse mental health outcomes in comparison to men, where 25% of women reported feeling more depressed, anxious, and lonely during the pandemic period [12]. Moreover, thoughts and feelings of suicide in the Canadian population have notably risen since the onset of COVID-19, whereby 6% of the Canadian population experienced thoughts or feelings of suicide [13]. In comparison to the general Canadian population, Indigenous peoples and communities, individuals with pre-existing mental health conditions, and individuals in lower-income brackets were 2 to 4 times more likely to have thoughts or feelings of suicide [13]. The lasting impact of the COVID-19 pandemic on the mental health and well-being of Canadians warrants concern as individuals, primarily vulnerable and marginalized populations, are already at greater risk of developing severe and chronic mental health disorders [14].

Stressors created by enforced social distancing and isolation measures have applied further pressure on an already overburdened, strained, and limited Canadian mental health care system [10]. Despite the recognizable need for increased mental health supports, available mental health services are not adequate to support this increased volume of need through conventional services such as face-to-face care [15,16]. In addition, due to constraints posed by COVID-19, it is no longer feasible or appropriate to provide in-person mental health care services under many circumstances [15,16]. Where face-to-face interventions are offered, these currently address acute and severe decompensation of mental health. There is a need to support the adaptation, transformation, and augmentation of our current infrastructure to increase capacity and ideally to support mental health and wellness at a population health level [10].

Digital interventions created in the response to COVID-19 are potential solutions to support population mental health during and after the pandemic. By digital interventions, we refer to those in the World Health Organization's (WHO) classification of digital health technologies [17], as well as the types outlined by the Mental Health Commission of Canada (MHCC) [18] such as websites, web-based programs, electronic knowledge platforms, mobile health apps (inclusive of texting), telemedicine, and social media. Digital interventions enable the provision of convenient and timely mental health care services and support through digital means. Digital interventions that have been created for non–COVID-19–related purposes (eg, for natural and human-made disasters, other pandemics) may also be relevant to support population mental health. This approach has been utilized for the identification of nondigital interventions during the COVID-19 pandemic [19].

Research Question and Objectives

The following research question was asked: what digital interventions could be used to support the mental health of the Canadian general population during the COVID-19 pandemic?

The objectives of the study were the following:

1. To identify populations that digital interventions might impact. We are specifically interested in understanding key equity areas related to sex/gender, socioeconomic status, race/ethnicity and culture, and relevance to Indigenous peoples and communities;
2. To determine what is known about the effect of these digital interventions and for whom;
3. To identify barriers and facilitators to the use of these digital interventions.

Methods

We conducted a rapid review of the academic and gray literature using the interim guidance from the Cochrane Rapid Reviews Methods Group with minor modifications made where appropriate [20].

Search Strategy

For the academic searches, our librarian team member created detailed search strategies and executed searches for Embase, PsycInfo, Medline, and Web of Science. We have included the preliminary search strategy for Medline in Multimedia Appendix 1. Search strategies for other databases were developed based on the Medline search strategy approach. For the gray literature review, we conducted searches of smartphone app stores, curated smartphone app libraries, and structured Google searches [21]. We conducted a brainstorming session with 3 members of the investigator team, inclusive of a person with lived experience of mental health problems or illnesses to develop a list of key terms the public may search when looking for smartphone apps to support their mental health during COVID-19. The list of key terms was then presented to and approved by the larger study team. The Google Play Store and Apple's App Store were searched using the terms identified during the brainstorming session. The top 10 smartphone apps per search term were included in this review.

We searched the following curated smartphone libraries: Practical Apps, Alberta Health Services App Library, Scarborough Health Network Mental Health App Library, eMentalhealth.ca, King's Western University Library, Health Navigator New Zealand, NHS App Library, and One Mind Psyberguide. A gray literature search on Google using a structured Google search was also completed (search string: COVID + Mental Health + apps). The structured Google search methodology aimed to identify information from a diverse range of locations to account for the personalization of Google search results [22]. Our librarian team member conducted structured searches of Google and Million Short search engines to identify web-based resources and/or smartphone apps that may support population mental health during COVID-19. Million Short, a Canadian web search engine, was used in addition to Google, as it identifies websites that would otherwise not be highly ranked in other search engine results [23]. We reviewed the first 30 search findings (unique websites) from the 62 searches completed using the Google Chrome web browser. Paid ads were not present within the searches completed. A complete list of Google and Million Short search strings are available in Multimedia Appendix 2.

Inclusion Criteria

The following inclusion criteria were utilized for academic searches:

- Academic articles must describe a digital mental health intervention;
- Digital interventions are classified based on both the MHCC technology types [18], and the WHO classification of digital interventions [17]. The MHCC and WHO classifications were mapped to one another. Table 1 presents the mapped breakdown of digital health intervention types;
- Published since 2000;
- Written in English;
- Described a population mental health treatment, assessment, promotion, or prevention intervention, inclusive of promoting mental well-being and delivering mental health services;
- Relevant to the COVID-19 context (eg, natural disasters, man-made disasters, other medical pandemics, etc) [19]. Web-based resources that were COVID-19 specific were included;
- Research articles, commentaries, reviews, and nonresearch articles were included.

The following inclusion criteria were utilized for gray literature searches:

- Available for use within Canada by the general public;
- Developed specifically for or modified for the COVID-19 pandemic. Resources that were modified for the COVID-19 pandemic include:
  - Resources that have been suggested as a mental wellness resource during the pandemic;
  - Resources that have been updated during COVID-19 to include relevant mental health resources (eg, included a statement or indication that the resource can be used to support one's mental health during COVID-19);
  - Resources that gave away a free trial, subscription, or section of their app or web-based intervention during the COVID-19 pandemic.

Table 1. Mapped classification of digital health interventions using the Mental Health Commission of Canada (MHCC) and World Health Organization (WHO) technology classifications.

WHO classification of digital health interventions for clients	MHCC types of e-mental health technologies
Targeted client communication	• App, website • Instant messaging • Social media • Portal/electronic medical record • Smartphone, wearable • Artificial intelligence, big data
Untargeted client communication	• App, website • Instant messaging • Social media • Portal/electronic medical record • Smartphone, wearable • Artificial intelligence, big data
Client to client communication	• App, website • Instant messaging • Social media • Smartphone, wearable • Artificial intelligence, big data
Personal health tracking	• Portal/electronic medical record • Smartphone, wearable • Artificial intelligence, big data
Citizen based reporting	• App, Website • Instant messaging • Social media • Smartphone • Artificial intelligence, big data
On-demand information services to clients	• Search engine • Artificial intelligence, big data
Telemedicine	• Telehealth

Screening Process

To calibrate the application of inclusion criteria to the identified citations in the academic literature review, 2 members of the investigator team applied the criteria independently to 30 citations ensuring an appropriate level of agreement (>80%) before further screening was conducted. The remaining citations were divided between the 2 screeners to ensure a rapid approach to citation screening. This was facilitated by an online system called Covidence [24] and was done in the following stages:

- Stage 1: citations identified from the academic database searches were uploaded into Covidence for screening;
- Stage 2: the abstracts and titles of all citations were screened utilizing the predetermined inclusion criteria. Questions regarding the eligibility of citations were discussed between the screeners, and the nominated principal applicant was consulted if a discrepancy was found;
- Stage 3: the remaining citations had the inclusion criteria applied by the screeners to the full text;
- Stage 4: preliminary data was then extracted from the articles that were included after the full-text screening was completed and entered into a data extraction table to assist with data synthesis.

Data Synthesis

For the included academic literature, a data extraction table was created that captured basic article characteristics and results related to the research question and objectives. To identify populations that may be impacted by the digital intervention, we also collected information pertaining to the following equity-related areas: (1) Indigenous peoples and communities, (2) gender/sex, (3) race/ethnicity and culture, and (4) socioeconomic status. For apps and web-based resources, a data extraction table was created that captured basic details of the interventions (eg, target population, cost) and their specific purpose(s). Synthesis of the data from the data extraction tables was done using thematic analysis and descriptive statistics.

Quality Assessment

We conducted a quality assessment of the included articles using the Standard Quality Assessment Criteria for Evaluating Primary Research Papers from a Variety of Fields resource (Kmet criteria) [25]. We also carried out an evaluation of the included mobile apps using the American Psychiatric Association's App Evaluation Model [26], while leveraging the app evaluation website developed by the Division of Digital Psychiatry at the Beth Israel Deaconess Medical Center [27]. For those apps that did not have an evaluation present within the website, we carried

out our own evaluation using the App Evaluation Model. This was also informed by the MHCC's guidance on app assessment and selection [28]. Regarding the website resources, no quality assessment was performed primarily due to the volume and variety of identified website resources (eg, telemedicine, virtual peer support groups, discussion forums, etc).

Results

Academic Literature Findings

Results of the academic search are summarized in a PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram shown in Multimedia Appendix 3. We found a total of 70 articles that met our inclusion criteria. While many articles specifically addressed COVID-19 (n=42, 60%), others were related to natural disasters (n=19, 27%) and human-made disasters (n=9, 14%). Most of the COVID-19–specific articles were commentaries or viewpoints (n=32, 46%). A total of 25 (36%) were primary studies and 13 (18%) were reviews. Identified articles originated primarily from the United States (n=39) but were also from China (n=6), Australia (n=4), the United Kingdom (n=4), India (n=2), Italy (n=2), New Zealand (n=2), Brazil (n=1), Canada (n=1), Croatia (n=1), Indonesia (n=1), Iraq (n=1), Ireland (n=1), Israel (n=1), the Netherlands (n=1), Pakistan (n=1), Spain (n=1), and Taiwan (n=1). A full data extraction table of all included articles is available upon request from the corresponding author.

Gray Search Findings

We found 174 smartphone apps in our initial search. A total of 135 were identified through curated libraries, 19 via searches in the Google Play Store and Apple's App Store, and 20 through web-based searches. Once the inclusion criteria were applied, a total of 31 mobile apps and 114 web-based resources were found. A complete list of the identified mobile apps and web-based resources can be found on the CAMH website [29].

Identified Interventions

A list of digital interventions and their respective purposes is shown in Multimedia Appendix 4. This includes smartphone apps and web-based resources that mirror the technology categories of the WHO classification and MHCC technology typology.

Populations That Might Benefit From or Be Disadvantaged by the Identified Digital Interventions

Most interventions impacted those with access to a device (eg, smartphone, laptop, or tablet) and an internet connection (cell phone data or wireless). Four interventions involved shifting away from in-person care to providing mental health care virtually through telemedicine platforms, videoconferencing platforms (eg, Zoom [30]), or in-house platforms during the COVID-19 pandemic [31-34]. Such interventions benefited those with a private or safe space to engage in their care [31-34]. Conversely, populations that were at a disadvantage for making use of digital interventions included those who lacked the appropriate technology or internet access (including older adults who may not be able to effectively use technology) and those living in unsafe conditions or lacking access to a private space. Additionally, most of these interventions offered regular services for existing clients, so new clients were at a disadvantage, as well as those in need of acute care.

There were 10 web-based mental health interventions focused on remote populations [35,36] and adapted for Indigenous peoples (First Nations, Inuit, and Métis) [36], victims of sexual abuse [36,37], adolescents and caregivers [38-40], and survivors of specific trauma [37,41-43]. While these advantaged a variety of populations, a few were available only in English and hence those who did not speak the language were at a disadvantage. A mobile app that focused on connection between family members and seniors [44] was available for English, Spanish, and French speakers, but, like the previously mentioned interventions, were limited to those with the know-how and technology to use it.

Two COVID-19–specific interventions—telephone and television support [45]—were advantageous for older adults and their caregivers; phone services were beneficial for individuals with substance use or opioid disorder [46]. In general, hotlines or phone-support interventions (including the three developed prior to COVID-19) [47-49] helped to expand the population to those with access to a landline or basic phone plan, including those living in transitory circumstances.

A high-risk population that emerged within our findings was veterans. Veterans were advantaged by targeted supports, including veteran-specific telemedicine programs [50], especially those who were poor, unemployed, single, or with a poor health status. Veteran-specific digital interventions such as educational and self-help resources also benefited family members [51]. A thorough list of the populations advantaged and disadvantaged by the included interventions is described in Multimedia Appendix 4.

We also collected additional information about the following equity-related areas: (1) Indigenous peoples and communities, (2) gender/sex, (3) race/ethnicity and culture, and (4) socioeconomic status. Belleville et al [36] adapted their intervention for diverse populations including members of the First Nations, Inuit, and Métis communities. Two studies addressed sex and gender considerations, recognizing that women exhibit more help-seeking behaviors [36] and were more open to sharing instances of sexual abuse [47]. Three studies addressed race/ethnicity and cultural considerations, including ones that were specifically adapted to fit a non-Western population [37], available in a variety of languages and offered translator services [47], and targeted at veterans [51]. Eleven studies considered the socioeconomic status of their end-users, providing free interventions for those who were publicly insured. Two interventions provided phone calls as an alternative to the internet [34,49], and one was tailored to older adults' digital health literacy [45].

What Is Known About the Effect of These Digital Interventions

Of the identified studies, 7 had information related to the effect of the intervention [36-40,45,49]. The majority (n=6) were found to be effective in reducing symptoms of posttraumatic stress disorder (PTSD), anxiety, depression, and loneliness in

the various medical, natural, and man-made disaster contexts [36-40,45]. For example, one study evaluated the use of a web-based mental health intervention in tornado-affected rural and urban regions of the United States [38]. Findings from this study demonstrated that there were no significant differences in the uptake and completion of the web-based mental health intervention by rural and urban households. This suggests that digital interventions may be used to support the mental health of individuals residing in rural geographic areas, given these communities often lack in-person access to mental health services [38]. Another study underscored the effectiveness of e-therapy (electronic therapy) in treating youth with mild to moderate anxiety. An emphasis was placed on the use of digital mental health interventions within the stepped care model to improve mental health care delivery, whereby primary care physicians can have access to a menu of digital mental health interventions to recommend to parents or caregivers concerned about their child's emotional or behavioral well-being [39,40].

Several international studies, specifically an internet-based intervention for PTSD in Iraq [37] and a community mental health relief program in Taiwan following an earthquake [49], highlighted the uptake and effect of digital mental health resources and interventions in politically and/or physically unstable regions. Individuals affected and displaced by both war or conflict and natural disasters sought mental health support through digital means and benefited from the digital support in place of access to in-person support [37,49]. In addition, a television-based intervention developed for older adults during the COVID-19 pandemic was found to be effective in reducing feelings of loneliness and distress during the isolation/quarantine period [45]. Adoption of and access to smartphones, TV devices, tablets, and computers facilitated connectedness and increased communication between older adults and their family members or caregivers. A summary of the effect for each of the identified interventions is described in Multimedia Appendix 5.

Barriers and Facilitators to the Use of These Digital Interventions

Most included articles identified a few barriers and facilitators to the uptake and use of digital mental health interventions. These were related to the (1) technology (eg, poor connectivity, user-friendly design), (2) people using the technology (eg, knowledge about how to use the digital intervention, interest in using the intervention), and (3) context/processes in place to support or detract from the uptake of the technology (eg, a private space to use the digital intervention, organizational supports if applicable). A sample of these barriers and facilitators is shown in Textbox 1.

Textbox 1. Barriers and facilitators to digital mental health intervention use.

Barriers:

- Difficulty using the technology
- Mistrust of the technology or security of data
- Legislation that prevents certain forms of care (eg, harm reduction)
- Lack of data sharing/interoperability
- Difficulty establishing a therapeutic alliance between people seeking care and providers due to technology-related challenges
- Poor connectivity

Facilitators:

- Organizational support (eg, help desk)
- Access to the technology, devices, or the software
- Access to training about the digital intervention
- Access to a specific type of mental health care
- Cost (free or provided at a limited cost)
- Ability of users to be anonymous if desired

A full list of the identified barriers and facilitators with details related to the specific type of digital intervention used is included in Multimedia Appendix 6.

Discussion

Principal Findings

This review identified that there are many digital interventions that could be used to support the mental health of the general Canadian population during the COVID-19 pandemic. These interventions vary in their purpose, approach, design, cost, and targeted user group. While some research and digital interventions addressed equity-related considerations, more research and focused attention should be paid to this area. Most digital interventions identified did not have any published data describing their effect within the context of COVID-19. The lack of data on the effectiveness is understandable given the timing of this review, which corresponds to the timing of the onset of the global pandemic (both in the same year) [19].

With an expanding plethora of digital mental health interventions available, with variability in cost, population focus, and type of technology used, it becomes difficult for people with lived experience of mental health problems or illnesses

and providers to know which intervention to select. In addition, unawareness of the effectiveness of interventions may make clinicians wary of making specific recommendations. Fortunately, there has been some effort to support the assessment of certain types of interventions. For example the American Psychiatric Association and the MHCC both have tools to support the selection and assessment of mobile apps [26,52]. A recently created resource lists the various app libraries/curated lists, app rating tools, and a selection of digital mental health interventions, aimed at both providers and people with lived experience alike [53]. The MHCC has also developed an implementation toolkit to support organizations in their digital mental health intervention implementations [54]. Furthermore, there has been discussion regarding a role of a "digital navigator" for integrating the use of technology in practice [55].

While we identified several studies evaluating digital mental health interventions during disaster, crisis, or pandemic situations, there has been limited focus on equity factors that may influence the use and ability to obtain benefits from the intervention in all subpopulations. The equity factors specifically reviewed in this study included relevance and inclusivity of Indigenous peoples and communities, sex and gender, race/ethnicity and culture, and socioeconomic status.

One finding of this work is the lack of resources that are specific to Indigenous peoples and communities, which is a concern in the Canadian context. To ensure that the results of future works are relevant and inclusive of Indigenous peoples and communities, a few key points should be considered. Researchers and intervention developers need to ensure that Indigenous peoples are included at every stage of development and implementation [56-59]. Interventions should (1) be developed by and/or with Indigenous organizations or communities; (2) implemented and evaluated by an Indigenous organization or communities; (3) developed in accordance with OCAP (Ownership, Control, Access, and Possession) principles (these principles are specific to First Nations Peoples [60]); (4) stored appropriately and in a location that can be easily accessed by the engaged/involved Indigenous peoples or communities; and lastly, (5) all elements, including language, should ensure cultural relevance and safety. A list of resources to support this work can be found on the NunatuKavut website [61].

Other equity factors explored in this work could benefit from utilizing an appropriate framework to underpin how equity factors should be understood, examined, and evaluated. Recent work advanced by Crawford and Serhal [62] provides a Digital Health Equity Framework for how future studies may approach exploring equity within a digital landscape, emphasizing the need to consider digital health within the larger contexts of socioeconomic location of individuals and communities, which are impacted by social determinants of health.

Strengths and Limitations

This review has several strengths and limitations. Strengths of this review included a quality appraisal of academic publications and a formal evaluation of mobile apps. Regarding limitations, this review specifically identified interventions that had been developed or modified to provide COVID-19–specific content unique to Canada. It is possible that digital mental health interventions that were developed prior to the pandemic, and without pandemic-specific content, could still be helpful. Additionally, there was great variability in the reported digital interventions, and while a quality assessment was conducted, there remains variability in the quality of the interventions available. Although we conducted several searches in a number of search engines and libraries, some digital health interventions that may meet the inclusion criteria and can support population mental health during COVID-19 might have been missed. The compiled list of interventions is not an exhaustive list of the digital mental health resources that exist to support population mental health. It presents mental health resources available to the general population and does not include those available through employment benefits programs or other workplace programs not available to the general public. In addition, the time it takes for research and publication to occur may have limited the COVID-19–specific content present in the academic literature.

Conclusion

Numerous digital interventions that could be used to support the mental health of the general population in Canada during the COVID-19 pandemic were identified. While there are similarities to some of the nontechnology based interventions identified in a recently published review of interventions to support mental health during emergency and disaster situations [19], digital interventions present the opportunity for mental health care to be delivered at a distance. However, additional preventative measures are needed to both sustain mental wellness and to address psychological distress before severe impacts ensue. Population-based interventions are increasingly needed as a way of reducing and preventing the potential mental health impacts experienced by Canadians as a result of job loss, social isolation, changes to everyday life, both now and into the foreseeable future. To date, the interventions developed or modified to meet the current need have had minimal evaluation to determine their efficacy, as well as applicability to populations who have traditionally been disadvantaged and who continue to experience health inequities. Numerous barriers to the use of digital technology also exist for a number of individuals. Thus, a broader conversation to include concepts of equity and access is essential as these tools are developed. This rapid review demonstrates that there has been progress toward the development and adaption of digital interventions to support mental health and wellness during the COVID-19 pandemic; however, much more work needs to be done to assess the impact of these technologies.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[DOCX File , 16 KB - mental_v8i3e26550_app1.docx]

Multimedia Appendix 2
Gray literature search strategy.
[DOCX File , 15 KB - mental_v8i3e26550_app2.docx]

Multimedia Appendix 3
PRISMA flow diagram.
[DOCX File , 35 KB - mental_v8i3e26550_app3.docx]

Multimedia Appendix 4
List of digital intervention purposes and populations advantaged or disadvantaged.
[DOCX File , 24 KB - mental_v8i3e26550_app4.docx]

Multimedia Appendix 5
Effect of digital interventions.
[DOCX File , 18 KB - mental_v8i3e26550_app5.docx]

Multimedia Appendix 6
Barriers and facilitators to digital intervention use.
[DOCX File , 19 KB - mental_v8i3e26550_app6.docx]

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Abbreviations

e-therapy: electronic therapy
MHCC: Mental Health Commission of Canada
OCAP: Ownership, Control, Access, and Possession
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PTSD: posttraumatic stress disorder
WHO: World Health Organization

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Original Paper

The Moderating Role of Coping Mechanisms and Being an e-Sport Player Between Psychiatric Symptoms and Gaming Disorder: Online Survey

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Abstract

Background: The emerging popularity of playing video games (*gaming*) as a hobby and as a professional sport raises awareness about both the benefits and possible downsides of the activity. Although a healthy and passionate hobby for most, a minority of gamers experience addiction-like symptoms and are considered to have gaming disorder (GD). GD has previously been found to be related to aversive conditions, such as depression or anxiety, as well as putatively maladaptive coping strategies.

Objective: The aim of this study is twofold: to explore the moderating effect of different coping strategies and type of video game usage (professional [e-sport] or recreational) on the relationship between psychiatric symptoms and GD.

Methods: A sample of 3476 gamers (n=3133, 90.13% males; mean age 23.20, SD 6.48 years) was recruited via the website and social networking site of the most popular gaming magazine in Hungary (*GameStar*).

Results: The main effect of psychiatric symptoms was moderate to large in all models, whereas the moderation effects were significant (P<.001) for 4 out of 8 coping strategies (ie, self-blame/self-distraction, denial, emotional/social support, and active coping). However, the explained variance of the models only increased negligibly (from 0.3% to 0.5%) owing to the moderation effect. The direction of the moderations was as expected (ie, putatively maladaptive strategies were associated with more GD symptoms when the level of psychiatric symptoms was high, while putatively adaptive strategies were associated with less). Furthermore, no considerable moderation effect of the player type (recreational vs professional players) was found on the association between psychiatric symptoms and GD (β=.04; P=.02; 0.1% change in the explained variance).

Conclusions: Future studies should be designed to better understand coping-related mechanisms in the context of video gaming and GD.

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KEYWORDS

gaming disorder; esports; professional gaming; video games; coping skills; psychiatric symptoms; psychiatry; mental health; gaming

Introduction

Video game playing (*gaming*) has become one of the most popular leisure activities globally irrespective of age and gender [1]. Its great popularity has led to the phenomenon of *e-sports*, which refers to professional competitive gaming where teams or individuals compete against each other in a video game [2-5]. There are now organized and sanctioned e-sport competitions worldwide that are hosted by sponsors, featuring live sports commentary. These are watched by large-scale audiences (both at scene and via online streaming platforms such as *Twitch.tv, YouTube, etc*), and there are big money prizes for the winners [6].

Although the overwhelming majority of gamers globally play in a healthy manner, a small minority experience addiction-like symptoms accompanied by marked psychological distress and significant impairment in personal, family, social, educational, occupational, and/or other important areas of functioning [7]. The severity of the problem is acknowledged by the inclusion of internet gaming disorder (IGD) in Section 3 (*Emerging Measures and Models*) of the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders in 2013 as a condition warranting further research [8] and by the inclusion of gaming disorder (GD) in the 11th revised edition of the International Classification of Diseases in 2019 as an official diagnosis [9]. Furthermore, there is a wide variety of terms used for problematic or addictive video gaming. This paper uses the term *GD* given that it is the official term proposed by the World Health Organization.

Similar to substance use or alcohol use disorders, GD has been found to be related to psychiatric symptoms such as depression and anxiety according to numerous epidemiological survey studies [10-12]. One important issue regarding these findings is whether there are factors that moderate these associations. More specifically, the negative effects of emotional or psychiatric distress on an individual's life may depend on the individual's ability to cope with it [13]. Coping can be defined as the cognitive and behavioral responses of individuals in an attempt to manage stressful situations and emotions associated with them [14]. Considering that the context and goals of the individual strongly determine the effectiveness of the strategies [15,16], the adaptive-maladaptive classification could arguably be criticized. However, some strategies may be labeled as putatively maladaptive if they are associated with poor outcomes, especially in the long term. For instance, dispositional rumination—defined as the tendency to dwell on distress-related thoughts passively and repetitively [17]—and avoidance are consistently associated with psychopathology [18]. Similarly, some strategies might be considered as putatively adaptive since they are generally associated with good adjustment. For instance, acceptance of mental experiences is related to better psychological health [19].

Several studies have investigated the association between coping strategies and GD. According to these findings, GD is associated with putatively maladaptive or dysfunctional coping styles [20], such as denial, behavioral disengagement [21], media-related coping, self-distraction, self-blame [22-24], catastrophizing, or rumination [25]. In addition, putatively adaptive coping styles such as active coping, positive reframing, and positive reappraisal have been applied less frequently in the case of gamers at risk of GD or have been negatively related to GD [22,25]. Effect sizes range from weak to strong in the case of putatively maladaptive strategies and weak to moderate in the case of putatively adaptive coping styles.

Furthermore, several studies have tested more complex models, in which coping styles have been assumed to mediate between psychiatric symptoms or stress and GD. According to such models, higher rates of stress or specific psychiatric problems such as depression have been associated with or predicted the use of dysfunctional coping styles (eg, avoidance or media-focused coping). This, in turn, has been associated with (or predicted higher rates of) GD or general problematic internet use. Effect sizes for the psychiatric symptoms or coping style associations have been moderate or moderate-to-strong, whereas those for coping style or GD associations have been weak or weak to moderate [26-28].

Although it is plausible to think that increased psychiatric symptoms (eg, depression) may increase the risk of using dysfunctional coping strategies [29], it is also plausible to assume that dispositional coping styles may act as moderators between symptoms and GD. This means that they can influence the association between psychiatric symptoms and GD. It is logical to hypothesize that among individuals who frequently use putatively maladaptive or dysfunctional coping styles when encountering stressful situations in their lives, the relationship between psychiatric symptoms and GD will be stronger than among those who use putatively adaptive coping strategies in general. Findings reporting that escapism (ie, playing videogames to avoid problems and difficulties) is the motive most consistently related to GD [30-32] supports this hypothesis. Therefore, instead of mediation models, this study aims to test whether coping styles (both putatively adaptive and maladaptive) moderate the psychiatric symptoms or GD relationship in the aforementioned way.

The second aim of this study is to test whether player type (recreational vs e-sport players) moderated the association between psychiatric symptoms and GD. The large amount of time and energy that e-sport players spend training to improve their gaming skills and be successful in competitions raises the question of whether e-sport players may be at a higher risk of developing GD than recreational gamers [33]. To date, very few studies have investigated this risk, even though it affects a high number of aspiring e-sport players globally. According to a few previous studies, e-sport players do not report considerably higher GD scores than recreational gamers, and GD-related mechanisms also appear to be similar among e-sport players and highly engaged recreational players [30,31,34]. Therefore, a second assumption was that e-sport players will not significantly differ from highly engaged recreational players in the psychiatric symptoms or GD association.

Methods

Participants and Procedure

Participants were recruited via the website and social networking site (ie, *Facebook*) of the most popular gaming magazine in Hungary (*GameStar*). Data were collected using a web-based questionnaire that focused on both healthy and problematic (ie, addictive) use of video games. Participation was voluntary and anonymous. Gamers younger than 18 years (14-17 years of age) were allowed to participate in the survey after providing parental consent to participate. Two shopping vouchers (60,000 Hungarian forint, approximately US $260 each) were used as incentives and raffled among the gamers who participated in the survey. A contact email address was asked by the participants who joined the raffle. The email addresses were used only to inform the winners, and all contacts were deleted afterward.

A total of 7815 participants participated in the survey. According to the aim of this study, participants who provided data for all study-relevant variables (ie, psychiatric symptoms, coping strategies, and symptoms of GD) were included in the data analysis. Consequently, the final sample comprised 3476 gamers (n=3133, 90.13% males; mean age 23.20, SD 6.48 years). The study was approved by the Institutional Review Board of the research team's university and was conducted in accordance with the Declaration of Helsinki.

Measures

Sociodemographic Variables

Major sociodemographic data were collected, including age, gender, the number of years spent in education and working, and marital status.

Variables Relating to Video Game Use

Data related to general video game usage were also collected. Participants were asked to report their approximate game time on average hours/weekday and average hours/weekend day. The approximate game time hours/day was calculated as (5 × week day + 2 × weekend day) / 7. The average gaming time hours/week was calculated as 5 × week day + 2 × weekend day. To identify e-sport gamers and recreational gamers in the sample, participants were asked to indicate the types of competitions (ie, online or offline via local area network competitions) and the frequency of e-sport events they attended in the previous year (response options: "I did not participate in such competitions in the past year"; "1-2 times in the past year"; "3-5 times in the past year"; "6-11 times in the past year"; "several times a month"; and "weekly or more frequently"). Following the classification method of Bányai et al [34] and taking into consideration the theoretical concept [2,3,6] and the methods of how e-sport tournaments are organized, gamers who participated in e-sport tournaments at least 6-11 times in the previous year were defined as "e-sport gamers." Gamers who participated in such tournaments only 5 times or fewer in the previous year were defined as "recreational gamers."

Coping Strategies

Coping strategies were assessed using the Brief COPE scale [35]. The Brief COPE is a self-report scale assessing 14 different coping strategies (ie, self-distraction, active coping, denial, substance use, use of emotional support, use of instrumental support, behavioral disengagement, venting, positive reframing, planning, humor, acceptance, religion, and self-blame). Each coping strategy is represented by 2 items that are rated on a 4-point Likert scale (ranging from 1="I haven't been doing this at all" to 4="I've been doing this a lot"). Several factors in the Brief COPE scale showed poor internal consistency in this study: self-distraction (α=.55), venting (α=.58), behavioral disengagement (α=.61), acceptance (α=.66), and planning (α=.69). Previous studies, which also found that the original factors of the Brief COPE questionnaire had low internal consistencies, explored alternative factor structures that yielded similar coping strategies but with better psychometric properties [36-38]. Following this conceptual framework, an exploratory factor analysis (EFA) was conducted to find an alternative factor structure for the Brief COPE. A total of 8 factors were identified according to the EFA, including emotional/social support, active coping, self-blame/self-distraction, humor, substance use, denial, religion, and acceptance. According to the aforementioned broad categorization, emotional/social support, active coping, humor, religion, and acceptance were considered to be putatively adaptive coping strategies, whereas self-blame/self-distraction, substance use, and denial were considered to be putatively maladaptive or dysfunctional coping strategies. The newly reconstructed factors showed better internal consistencies ranging between 0.78 and 0.92, except for the acceptance (α=.66) and self-blame/self-distraction factors (α=.68), which had α values below the .70 threshold (Tables 1 and 2).

Table 1. Factors obtained using exploratory factor analysis with Promax rotation.

Items of Brief COPE	1	2	3	4	5	6	7	8
“I’ve been getting help and advice from other people.” (COPE 10)	0.88	__[a]	—	—	—	—	—	—
“I've been getting emotional support from others.” (COPE 5)	0.85	—	—	—	—	—	—	—
“I've been getting comfort and understanding from someone.” (COPE 15)	0.85	—	—	—	—	—	—	—
“I’ve been trying to get advice or help from other people about what to do.” (COPE 23)	0.79	—	—	—	—	—	—	—
“I've been saying things to let my unpleasant feelings escape.” (COPE 9)	0.63	—	—	—	—	—	—	—
“I've been taking action to try to make the situation better.” (COPE 7)	—	0.82	—	—	—	—	—	—
“I've been concentrating my efforts on doing something about the situation I'm in.” (COPE 2)	—	0.82	—	—	—	—	—	—
“I've been trying to come up with a strategy about what to do.” (COPE 14)	—	0.79	—	—	—	—	—	—
“I've been thinking hard about what steps to take.” (COPE 25)	—	0.69	—	—	—	—	—	—
“I’ve been criticizing myself.” (COPE 13)	—	—	0.86	—	—	—	—	—
“I’ve been blaming myself for things that happened.” (COPE 26)	—	—	0.85	—	—	—	—	—
“I've been turning to work or other activities to take my mind off things.” (COPE 1)	—	—	0.58	—	—	—	—	—
“I've been making fun of the situation.” (COPE 28)	—	—	—	0.96	—	—	—	—
“I've been making jokes about it.” (COPE 18)	—	—	—	0.96	—	—	—	—
“I've been using alcohol or other drugs to make myself feel better.” (COPE 4)	—	—	—	—	0.95	—	—	—
“I've been using alcohol or other drugs to help me get through it.” (COPE 11)	—	—	—	—	0.95	—	—	—
“I've been saying to myself ‘this isn't real’.” (COPE 3)	—	—	—	—	—	0.90	—	—
“I've been refusing to believe that it has happened.” (COPE 8)	—	—	—	—	—	0.89	—	—
“I've been praying or meditating.” (COPE 27)	—	—	—	—	—	—	0.90	—
“I've been trying to find comfort in my religion or spiritual beliefs.” (COPE 22)	—	—	—	—	—	—	0.90	—
“I've been accepting the reality of the fact that it has happened.” (COPE 20)	—	—	—	—	—	—	—	0.87
“I've been learning to live with it.” (COPE 24)	—	—	—	—	—	—	—	0.86

[a]Factor loadings <0.10.

Table 2. Factors names and Cronbach alphas obtained using exploratory factor analysis with Promax rotation.

Factor names	Cronbach alpha
Emotional/social support	.86
Active coping	.79
Self-blame/ self-distraction	.68
Humor	.92
Substance use	.92
Denial	.78
Religion	.78
Acceptance	.66

Psychiatric Symptoms

Psychiatric symptoms were assessed using the Hungarian version of the Brief Symptom Inventory (BSI [39,40]). The scale comprises 53 items on a 5-point Likert scale (from *not at all*=0 to *extremely*=4), assessing 9 symptoms (ie, somatization, obsession-compulsion, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism). In this study, 3 subscales of the BSI were used: depression (6 items), anxiety (6 items), and psychoticism (5 items). From the 3 BSI subscales, a summarized index named *Psychiatric Symptoms* was calculated to determine the intensity of general distress, which showed a strong relationship with GD in previous studies [11,30,31,34]. The *Psychiatric Symptoms* index with its respective 17 items showed good internal consistency in this study. Cronbach alpha was .93.

Gaming Disorder

The symptoms of GD were assessed using the Hungarian version of the 10-Item Internet Gaming Disorder Test (IGDT-10 [41]). The IGDT-10 was developed to assess the 9 criteria of IGD as proposed in the DSM-5. Each item of the IGDT-10 assesses 1 DSM-5 criterion, except for the final criterion (eg, "jeopardy or losing a significant relationship, job, or educational or career opportunity because of participation in internet games"), which was operationalized via 2 items to avoid double-barreled questioning. The IGDT-10 has 3 response options (*never*=0, *sometimes*=1, and *often*=2). To follow the dichotomous structure of the DSM-5, response options were recoded in the following way: *never* and *sometimes* options were recoded as *no* (0), while *often* responses as *yes* (1). The ninth and 10th items were recoded into a single item (ie, if any of the 2 original items had an "often" response, the new item was coded as "yes") to resemble the original structure of the IGD. Composite reliability of the IGDT-10 was 0.88. Following the ICD-11 [9] classification of GD, the IGDT-10 scores specified in this study are used as an indicator of GD.

Statistical Analysis

Data analysis was conducted using SPSS version 22.0 [42] with the PROCESS modeling tool version 2.16.3 [43]. EFA was conducted with principal component analysis with Promax rotation to explore the alternative factor structure of Brief COPE [44]. In the moderation models, the variable of psychiatric symptoms was the independent variable, whereas GD was the outcome variable. Coping strategies and player type (ie, recreational players or professional e-sport players) were the moderators. Player type was coded as 1=recreational player and 2=professional e-sport player. All variables in the regression models were continuous variables, except for player type. Age and gender were added to the models as covariates. Given the high number of moderation analyses in the case of coping styles, Bonferroni correction was applied. More specifically, the significance level (P<.05) was divided by the number of tests (n=8 different coping styles). Consequently, a P value of .006 was used as an indicator of statistical significance.

Results

Descriptive Statistics

Most of the 3476 gamers in the sample were male (n=3133, 90.13%), and their ages ranged from 14 to 58 years. The average age was 23.2 (SD 6.48) years. The years they spent in education was approximately 13.2 years (SD 3.04). The findings indicated that 57.33% (n=1993) were single, 35.62% (n=1238) were in a relationship, 5.78% (n=201) were married, 0.48% (n=17) were divorced, 0.06% (n=2) were widowed, and 0.72% (n=25) did not provide information regarding their marital status. Over half of the gamers in the sample were still studying (n=1981, 56.99%), 57.31% (n=1992) worked part time or full time, and 17.52% (n=609) of the gamers who were still studying in the educational system also worked. On an average day, the participants played video games for 2.6 (SD 1.31) hours per day and 18.2 (SD 9.20) hours per week. Approximately 1 in 20 gamers (n=161, 4.63%) identified as e-sport gamers, based on their e-sport tournament participation (ie, they participated in e-sport tournaments at least 6-11 times in the past year).

Factor Analyses

First, confirmatory factor analysis was conducted on the sample to test the model fit of the 14-factor structure of the Brief COPE scale. The model had an acceptable fit to the data (χ^2_{231}=45551.7; P<.001; comparative fit index 0.963; Tucker-Lewis index 0.947; root mean square error of approximation 0.036 [between 0.035 and 0.038]; squared residual 0.03). However, many of the originally proposed factors had low internal consistencies, such as self-distraction (0.55), venting (0.58), behavioral disengagement (0.61), acceptance (0.66), and planning (0.69). Owing to this and following the approach of previous studies, an EFA was performed to identify an alternative factor structure of the Brief COPE. Principal component analysis with Promax rotation was performed. The following items had high cross-loadings and were therefore excluded from further analyses: items 6, 12, 16, 17, 19, and 21. A new EFA was then performed using Promax rotation. The Kaiser-Meyer-Olkin (KMO) index was also calculated to measure sample size adequacy. In this sample, EFA produced a good KMO value (0.74) [45]. Bartlett test of sphericity was χ^2_{253}=31803.7 (P<.001), indicating that the correlation structure was adequate for factor analyses. On the basis of the scree plot, the proportion of total variance, the eigenvalue-one criterion, and the interpretability of the factors, an eight-factor solution, appeared to best fit the data, accounting for 72.75% of variance. The results of the EFA analysis are presented in Tables 1-3.

Table 3. Correlation matrix of the study's variables.

Variables	BSI[a]	IGD[b]	Emotional/social support	Active coping	Self-blame/self-distraction	Humor	Substance use	Denial	Religion	Acceptance
BSI										
r	—[c]									
P value	—									
IGD										
r	0.41	—								
P value	<.001	—								
Emotional/social support										
r	−0.06	−0.04	—							
P value	.001	0.01	—							
Active coping										
r	−0.18	−0.14	0.39	—						
P value	<.001	<.001	<.001	—						
Self-blame/self-distraction										
r	0.60	0.30	0.14	0.03	—					
P value	<.001	<.001	<.001	.06	—					
Humor										
r	−0.01	0.00	0.16	0.22	0.10	—				
P value	.53	.79	<.001	<.001	<.001	—				
Substance use										
r	0.22	0.10	0.10	−0.01	0.24	0.12	—			
P value	<.001	<.001	<.001	.60	<.001	<.001	—			
Denial										
r	0.41	0.24	0.12	0.00	0.40	0.06	0.18	—		
P value	<.001	<.001	<.001	.91	<.001	.001	<.001	—		
Religion										
r	0.10	0.06	0.15	0.11	0.10	0.06	0.07	0.10	—	
P value	<.001	<.001	<.001	<.001	<.001	.001	<.001	<.001	—	
Acceptance										
r	0.15	0.10	0.08	0.11	0.22	0.21	0.08	0.11	0.04	—
P value	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	.03	—

[a]BSI: Brief Symptom Inventory.

[b]IGD: internet gaming disorder.

[c]Not applicable.

The Moderation Models

To investigate the moderating effect of coping strategies on the association between psychiatric symptoms and the symptoms of GD, 8 moderation models were tested. The variable of psychiatric symptoms was entered as the independent variable, GD was the outcome variable, and coping strategies were the moderators. Gender and age were treated as control variables and were added to the models as covariates.

The main effect of psychiatric symptoms was moderate to large (ranging from 0.35 to 0.40) in all 8 models. The interaction terms (ie, moderation effects) were significant for 4 of the 8 coping strategies. However, these did not increase the explained variance of the models considerably (R^2 change ranged from 0.003 to 0.005 or 0.3% to 0.5% change in the variance; Table 4). More specifically, the moderator effects of self-blame/self-distraction (β=.07; *P*<.001) and denial (β=.05; *P*=.001) strategies on the association between psychiatric symptoms and the symptoms of GD were significant. When the

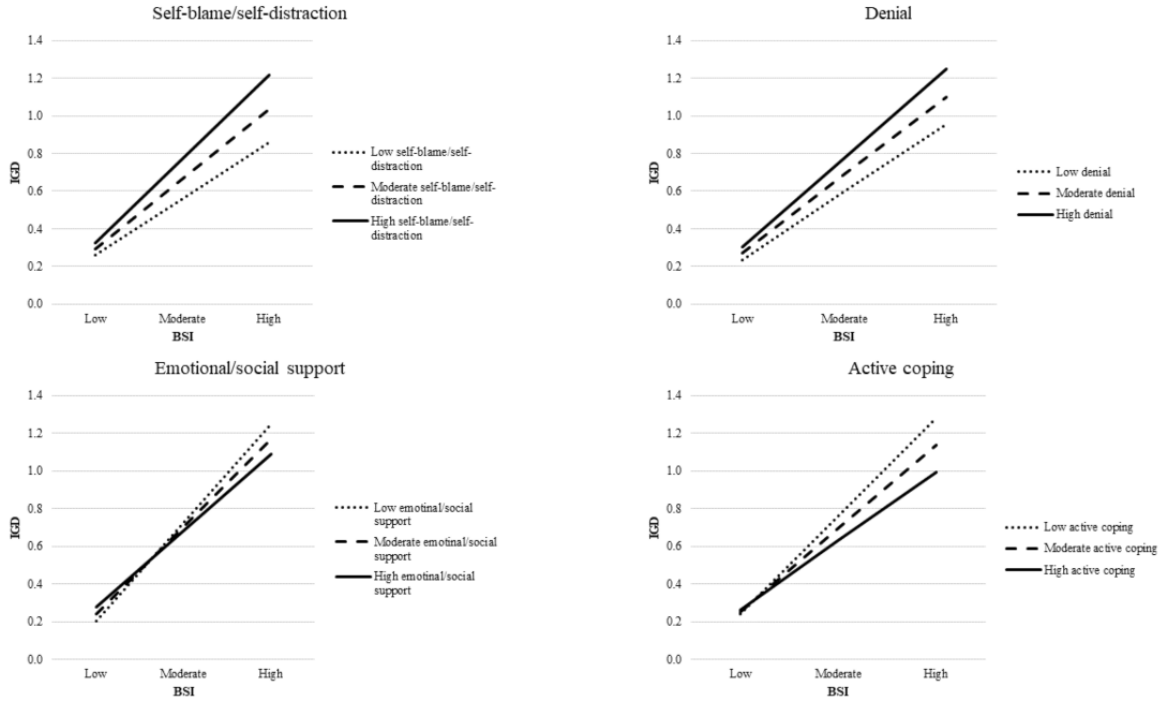
level of psychiatric symptoms was low, the level of GD symptoms was also low, irrespective of the levels of these coping styles. However, when the level of psychiatric symptoms was high, the level of GD symptoms varied based on the level of coping styles the players applied. Those who use self-blame/self-distraction and denial coping styles more experience significantly more GD symptoms than those who use these coping styles less (Figure 1). Moreover, the moderating effect of emotional/social support (β=−.05; *P*=.001) and active coping (β=−.06; *P*<.001) on the relationship between psychiatric symptoms and GD was also significant. More specifically, when the level of psychiatric symptoms was low, the level of GD symptoms was also low, irrespective of the levels of these coping styles. However, when the level of psychiatric symptoms was high, the level of GD symptoms varied based on the level of coping styles the players applied. Those who use emotional/social support and active coping more experience significantly less GD symptoms than those who use these coping styles more (Figure 1). However, the moderating effect of coping strategies on the association between psychiatric symptoms and symptoms of GD was generally weak in all models. Furthermore, the moderating effects of the other coping strategies, namely acceptance (β=.04; *P*=.02), substance use (β=−.04; *P*=.02), humor (β=−.02; *P*=.21), and religion (β=.00; *P*=.98) were not significant after Bonferroni correction was applied (see the *Statistical Analysis* section).

Table 4. Moderation analyses of 8 coping styles on the association between psychiatric symptoms and symptoms of gaming disorder.

Models of moderation analyses	β	*P* value	R^2	R^2 change due to the interaction	*P* value
Model 1			0.179	0.003	.03
BSI[a]	.394	<.001			
Emotional/social support	−.018	.25			
BSI×emotional/social support	−.052	.001			
Model 2			0.184	0.005	.002
BSI	.377	<.001			
Active coping	−.056	<.001			
BSI×active coping	−.071	<.001			
Model 3			0.185	0.004	.004
BSI	.316	<.001			
Self-blame/self-distraction	.090	<.001			
BSI×self-blame/self-distraction	.069	<.001			
Model 4			0.177	0.000	.40
BSI	.400	<.001			
Humor	.003	.82			
BSI×humor	−.019	.21			
Model 5			0.178	0.001	.09
BSI	.399	<.001			
Substance use	.030	.07			
BSI×substance use	−.039	.02			
Model 6			0.184	0.003	.02
BSI	.353	<.001			
Denial	.076	<.001			
BSI×denial	.053	.001			
Model 7			0.177	0.000	.99
BSI	.399	<.001			
Religion	.019	.23			
BSI×religion	.000	.98			
Model 8			0.179	0.001	.11
BSI	.391	<.001			
Acceptance	.047	<.001			
BSI×acceptance	.036	.02			

[a]BSI: Brief Symptom Inventory.

Figure 1. Two-way interaction effect between coping strategies and psychiatric symptoms on gaming disorder. Brief Symptom Inventory represents the scores of Brief Symptom Inventory of psychiatric symptoms. Gaming disorder represents the scores of the 10-Item Internet Gaming Disorder Test. BSI: Brief Symptom Inventory; IGD: internet gaming disorder.



Finally, the moderating role of player type (recreational vs e-sport players) was investigated in the association between psychiatric symptoms and symptoms of GD. The main effect of psychiatric symptoms was also moderate to large (β=.39) in this model. Furthermore, although the interaction term was significant (β=.04; *P*=.02), the R^2 change due to the interaction was negligible (0.001% or 0.1% change in the explained variance) and nonsignificant (Table 5). Therefore, the results suggest that e-sport players with more severe psychiatric symptoms are not at a considerably higher risk of encountering symptoms of GD compared to recreational players.

Table 5. Moderation analyses of player style on the association between psychiatric symptoms and symptoms of gaming disorder.

Models of moderation analyses	β	*P* value	R^2	R^2 change due to the interaction	*P* value
Model			0.178	0.001	.11
BSI[a]	.394	<.001			
e-sport	.035	.03			
BSI×e-sport	.038	.02			

[a]BSI: Brief Symptom Inventory.

Discussion

This study explored the moderating effect of a wide range of coping strategies and player type (recreational vs e-sport players) on the association between psychiatric symptoms and GD. It was assumed that individuals who frequently used putatively maladaptive or dysfunctional coping styles when encountering stressful situations in their lives would have stronger psychiatric symptoms or GD bonds than those who used putatively adaptive coping strategies in general. In addition, it was assumed that e-sport players would not significantly differ from recreational players in their psychiatric symptoms or GD association. According to the results regarding coping strategies, the main effect of psychiatric symptoms was moderate to large in all models, which is in line with previous research findings [46-50]. The interaction terms (ie, moderation effects) were significant for 4 of the 8 coping strategies (ie, self-blame/self-distraction, denial, emotional/social support, and active coping). However, the explained variance of the models only increased negligibly (from 0.3% to 0.5%). The direction of the moderations was as expected (ie, putatively maladaptive strategies were associated with more GD symptoms when the level of psychiatric symptoms was high, whereas putatively adaptive strategies were associated with less).

However, the negligible effect sizes of these moderations make the results more comparable to those reported by Brand et al [29]. They tested whether dysfunctional coping styles, namely denial, substance use, and disengagement, moderate the association between psychopathological aspects (ie, depression and social anxiety) and general internet addiction (including

online gaming) but found no considerable moderation effect. In contrast, they found that dysfunctional coping styles mediated between psychopathological aspects and general internet addiction. According to their explanation, higher symptoms of depression and social anxiety can increase the risk of dysfunctional coping strategies, which is associated with higher internet addiction rates. Similarly, many other studies have reported that specific coping styles (eg, avoidance, media-focused coping) mediate between psychiatric symptoms or stress and GD. Given that specific coping styles (especially putatively maladaptive ones as aforementioned) are associated with psychiatric symptoms at moderate or moderate-to-strong levels and with GD at weak or weak-to-moderate levels [26-28] (and in this study; Table 1), it was expected that they would have a mediating effect. A mediating effect suggests that when experiencing high levels of psychiatric symptoms, individuals are more likely to use specific putatively maladaptive coping styles. For instance, in a naturalistic study, a high level of depressive symptoms was associated with an increased use of experiential avoidance on a daily basis [51].

Nevertheless, as mentioned in the *Introduction*, it is also plausible to think that individuals who frequently (ie, habitually) use putatively maladaptive or dysfunctional coping styles when encountering stressful situations in their lives have stronger psychiatric symptoms or GD bonds than those who use putatively adaptive coping strategies in general. However, it has also been suggested that in concrete situations, numerous factors influence the coping or emotion regulation strategy selection applied by an individual [52]. This would explain why no considerable moderation effects were found even if coping strategies were dispositional or trait-like to a certain degree. Overall, additional studies are necessary to confirm these findings, and longitudinal studies and experiments should be designed to explore the causal relationships in the etiology of GD and to better understand these crucial coping-related mechanisms.

Finally, the assumption regarding the effect of player type (recreational vs e-sport players) on the association between psychiatric symptoms and GD was met because the change in explained variance of the moderation model was negligible (0.1%). To date, very few empirical studies have investigated whether e-sport players are at a higher risk of developing GD than recreational gamers. Studies that compared e-sport players and recreational players found significant differences in motivation [34,53] but reported no significant differences in GD and GD-related mechanisms (eg, the mediation effect of gaming motives between psychiatric symptoms and GD; Bányai et al [34]). This is also in line with findings suggesting that increased time spent gaming is not associated with psychiatric problems and is not a good predictor of GD [54]. These results suggest that e-sport players are not necessarily at a higher risk of developing GD than those who are highly engaged recreational gamers. This is also plausible, knowing how goal-oriented and structured e-sport training is [6]. Players have a tight daily schedule, including proper time for eating healthily, sleeping properly, and performing physical exercise. Moreover, they often train in teams and cultivate social bonds while playing as well. Nevertheless, it is important to conduct more research in this field of e-sports and to investigate the risk of GD among e-sport players [33,55].

This study has several limitations that should be noted when interpreting the findings. Although the sample of this study was large, because of its self-selected nature, the results should be generalized with caution. Furthermore, biases of self-report surveys (eg, memory recall and social desirability) should also be considered when interpreting the results. The categorization of e-sports and recreational gamers was based on the number of self-reported gaming competitions they engaged in (ie, frequency of e-sport competitions). Future studies should use more standardized methods for this categorization. Coping strategies were assessed generally and did not consider how individuals cope with different types of stressors. However, it is worth noting that habitually used maladaptive emotion regulation strategies are associated with increased negative affect and atypical cortisol responses to psychosocial stressors in laboratory studies [56]. This suggests that the frequent use of these strategies in different situations may create a vulnerability to mental health problems. Finally, due to the cross-sectional design of the study, causal explanations could not be drawn. Longitudinal and experimental studies should be conducted to address this limitation.

Despite these limitations, this study investigated important questions using a large sample of highly engaged video game players and a subsample of e-sport players. The relationship between psychiatric symptoms and GD has been consistently confirmed. Therefore, understanding factors that attenuate or aggravate this relationship will help in planning better intervention programs. Strategies individuals routinely use to cope with stress and regulate their negative affect can be considered when considering these factors. Understanding why a given individual uses specific affect regulation strategies in a given situation or across situations and the emotional or behavioral consequences of the ways of affect regulation [57] could be an essential component of personalized treatments targeting mental health problems including GD. Furthermore, in relation to prevention and intervention programs, experts should focus on both the coping strategies of the individuals and their style of video game usage. Playing video games can be viewed as a coping strategy. As a media-focused coping style, video game playing could have similar outcomes as self-distraction and behavioral disengagement among some problematic gamers or players diagnosed with GD [22,58,59] when playing games to avoid aversive and stressful situations [60]. Gaming is a recreational activity that primarily serves pleasure, relaxation, and/or stress-relief. However, gamers can also avoid discomfort and escape from their problems in real life. In this regard, future research should focus on the style of video game playing and how this activity is integrated into gamers' lives (eg, recreation, e-sport or problematic gaming, or an escape option from reality). Individual coping styles and emotion regulation strategies also play a role in this and therefore should be considered in the prevention and treatment processes.

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Conflicts of Interest

Eötvös Loránd University (ELTE) receives funding from Szerencsejáték Ltd to maintain a telephone helpline service for problematic gambling. ZD has also been involved in research on responsible gambling funded by Szerencsejáték and the Gambling Supervision Board and provided educational materials for the Szerencsejáték's responsible gambling program. The University of Gibraltar receives funding from the Gibraltar Gambling Care Foundation. However, the funding is not related to this study, and the funding institution had no role in the study design or the collection, analysis, and interpretation of the data, writing the manuscript, or the decision to submit the paper for publication.

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Abbreviations

BSI: Brief Symptom Inventory
EFA: exploratory factor analysis
GD: gaming disorder
IGD: internet gaming disorder
IGDT-10: 10-Item Internet Gaming Disorder Test

KMO: Kaiser-Meyer-Olkin

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Original Paper

The Role of Intolerance of Uncertainty and Working Alliance in the Outcome of Cognitive Behavioral Therapy for Generalized Anxiety Disorder Delivered by Videoconference: Mediation Analysis

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Abstract

Background: Previous meta-analyses have shown a significant relationship between working alliance and treatment outcome in general. Some studies have examined the relationship between working alliance and treatment outcome during telepsychotherapy, but to the best of our knowledge, no study has examined the mediating role of individual components of the working alliance.

Objective: As part of a clinical trial of cognitive behavioral therapy (CBT) for generalized anxiety disorder (GAD) delivered by videoconference (VC), the aim of this study is to examine the mediating role of intolerance of uncertainty on the relationship between the components of the working alliance and treatment outcome.

Methods: A sample of 46 adults with primary GAD received 15 sessions of CBT for GAD delivered over VC. Participants completed the measure of working alliance immediately after the fifth therapy session. The degree of change in intolerance of uncertainty (a key psychological process) was assessed from pre- to posttreatment. Treatment outcome was assessed via changes in GAD symptoms from pretreatment to the 6-month follow-up.

Results: The results revealed that the therapeutic bond did not predict treatment outcome (r=−0.23; P=.12). However, agreement on therapeutic goals and tasks did predict treatment outcome (r=−0.42; P=.004 and r=−0.37; P=.01, respectively). In addition, the relationship between consensus on therapeutic tasks and treatment outcome was completely mediated by changes in intolerance of uncertainty (unstandardized β=−0.03; r^2=0.12), whereas consensus relative to treatment goals had a direct impact on treatment outcome.

Conclusions: These results provide a better understanding of the differential role of the components of the working alliance in telepsychotherapy as a facilitative factor for changes in key cognitive processes, leading to therapeutic change.

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KEYWORDS

working alliance; videoconference; cognitive behavioral therapy; intolerance of uncertainty; generalized anxiety disorder; treatment; outcome; therapy; anxiety; uncertainty; telehealth

Introduction

Background

Anxiety disorders are among the most prevalent psychological disorders [1]. Several psychological treatments have been developed and validated for anxiety disorders [2], but the accessibility of these treatments remains limited [3]. The lack of access to available adapted services leads to several financial (eg, travel and work absenteeism) and personal (eg, time away from the family) consequences [4]. Telepsychotherapy offers an interesting solution to the above-mentioned problems in that it can limit travel costs, resulting in increased access to services from professionals specialized in empirically supported treatments. Several technologies can be used to provide remote treatment (ie, telephone, internet, and video). Videoconference (VC) can facilitate access to care because it offers an interactive communication system that provides access to verbal and nonverbal content between the patient and therapist [5-8].

Several researchers and clinicians have argued that the working alliance is a key element involved in therapeutic change [9]. The working alliance, as defined by Bordin [10], involves 3 components: (1) agreement on global treatment goals, (2) agreement on specific therapeutic tasks, and (3) the establishment of a therapeutic bond between the patient and therapist. First, the patient and therapist should share the same objectives that are addressed during treatment. Second, the consensus on tasks is improved when the patient considers that the tasks included in the therapy are logical, accessible, and relevant to the therapeutic objectives. In cognitive behavioral therapy (CBT), agreement on tasks facilitates interventions that target unhelpful thoughts and behaviors, and agreement on goals is essential to draw a shared treatment plan. Third, the bond refers to the trust and constructive attachment between the patient and therapist. Together, these 3 aspects contribute to the development of a strong and effective working alliance, as conceptualized and assessed by the Working Alliance Inventory (WAI) [11].

According to many authors, the working alliance has a considerable impact on treatment efficacy [12]. In 2 meta-analyses [9,13], the authors found that the working alliance, most commonly assessed with the WAI, predicted general treatment efficacy. It explained 5% [9] to 7.5% [13] of the variance in treatment outcome. More recently, Buchholz and Abramowitz [14] critically reviewed the literature on the working alliance during CBT for anxiety disorders. Their findings highlighted the need for more studies on the contribution of the working alliance to treatment outcome. They found 7 studies on anxiety disorders, suggesting that the global measures of alliance predicted treatment outcome, and 4 studies that did not find this result [14]. The authors found only 3 studies that investigated the specific role of the components of the working alliance. They confirmed the observation of Horvath [15] that there is a "practical vacuum in the literature." All 3 studies (ie, 1 on posttraumatic stress disorder and 2 on obsessive-compulsive disorder) revealed that the agreement on tasks was related to treatment outcome. In summary, the data suggest that the agreement on therapeutic tasks is a component of the working alliance, which is most consistently related to therapeutic change.

In addition to the role of the working alliance, CBT models suggest that changes in cognition and behaviors as well as the ability to tolerate distress are the most important factors leading to therapeutic change [16-18]. Different therapeutic strategies, such as behavioral experiments and exposure, are suggested to inhibit maladaptive interpretations and beliefs, to change maladaptive behavioral responses, and to build a stronger ability to tolerate distress [18-20]. According to CBT models, the primary factor that explains therapeutic change is not the working alliance but rather the changes in cognition and behaviors. Working alliance is considered as a facilitative factor for changes in key processes that generate therapeutic change [21].

Some clinicians have expressed concerns that VC-based psychotherapies might hinder the establishment of a sound working alliance (refer to the study by Connolly et al [7] for a detailed review) [22]. Although several studies have examined the role of the working alliance in face-to-face therapy [13], only a handful of studies have examined the role of the working alliance in e-therapy (ie, VC, virtual reality, chat, or email) [23,24]. Overall, the results suggest that the use of VC-based psychotherapies does not interfere with the quality of the working alliance [25-27]. Although these results are encouraging, further studies are needed to understand the exact role of the working alliance and its components in telepsychotherapy. An important next step is to investigate how the 3 components of the working alliance affect treatment outcome in VC when taking into account known key treatment mechanisms. We chose to explore this question in the context of generalized anxiety disorder (GAD), which is a disorder characterized by chronic and excessive worry and anxiety that is difficult to control. GAD is a common anxiety disorder [1] and is associated with several consequences, such as higher levels of unemployment, health service use, and risk of cardiovascular disorders [28,29]. According to Roberge et al [30], approximately 80% of the people with GAD do not receive an appropriate treatment due to geographical constraints (ie, diminished availability in rural areas). Only a few studies have examined the association between the working alliance and therapeutic change for patients with GAD [14,31]. From these studies, 2 studies suggest that a strong working alliance is associated with a greater change in GAD symptoms following face-to-face CBT [31,32]. However, 2 studies did not find such a result following face-to-face CBT [33] or internet-delivered CBT [34]. The contribution of the components of the working alliance to change in GAD symptoms, especially in CBT delivered by VC, has not yet been studied. At this point, it is

unclear whether any of these components can predict treatment outcome or facilitate changes in key cognitive processes.

Different cognitive behavioral models have been proposed for GAD. Each model suggests a specific vulnerability factor that contributes to the etiology and maintenance of pathological symptoms, such as cognitive avoidance [35] and metacognitive beliefs [36]. Our group has developed and validated a cognitive behavioral model of GAD that focuses on the role of intolerance of uncertainty [37]. Robichaud et al [38] defined intolerance of uncertainty as a dispositional characteristic arising from a set of catastrophic beliefs about uncertainty and its consequences. According to Robichaud et al [38], this set of beliefs leads to negative and unhelpful cognitive, behavioral, and emotional reactions in uncertainty-inducing situations (ie, situations that are novel, unpredictable, or ambiguous). Data suggest that intolerance of uncertainty is a causal risk factor for high levels of worry and GAD and that it plays a key role in the etiology of GAD [39-43]. A total of 4 randomized clinical trials support the efficacy of CBT for GAD, focusing on intolerance of uncertainty, compared with a waiting list [44,45], supportive therapy [46], and applied muscular relaxation [47]. An independent clinical trial [48] found that change in intolerance of uncertainty, as measured with the Intolerance of Uncertainty Scale (IUS) [49], mediated change in worry, whereas change in worry did not mediate change in intolerance of uncertainty. According to this model, decreases in intolerance of uncertainty play an active role in the reduction of GAD symptoms. Therefore, it is crucial to understand the variables that contribute to a greater change in key factors (eg, intolerance of uncertainty) that subsequently lead to change in symptoms (eg, worry and anxiety).

Objectives

Using data from a clinical trial of CBT delivered by VC for GAD, the goal of this study is to gain a better understanding of the relationship between the different components of the working alliance and treatment outcome. First, we examined whether any of the 3 components of the working alliance, as perceived by the participant and as defined by Bordin [10], would predict treatment outcome. We hypothesized that, of all the components, agreement on the task would predict the treatment outcome (*Hypothesis 1*). Second, we explored whether a change in intolerance of uncertainty would mediate the relationship between the components of the working alliance and treatment outcome (*Hypothesis 2*).

Methods

Study Participants

Our sample consisted of 46 adults (40 women) with primary GAD participating in a randomized controlled trial (described elsewhere; refer to the studies by Watts et al [27] and Bouchard et al [50]) and allocated to receive psychotherapy delivered by VC. The mean age was 42.39 (SD 15.80) years, ranging from 20 to 74 years. The participants' level of education varied between high school (6/46, 13%), college (14/46, 30%), and university (26/46, 56%). Participants were recruited from 5 urban areas in the province of Québec. The severity of GAD was assessed using the 9-point (0-8) Clinician's Severity Rating (CSR) of the Anxiety Disorders Interview Schedule for the Diagnostic and Statistical Manual of Mental Disorders-IV (ADIS-IV). CSR ratings of 4 and higher correspond to the range associated with sufficient clinical severity to warrant the presence of a diagnosis. The mean severity of GAD before treatment was 5.37 (SD 1.07; range 4-7).

Measures

The ADIS-IV [51] is a structured interview used to determine the presence and severity of several psychological disorders, such as anxiety, mood, substance use, and psychotic disorders. The ADIS-IV was used in this study to establish if participants met the diagnostic criteria of GAD for eligibility (ie, severity above 4 on the CSR). Good interrater reliability has been reported for the severity of GAD (r=0.72) [52].

The Penn State Worry Questionnaire (PSWQ) [53] was used to assess the GAD symptom of worry and was our measure of treatment outcome. It has 16 items that measure the tendency to worry uncontrollably and excessively. Each item was evaluated on a 5-point Likert scale. Examples of items include *My worries overwhelm me* and *Once I start worrying, I cannot stop*. The French translation of the PSWQ has excellent internal consistency (α=.82) and test-retest reliability (r=0.86) [54]. To measure treatment outcome, PSWQ was administered at pretreatment and at the 6-month follow-up.

The IUS [49] was our measure of the process of change (ie, our mediator). It has 27 items measuring catastrophic beliefs about uncertainty and the consequences of being uncertain. The items were evaluated on a 5-point Likert scale. Examples of items include *Uncertainty makes life intolerable* and *The smallest doubt can stop me from acting.* The IUS measures the implications of the state of uncertainty and attempts to control future events. The IUS, which was originally developed in French, has good metric proprieties. It has excellent internal consistency (α=.91) [49] and good test-retest reliability (r=0.78) [55]. To measure the treatment process, the IUS was administered at pretreatment and posttreatment.

The WAI [11] assesses the quality of the working alliance. The WAI has 36 items rated by the participant on a 7-point Likert scale. The higher the total score, the more the patient (respondent) perceives a good working alliance with his or her therapist. This instrument is based on the conceptualization of the working alliance and its 3 components by Bordin [10], which are measured by 3 subscales: (1) WAI-Goal (eg, *We have established a good understanding of the kind of changes that would be good for me*), (2) WAI-Task (eg, *My therapist and I agree about the things I will need to do in therapy to help improve my situation*), and (3) WAI-Bond (eg, *I believe my therapist is genuinely concerned for my welfare*). The WAI has excellent internal consistency (α=.96) [11] and acceptable test-retest reliability (r=0.73) [9]. In addition, the 3 subscales showed appropriate levels of intercorrelation (r=0.69-0.92). Like the original English version of the WAI, the French translation [56] has sound psychometric properties. Although several instruments have been developed to measure the quality of the working alliance, the WAI is the most frequently used questionnaire in both research and clinical settings [9,13]. To make an informed assessment of the quality of the working

alliance without being unduly influenced by their progress in therapy [27,57], the participants completed WAI after the fifth therapy session.

Procedure

The study was approved by the relevant ethics review boards, registered as a clinical trial, and conducted in accordance with ethical codes of conduct (eg, free and informed consent; refer to the study by Watts et al [27] for details). Participants were assessed by a team psychologist using the ADIS-IV (refer to the study by Watts et al [27] for the CONSORT [Consolidated Standards of Reporting Trials] flow chart). Those who met the eligibility criteria (n=148) were randomly assigned to 1 of the 2 conditions (ie, face-to-face CBT, n=79 or CBT delivered by VC, n=69). For this study, we only included the 46 participants assigned to the VC condition who completed treatment and had no missing values on the measures at all assessment points. Each participant was randomly assigned to 1 of the therapists for the duration of the treatment, and they never met face-to-face. They completed an individual CBT program of 15 weekly sessions based on the Intolerance of Uncertainty model, as described in the study by Robichaud et al [38]. The participants traveled to the closest city from where they live (ie, the 5 treatment centers) to receive the treatment delivered by VC through the specialized equipment that provides encrypted communication and ensures confidentiality. During each session, participants sat alone in an office, facing a television and a Tandberg Edge 95 MXP system located 2 meters away, whereas their therapist was located at a different site using a similar VC system. All units installed in clinics corresponded to the standards established for telehealth [58]. For more details on the methodology, refer to the study by Watts et al [27].

Analytical Strategy

Pearson correlation analyses were performed between the score of each of the 3 subscales of the WAI and changes in the PSWQ (from pretreatment to the 6-month follow-up). After testing the first hypothesis, we conducted mediation analyses with bootstrapped samples (5000 samples and bias-corrected 95% CIs) using the PROCESS macro for mediation in IBM SPSS [59]. In each analysis, the predictor was the component of the WAI (the subscales that predicted change in the PSWQ), the mediator was the residualized change scores (RCSs) on the IUS (from pre- to posttreatment), and the outcome variable was the RCS on the PSWQ (from pretreatment to the 6-month follow-up). In mediation analyses, it is important to have a study design that allows for conclusions about causality. As we were interested in the role of a phenomenon occurring during psychotherapy (the working alliance) on changes that occurred over treatment, selecting appropriate time points was important for measuring change. Some overlap was unavoidable with the use of pretreatment scores to measure intolerance of uncertainty and GAD symptoms. To fully capture the change in intolerance of uncertainty, the change from pretreatment to posttreatment was used. To minimize the overlap and increase the potential of addressing causality, changes in symptoms from pretreatment to follow-up were used to measure long-term outcome. This limitation should be considered when interpreting mediation analyses.

No extreme multivariate data points were observed using Mahalanobis distance (P<.001). No transformation was performed on the data. The means, SDs, and ranges of the questionnaires are presented in Table 1.

Table 1. Descriptive statistics for all study measures during cognitive behavioral treatment for generalized anxiety disorder delivered by videoconference (N=46).

Variable	Mean (SD)	Score range
WAI-Goal[a] at session 5	76.35 (7.94)	50-84
WAI-Task[b] at session 5	78.30 (6.85)	54-84
WAI-Bond[c] at session 5	75.61 (8.28)	49-84
IUS[d] at pre-tx[e]	83.67 (20.00)	41-122
IUS at post-tx[f]	53.34 (17.78)	28-91
PSWQ[g] at pre-tx	68.15 (6.26)	50-80
PSWQ at the 6-month follow-up	44.84 (10.46)	20-65

[a]WAI-Goal: Working Alliance Inventory, goal subscale.

[b]WAI-Task: Working Alliance Inventory, task subscale.

[c]WAI-Bond: Working Alliance Inventory, bond subscale.

[d]IUS: Intolerance of Uncertainty Scale.

[e]pre-tx: pretreatment.

[f]post-tx: posttreatment.

[g]PSWQ: Penn State Worry Questionnaire.

Results

Working Alliance and Treatment Outcome

The first hypothesis was that patient-perceived agreement on task would predict changes in the level of worry from pretreatment to the 6-month follow-up. The hypothesis was partially supported, as 2 of the 3 subscales of the WAI were correlated with changes in PSWQ scores. Specifically, the WAI-Goal and WAI-Task subscales significantly predicted changes in the PSWQ. However, the WAI-Bond subscale did not significantly predict changes in the PSWQ scores. Thus, both agreement on goals and agreement on tasks were associated with greater decreases in the GAD symptom of worry following a CBT delivered by VC. A correlation matrix including all variables is presented in Table 2.

Table 2. Correlation matrix (Pearson *r* and two-tailed *P* value) of all study measures during cognitive behavioral treatment for generalized anxiety disorder delivered by videoconference (N=46).

Variable	WAI-Goal[a] at session 5	WAI-Task[b] at session 5	WAI-Bond[c] at session 5	RCS[d] Intolerance of Uncertainty Scale (pretreatment to posttreatment)	RCS Penn State Worry Questionnaire (pretreatment to the 6-month follow-up)
WAI-Goal at session 5					
r	1	0.87	0.73	−0.31	−0.42
P value	—[e]	<.001	<.001	.03	.004
WAI-Task at session 5					
r	0.87	1	0.63	−0.43	−0.37
P value	<.001	—	<.001	.003	.01
WAI-Bond at session 5					
r	0.73	0.63	1	−0.16	−0.23
P value	<.001	<.001	—	.28	.12
RCS Intolerance of Uncertainty Scale (pretreatment to posttreatment)					
r	−0.31	−0.43	−0.16	1	0.55
P value	.03	.003	.28	—	<.001
RCS Penn State Worry Questionnaire (pretreatment to the 6-month follow-up)					
r	−0.42	−0.37	−0.23	0.55	1
P value	.004	.01	.12	<.001	—

[a]WAI-Goal: Working Alliance Inventory, goal subscale.

[b]WAI-Task: Working Alliance Inventory, task subscale.

[c]WAI-Bond: Working Alliance Inventory, bond subscale.

[d]RCS: residual change score.

[e]Not applicable.

Mediation Analyses

The second hypothesis was that a change in intolerance of uncertainty would mediate the relationship between the working alliance and treatment outcome. Considering that we performed 2 mediation analyses, we applied Bonferroni corrections and adjusted significance levels ($P<.025$).

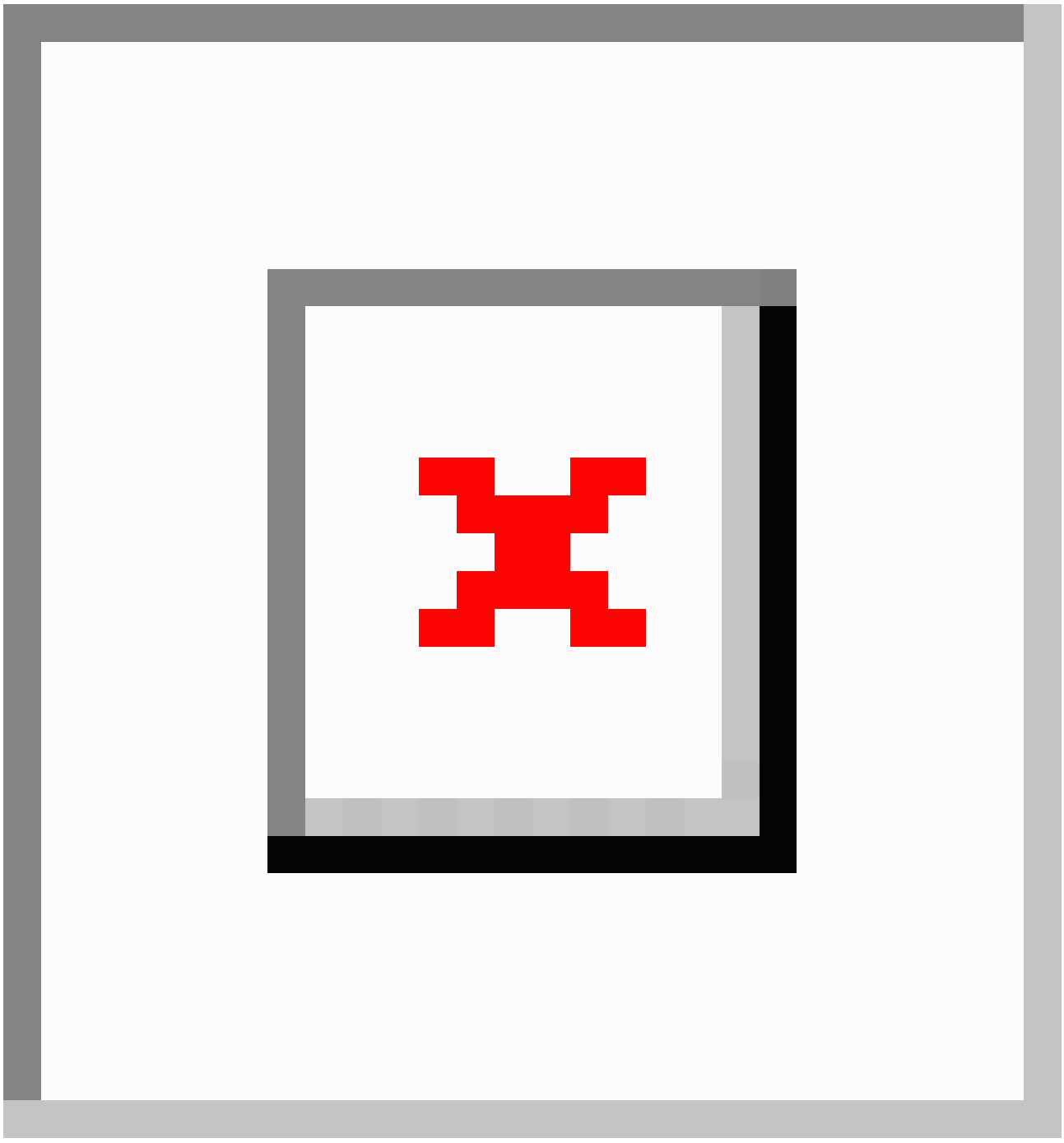
WAI-Goal Subscale

The first mediation model with the goal subscale of the WAI was not supported. The relationship between the WAI-Goal subscale and change on the IUS was not significant (unstandardized $\beta=-0.04$; $P=.03$). Changes in intolerance of uncertainty did not mediate the relationship between agreement on goals and treatment outcome (due to the Bonferroni correction). However, it is important to note that the relationship was close to being significantly supported.

WAI-Task Subscale

The second mediation model, with the task subscale of the WAI, was supported. Scores on the WAI-Task subscale significantly predicted change on the IUS. Moreover, change on the IUS significantly predicted change on the PSWQ. Once the indirect effect was taken into account, the direct effect of the WAI-Task subscale on change on the PSWQ was no longer significant. The WAI-Task subscale had a significant indirect effect on change on the PSWQ (pretreatment to the 6-month follow-up), which was mediated by the change on the IUS (pretreatment to posttreatment). The indirect effect had a medium effect size ($r^2=0.12$). Changes in intolerance of uncertainty completely mediated the relationship between agreement on task and the change in the GAD symptom of worry. The results are shown in Figure 1.

Figure 1. Summary of the mediation analysis with the Working Alliance Inventory task subscale during cognitive behavioral treatment for generalized anxiety disorder delivered by videoconference (N=46). *b*: unstandardized beta coefficient; IUS: Intolerance of Uncertainty Scale; PSWQ: Penn State Worry Questionnaire; RCS: residual change score; WAI-Task: Working Alliance Inventory, task subscale.



Discussion

Principal Findings

The aim of this study is to provide a better understanding of the mechanisms of change during CBT for GAD delivered by VC. We examined the mediating role of uncertainty intolerance in the relationship between the selected components of the working alliance and treatment outcome. The results showed that (1) the therapeutic bond does not significantly predict treatment outcome; (2) agreement on therapeutic goals predicts treatment outcome but does not predict change in intolerance of uncertainty; and (3) agreement on therapeutic tasks predicts treatment outcome, and this effect is completely mediated by change in intolerance of uncertainty.

First, the results showed that a stronger therapeutic bond is not related to a greater change in symptoms. This result is in line with previous studies that investigated the 3 components of the working alliance during face-to-face CBT for several psychological disorders, including anxiety disorders [14]. Watts et al [27] compared the working alliance in VC and in face-to-face in our sample and found no evidence that it was poorer in VC (it was actually significantly stronger), suggesting that our findings are not simply the result of an impoverished therapeutic bond in VC. Bouchard et al [60] also found no

predictive impact of the therapeutic bond on treatment outcome, in VC or in face-to-face, for patients with panic disorder and agoraphobia. The results of this study add to a growing body of evidence suggesting that the working alliance predicts treatment outcome because of the agreement on goals and tasks. In their review of the VC literature, Simpson and Reid [61] reported that several studies support the notion that VC treatments can generate a strong therapeutic bond right from the onset of treatment [26,62,63]. For example, Germain et al [26] found no significant difference in the quality of the bond between a VC-based treatment and a face-to-face treatment for posttraumatic stress disorder. Our results add to the literature by providing data that are specific to GAD and by showing that the bond does not predict change in outcome. Thus, although a strong therapeutic bond between the patient and therapist is considered to be a prerequisite for successful CBT [21], it does not appear to be a predictor of improvement.

A second interesting result from this study is that agreement on therapeutic goals predicted treatment outcome. This was somewhat unexpected because studies conducted with other disorders have produced conflicting findings [64,65]. Of note, the relationship between agreement on goals and change in intolerance of uncertainty was nonsignificant (due to the Bonferroni correction). A posteriori power analysis showed that our study was not optimally statistically powered; at least 126 participants would be required to test the mediation model with a power of 0.80 and *without* the use of a Bonferroni correction for type 1 error [66]. The absence of a significant relationship is slightly surprising because, in CBT, agreement on general goals is expected to be related to core therapeutic processes. Although agreement on goals was related to treatment outcome but not to the core mechanism of change in CBT of GAD, the pattern of results led to a mediation effect of intolerance of uncertainty that was close to reaching the threshold of statistical significance. Overall, the findings may be explained by the specific nature of GAD and its treatment. Many patients with GAD seek treatment to gain more control over their anxiety and gain more certainty. However, to be truly effective, the treatment must not target anxiety but *the tolerance* of uncertainty [46,47]. This slight nuance in goals may lead to a weaker fit with uncertainty. These results suggest that the need to be in agreement with the goals of the treatment of GAD is important to treatment success and independent of strengthening tolerance of uncertainty. As agreement on goals correlated strongly with agreement on tasks, addressing the (lack of) usefulness of worrying and the importance of tolerating uncertainty must not be neglected. Future studies should investigate the mediational relationship between the agreement on goals and changes in intolerance of uncertainty with a larger sample.

Third, our results reveal that intolerance of uncertainty mediates the relationship between agreement on tasks and changes in symptoms when CBT is delivered by VC. This result is relevant to CBT in general, as it shows that agreement on therapeutic tasks leads to greater change in beliefs about uncertainty, which then leads to a decrease in GAD symptoms. Our results are also relevant to CBT delivered by VC for GAD by showing that a component of the working alliance acts as a facilitative factor for change in the key process of the disorder (in this case, intolerance of uncertainty), which ultimately leads to therapeutic change. Several studies have suggested that building a working alliance is not an end in and of itself in the treatment of anxiety disorders but rather a basis upon which patients and their therapists can work to reach changes in core beliefs that maintain the disorder [26,61,62]. However, this study is the first to support this hypothesis with data from psychotherapy delivered by VC. Moreover, it is the first study to address the working alliance in the field of VC, which tests a mediation effect for a cognitive change variable. Our results suggest that when patients perceive the tasks in therapy as logical, accessible, and relevant to the therapeutic objectives, they may be more prone to tolerate distress to attain clinical change in maladaptive beliefs and behaviors. Overall, VC does not seem to be a barrier to the establishment of a sound working alliance or successful therapy.

Strengths and Limitations

It is important to highlight some of the limitations of this study. First, the data were obtained using self-report questionnaires completed by the participants. We did not use a measure of the therapist's impression of the working alliance, and we did not obtain an independent clinician's impression of GAD symptoms. Second, the measure of the working alliance was completed on only 1 occasion, as opposed to several times over the course of therapy (in which case, an aggregated score could have been used). The content of the specific session that immediately preceded the completion of the WAI may have had an impact on the perception of the working alliance, whereas a mean score aggregated over several sessions might be less unstable. Finally, the change scores for intolerance of uncertainty (pretreatment to posttreatment) and for GAD worry (pretreatment to 6-month follow-up) overlap in terms of their timing; both change scores use the pretreatment time point. To overcome this limitation, we could have examined changes in GAD symptoms from posttreatment to the 6-month follow-up and changes in intolerance of uncertainty from pre- to posttreatment. However, such an attempt to avoid using the same time point would have resulted in measuring fluctuations in worry *after* therapy and not during therapy. Given that our research questions focus on the change in symptoms occurring during therapy and not on the maintenance of therapeutic gains after treatment, this limitation was unavoidable.

Simpson and Reid's [61] review of the role of the working alliance during VC-based treatment suggests several benefits regarding the use of this technology. First, despite the physical distance, patients and therapists report feeling that they are in the same room and that they are absorbed by the interaction. Different authors have argued that the feeling of telepresence can facilitate the establishment of a sound therapeutic bond and of collaborative goals specific to the working alliance [24,67]. Furthermore, VC can reduce the feeling of being intimidated or pressured while increasing the feeling of control over the treatment. Simpson and Reid [61] also concluded that across the various studies identified, the working alliance is generally strong, although some studies have found it to be lower [23]. Nevertheless, these authors suggest several factors that may influence the quality of the working alliance and that deserve to be studied more thoroughly, such as the level of telepresence, therapist competence, or patient attitudes and beliefs.

Conclusions

To summarize, the results of this study document the role of the different components of the working alliance in CBT delivered by VC. This study also documents the mechanisms of change during treatment for GAD. Our results suggest that the 2 components of the working alliance predict treatment outcome. Agreement on goals has a direct impact on changes in symptoms, whereas agreement on tasks has an indirect effect via changes in intolerance of uncertainty. Our results suggest that it is important to ensure that the patient and therapist agree on the goals and tasks to be performed in therapy to ensure optimal treatment success. Our results also highlight the role of the working alliance in understanding the mechanisms of change in GAD. Future studies should examine whether the relationship between working alliance and treatment outcome is, in fact, due to agreement on the goals and tasks to be performed in therapy, rather than on the therapeutic bond.

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Conflicts of Interest

None declared.

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Abbreviations

ADIS-IV: anxiety disorders interview schedule for the Diagnostic and Statistical Manual of Mental Disorders-IV
CBT: cognitive behavioral therapy
CSR: Clinician's Severity Rating
GAD: generalized anxiety disorder
IUS: Intolerance of Uncertainty Scale
PSWQ: Penn State Worry Questionnaire
RCS: residualized change score
VC: videoconference
WAI: Working Alliance Inventory

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Original Paper

Transdiagnostic Internet Intervention for Indonesian University Students With Depression and Anxiety: Evaluation of Feasibility and Acceptability

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Abstract

Background: University students with depression and anxiety do not easily receive or seek treatment; therefore, internet-based interventions have been suggested to be a promising way to improve treatment accessibility and availability. However, it has not been examined whether a guided, culturally adapted, transdiagnostic, internet-based intervention is effective for treating symptoms of depression, anxiety, or both among university students in Indonesia.

Objective: This study aims to investigate the feasibility (acceptability and satisfaction, usability, and uptake) of a guided, culturally adapted, transdiagnostic, internet-based intervention among university students with symptoms of depression, anxiety, or both in Indonesia.

Methods: Students from Universitas Gadjah Mada, Yogyakarta, Indonesia, were screened for symptoms of depression, anxiety, or both, and filled online informed consent, demographic questionnaires, and a quality of life measure at pretreatment assessment (T0). Subsequently, the participants started the intervention. Seven weeks after T0, the primary outcomes of this feasibility study were analyzed at posttreatment assessment (T1) using the 8-item Client Satisfaction Questionnaire (CSQ-8) and the System Usability Scale (SUS). Mean and SDs for the CSQ-8 and SUS were calculated to examine feasibility. Within-group secondary outcomes (depression, anxiety, and quality of life) were inspected for outliers and normal distribution. Paired-sample t tests were used to investigate differences between time points of secondary outcomes. A mixed-method approach of quantitative and qualitative analyses was adopted. Both the primary and secondary outcomes were additionally explored with an individual semistructured interview and synthesized descriptively.

Results: A total of 50 participants completed the intervention. We found a moderate to high level of satisfaction and acceptability, a slightly below-average level of desirable usability (≥70), and an adherence rate of 52% which was higher than expected given the novelty of the intervention. Results for the secondary outcomes indicated a decrease in depression and anxiety. For depression, the overall mean difference between the 2 time points for depression was 3.92 (95% CI 2.75-5.1; Hedges *g* 1.15; *P*<.001). For anxiety, the overall mean difference between the 2 time points was 3.34 (95% CI 2.06-4.61; Hedges *g* 1.02; *P*<.001). Further, a moderate effect in improving quality of life was found (*g*=0.50). Overall, participants were positive about the online intervention and ECoaches (online guidance), and they found the intervention to be culturally appropriate.

Conclusions: A culturally adapted, transdiagnostic, internet-based intervention appears to be acceptable and feasible for reducing symptoms of depression, anxiety, or both, and increasing quality of life in university students in Indonesia. Future studies should include a randomized controlled trial to assess the effectiveness of such interventions as they may supplement existing counseling services in universities, reduce the treatment costs, and maximize treatment accessibility in low-resourced settings.

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KEYWORDS

anxiety; cultural adaptation; depression; guided; internet-based intervention; transdiagnostic; university students

Introduction

University students may experience common mental health disorders such as depression and anxiety [1-3]. Epidemiological studies [4] have shown that depression and anxiety are prevalent in college students (31%). This percentage is significantly larger when compared with nonstudents (21.4%) in the same age group [5]. The prevalence of anxiety and depression among university students may be influenced by the complexity of the transition from late adolescence to young adulthood [6]. This common mental health risk has been associated with academic demands [7], social adjustment [8], and financial challenges that students may face [9]. Depression and anxiety can be effectively treated with either pharmacotherapy or psychotherapy [10]. This is in line with the biopsychosocial approach suggested by the World Health Organization (WHO) for managing common mental disorders. The biopsychosocial approach promotes a thorough understanding that mental health issues are an outcome of biological, psychological, and social factors [11]. Effective treatment is imperative as it may prevent a series of negative cascades, such as poor academic adjustment, study dropout, and chronicity [12,13]. Many universities have counseling services that play an important role in improving mental health care by providing effective, accessible, and confidential ways to detect, prevent, and treat common mental disorders in students. The effectiveness of university counseling services for students with high levels of distress has been reported [14]. However, most university students do not receive or seek treatment at counseling services for their psychological problems [6] due to stigma, lack of time, lack of motivation, or they have a preference for a self-management approach [15]. In addition, the low university mental health service availability and high underutilization are very common in non-Western countries [16,17]. In Indonesia, university counseling services are unevenly distributed across universities, as they are mostly dependent on the presence and service of faculties of psychology in the universities.

Therefore, novel therapeutic delivery formats for university students with depression and anxiety may be a feasible way to improve treatment accessibility. Digital technologies offer an excellent opportunity for improving treatment availability and accessibility, especially in low- and middle-income countries, given the widespread acceptance of internet and mobile phone use among university students. Studies on interventions delivered via the internet have shown promising outcomes for students in Western countries due to their anonymity, accessibility, and adaptability to student needs [18,19]. Another known characteristic of internet-based interventions is that they can also be delivered with some form of human guidance (eg, by an ECoach) or can be purely self-guided [20]. Guided internet-based interventions were reported to be more effective compared to self-guided interventions, possibly because participants receive feedback and motivation, and this encourages them to proceed with the sessions and understand the content of the intervention better [21].

For Indonesian university students, internet-based interventions may have a high level of feasibility for a number of reasons. First, internet use is widespread among Indonesian university students (74.23% use the internet), compared to the general Indonesian population, with 94% of them using the internet on their mobile phones [22]. Second, guided internet-based interventions may be more attractive than face-to-face treatment in and outside the university, as the latter involves a high cost that might not be affordable for Indonesian students. Thus, internet-based interventions may be more favorable because they include minimal asynchronous support at a much lower cost than face-to-face interventions. Besides, such interventions can be accessed anywhere [20,23], at any time, and are thus more flexible for students who have very demanding daily schedules at the university.

Third, online interventions can reduce the fear of being exposed to others because students can access the online interventions anonymously [23]. By contrast, students may not utilize internet interventions for a number of reasons including time constraints due to their study duties, lack of nonverbal communication with the ECoach, and the high demand of self-discipline associated with self-help interventions [24]. Fourth, in Indonesia, internet-based interventions for depression and anxiety are currently not available for either university students or for the general population. The first randomized control trial on

internet-based behavioral activation for adult depression in Indonesia [25,26] showed promising results with lower symptoms at posttest assessment in favor of the intervention with minimum support by a lay counselor who did not have professional education and qualifications in mental health care. However, the intervention was tested in the general population, and thus, it remains unclear whether these interventions are also effective in university students with elevated symptoms of depression and anxiety. Additionally, given that depression and anxiety are highly comorbid conditions [27,28], a transdiagnostic approach could be beneficial as it targets both symptoms of depression and anxiety simultaneously. Findings on transdiagnostic interventions for university students in Western countries with common mental disorders have been encouraging. More specifically, such interventions have shown to reduce symptoms of common mental disorders with moderate to large effect sizes in the range of 0.42-0.80 for outcomes such as depression and anxiety [23,29-31].

To the best of our knowledge, it has not yet been examined whether guided, culturally adapted, transdiagnostic, internet-based interventions are feasible in treating symptoms of depression or anxiety or both among university students in non-Western countries, such as Indonesia. Therefore, in this pilot study, we aimed to investigate the feasibility (defined as acceptability, satisfaction, usability, and uptake) of a guided, culturally adapted, transdiagnostic internet-based intervention among university students with symptoms of depression, anxiety, or both in Indonesia. This paper reports the results of stage 3 from a theory-based cultural adaption framework, namely, preliminary adaptation test [32]. The first 2 stages of the framework, namely, information gathering and preliminary adaptation design, are reported in the protocol paper of this study [33].

Methods

Participants

Participants were recruited via our study website [34], which was disseminated on posters, social media platforms, and business cards containing brief information about the study. As we described in our protocol [33], there is no golden standard for calculating the sample size of a pilot study [35]. For our study, we performed a post hoc power calculation to describe statistically the power of our chosen sample (n=50 participants). Further details can be found in our study protocol [33]. Participants were eligible if they (1) were students at Universitas Gadjah Mada Yogyakarta with access to broadband internet, (2) were 18 years of age or older, (3) could speak and read Bahasa Indonesia fluently, and (4) experienced mild to moderate depression, anxiety, or both (9-item Patient Health Questionnaire [PHQ-9] score >4, 7-item Generalized Anxiety Disorder [GAD-7] score >4, or both). Exclusion criteria were (1) moderately severe depression, anxiety, or both (PHQ-9 score >14, GAD-7 score >14, or both) and (2) currently receiving psychological treatment for depression, anxiety, or both.

Procedures

Students who were interested in participating in the pilot study filled in their demographic details on the digital registration form on our study website. Subsequently, the students received an email with a link, which directed them to the pretreatment assessment (T0) consisting of the study's screening questionnaires: the Indonesian version of the PHQ-9 [36,37] and the GAD-7 scale [36,37]. After completing the PHQ-9 and GAD-7 at the screening, participants were asked to provide an informed consent for using their responses to these questionnaires in our analyses (retrospectively). For pragmatic reasons, these eligibility screening scores were also used as a baseline assessment for included participants. Subsequently, an information sheet was provided to them through an emailed link containing an explanation of the study and an online informed consent form that needed to be signed before being able to participate. Those who consented to participate received additional questions about their demographics and quality of life using the Indonesian version of the Euro Quality of Life 5 Dimension-5 Level Scale (EQ5D5L) [38]. The EQ5D5L was used because performance and changes in mental health are captured through one of its dimensions (depression/anxiety) and it is a widely used generic quality of life scale that is also usable for health economic calculations. After completing these additional questionnaires, participants were assigned online to an ECoach (a trained Clinical Psychology Master's student from the Faculty of Psychology at Universitas Gadjah Mada or a licensed Psychologist) and were given secure login details. Subsequently, the I-AiMentalWELLness (*Saya menuju mental sehat*) online intervention was activated for them through Mind District [39], an eHealth platform providing digital therapy.

The posttreatment assessment (T1) was given 7 weeks after the pretreatment assessment (T0) and consisted of the primary outcomes of this feasibility study, namely, participants' reported acceptability and satisfaction, usability, and uptake.

Further details about the procedures of this pilot study can be found in our protocol paper [33]. Ethical approval was obtained from the Medical and Health Research Committee of the Medical Faculty in Universitas Gadjah Mada/DR Sardjito General Hospital (reference number: KE/FK/0098/EC/2018).

Measures

Primary Outcomes

The participants' reported acceptability and satisfaction, as well as the usability and uptake of the I-AiMentalWELLness (*Saya menuju mental sehat*) intervention were the primary outcomes of this feasibility study. Acceptability and satisfaction were measured using the Indonesian version of the 8-item Client Satisfaction Questionnaire (CSQ-8) [40]. Moreover, we used the Indonesian version of the System Usability Scale (SUS) [41] as a usability outcome. While the psychometric properties for the Indonesian version of the CSQ-8 and the SUS are currently not available, both had good psychometric properties in studies conducted in Western countries (CSQ-8 and SUS Cronbach =.93 and .90, respectively) [42-44]. The internal consistency for CSQ-8 and SUS in this study was good with Cronbach α=.87 and .83, respectively. Moreover, the CSQ-8 has been adapted to internet-based interventions (CSQ-I) and has demonstrated overall good psychometric properties in 2 studies [45].

In the study protocol, we reported that intervention uptake would be measured by participants' adherence to the intervention. Adherence was defined as the number of log-ons, time spent on site, and number of sessions attempted. However, due to the technical limitations of the platform used, we could not measure adherence using the numbers of log-ons and time spent online as we originally intended to do [33]. Thus, in this paper, we have described adherence as the number of participants who completed the sessions in the online intervention divided by the number of participants who started the intervention [46]. We also calculated the initial uptake rates by dividing the number of participants who responded to the invitation link from the number of participants who initially expressed interest in participating in the study. We did so to give an overall impression about how many students remained interested in doing the intervention when they had the option to do so.

Secondary Outcomes

Secondary outcome measures included depression, anxiety, and quality of life, which were measured using PHQ-9, GAD-7, and EQ5D5L, respectively. The psychometric properties for the Indonesian version of PHQ-9 and GAD-7 are currently not available. Nonetheless, both PHQ-9 and GAD-7 have demonstrated good psychometric properties in studies conducted in Western countries. The PHQ-9 had high internal consistency (α=.89) and a reliability value of 0.84 [47]. Meanwhile, GAD-7 indicated good internal consistency (α=.92) and test–retest reliability of 0.83 [48]. The internal consistency for PHQ-9 was on the edge of being satisfactory (Cronbach α=.70) and that for GAD-7 was good (Cronbach α=.83). The test–retest reliability of the Indonesian version of EQ5D5L was assessed with sequential measurements using the weighted kappa. Results indicated fair agreements of 0.35, 0.30, 0.37, and 0.39 for the dimensions of mobility, self-care, usual activities, and anxiety/depression, respectively [49]. Meanwhile, the intraclass correlation coefficient for Visual Analog Scale was reported as 0.32, indicating a moderate value [49].

Semistructured Interviews

Both the primary and secondary outcomes of this feasibility study were explored additionally with an individual semistructured interview to obtain a broader perspective and realistic understanding of acceptability, satisfaction, and usability concerning the culturally adapted online intervention for our student population. The semistructured interviews were conducted after participants completed the interventions, by videoconferences between the first author (MR) in The Netherlands and 10 participants in Indonesia. We took account of heterogeneous factors by ensuring equal representation of age, gender, educational, and ethnic background to gain a better understanding of the primary outcome. The demographic characteristics of the participants included in the semistructured interview are reported in Table 1.

Table 1. Demographic characteristic of participants included in the semistructured interview (N=10).

Characteristics	Value
Age (years), mean (SD); range	24.5 (6.73); 19-41
Gender, n (%)	
Female	6 (60)
Male	4 (40)
Ethnicity, n (%)	
Java	8 (80)
Other	2 (20)
Level of education, n (%)	
Bachelor	6 (60)
Doctorate	1 (10)
Master	3 (30)
Study program, n (%)	
Psychology	3 (30)
Medical	2 (20)
Other	5 (50)

The interview questions were modified from the study of Devi et al [50] to fit the purpose of this study (Multimedia Appendix 1). The participants' responses were audio-recorded, and additional note taking was also performed during data collection by the first author and 1 team member (local supervisor) in Indonesia. The interview time range was approximately 30 minutes and was conducted in Bahasa Indonesia.

The secondary outcomes were further explored to understand (1) each participant's evaluation of his/her ECoach, and (2) the cultural appropriateness of the adapted internet-based intervention. These interview questions were modified [51] to fit the purpose of the study. The interview questions can be found in Multimedia Appendix 1.

The I-AiMentalWELLness Intervention

This intervention targets common cognitive and behavioral processes of both anxiety and depression across all sessions; therefore, it is considered a transdiagnostic intervention. Moreover, this intervention was based on cognitive behavioral therapy principles [51,52]. It was originally developed for the general population in Germany and Switzerland [53] and then adapted to meet the needs of domestic and international university students in The Netherlands [54,55]. For the purpose of this study, the current version was culturally adapted from English to Bahasa Indonesia for the student population based on the heuristic theoretical framework [32] which entails (1) information gathering, (2) preliminary adaptation design, (3) preliminary testing, (4) adaptation refinement, and (5) cultural adaptation trial. As reported in the study protocol [33], the first and second phase involved end users (students) as part of the developmental process of the current intervention. Further, the cultural adaptation process concerned all elements of the intervention including language, images, testimonials, and other examples that might not be applicable to the Indonesian culture. Core components of the intervention (eg, behavioral activation, problem solving, cognitive restructuring) remained unchanged. More specifically, after the focus group discussions, we omitted all parts related to unmarried cohabitation, sexual activities, and terms related to alcoholic beverages due to the majority of university students being Muslim. These topics are considered inappropriate in the Islamic religion. We have also changed all parts related to medication such as antidepressants and sleep medication, winter-related sports, and membership in sports and music school. These culturally adapted changes did not influence the main therapeutic components of the internet-based cognitive behavioral therapy intervention (eg, cognitive restructuring) but they solely reflected the local context. An image of one of the sessions in the I-AiMentalWELLness (*Saya menuju mental sehat*) intervention is provided in Multimedia Appendix 2.

The online intervention consisted of 7 sessions and an additional booster session, which took place 4 weeks after the seventh session of the intervention was completed. The purpose of the booster session was to refresh the memory of the participants about what they learned in the previous 7 sessions of the intervention. It aimed at reinforcing the progress that has been made throughout the interventions and to prepare in case the participants encounter a new episode of, for example, depressive mood. The transdiagnostic approach for anxiety or depression is found particularly in sessions 5 and 6. For further detailed description of the intervention's content, the reader is referred to Table 2.

Table 2. The content of the intervention.

Module	Content description
Session 1: Identifying my needs	Goal setting and behavioral activation
Session 2: Taking action	Problem solving
Session 3: Worth knowing	Psychoeducation on depression and anxiety
Session 4: Thoughts pattern	Cognitive restructuring
Session 5: Dealing with challenges	Solve problems concerning depressive symptoms or exposure to anxiety-provoking situations
Session 6: In daily practice	Solve problems concerning depressive symptoms or exposure to anxiety-provoking situations
Session 7: Future plan	Planning for the future
Session 8: Strong going forward	Booster session
OM[a] 1: Sleep	Information related to sleep or how to sleep better
OM 2: Perfectionism	Identify high standards and understanding the vicious cycle of perfectionism
OM 3: Gratitude and appreciating good things	Express gratitude and appreciate goodness in life
OM 4: Self-worth	Understanding low self-worth and how to increase it
OM 5: Relaxation	Progressive muscle relaxation
OM 6: Acceptance	Learning to accept unfulfilled needs
OM 7: What is brooding and when is it excessive?	Information on rumination and learning how to overcome it

[a]OM: optional modules.

Each session consisted of text, exercises, testimonials, and audio recordings with a duration of approximately 60 minutes to complete. A monetary incentive of Indonesian Rupiah (IDR) 125.000 (equivalent to €7/US $8.5) was given to participants who completed sessions 1-4 and another IDR 125.000 (equivalent to €7/US $8.5) was given to participants who completed sessions 5-8. This monetary incentive was meant to compensate the prepaid cards that participants used to access internet via their mobile phones. Participants were only allowed to complete a maximum of 2 sessions per week to have enough time to integrate the skills acquired from the intervention into their daily life. After the completion of each session, participants received individualized asynchronous feedback from their ECoach through the messaging system of the platform.

According to our protocol, each ECoach was advised to spend a maximum of 30 minutes to give feedback per participant at the end of each session. The feedback was brief and of motivational nature to encourage participants to continue with the intervention. Participants were able to move to the next session only after reading the feedback of their ECoach. Furthermore, participants were allowed to contact their ECoach whenever they wanted via the messaging system in the platform. In such case, the ECoaches were advised to respond within 48 hours. When the feedback had been read by the participant, subsequently, the ECoach unlocked the next intervention session. The feedback was of a motivational nature, meaning it consisted of positive reinforcement and encouragement, which reflected on participants' responses to the online exercises and homework assignments.

Statistical and Descriptive Analysis of Qualitative Data

Quantitative analyses were conducted using the IBM SPSS version 25. Because the primary outcomes regarding acceptability, satisfaction, and usability were only assessed after completion of the interventions, these were analyzed only at posttreatment assessment. We calculated means and SD for the CSQ-8 and SUS to display feasibility. Descriptive statistics were used to summarize (1) participants' demographic information (age, gender, employment, ethnicity, marital status, study program, and level of education) and (2) participants' uptake.

For the quantitative analyses of within-group secondary outcomes, data were inspected for outliers and normal distribution. In order to investigate differences between pre- and post-assessment of secondary outcomes, paired-sample *t* tests were used. To investigate baseline differences between completers and dropouts, an independent sample *t* test or a Mann–Whitney *U* test was used. Effect sizes were measured using Hedges *g*, and interpreted as small=0.2, medium=0.5, and high effect=0.8 [56].

In the protocol, we suggested performing thematic analysis according to the guidelines [57] to analyze the transcripts of the interviews with the participants. However, the data were not suitable for this approach because the participants did not elaborate in depth on the questions asked. Thus, we did not analyze the results of the interview but instead we descriptively synthesized the qualitative data for both primary (acceptability, satisfaction, and usability regarding the internet-based intervention) and secondary outcomes (ECoach evaluation and cultural appropriateness of the adapted internet-based intervention).

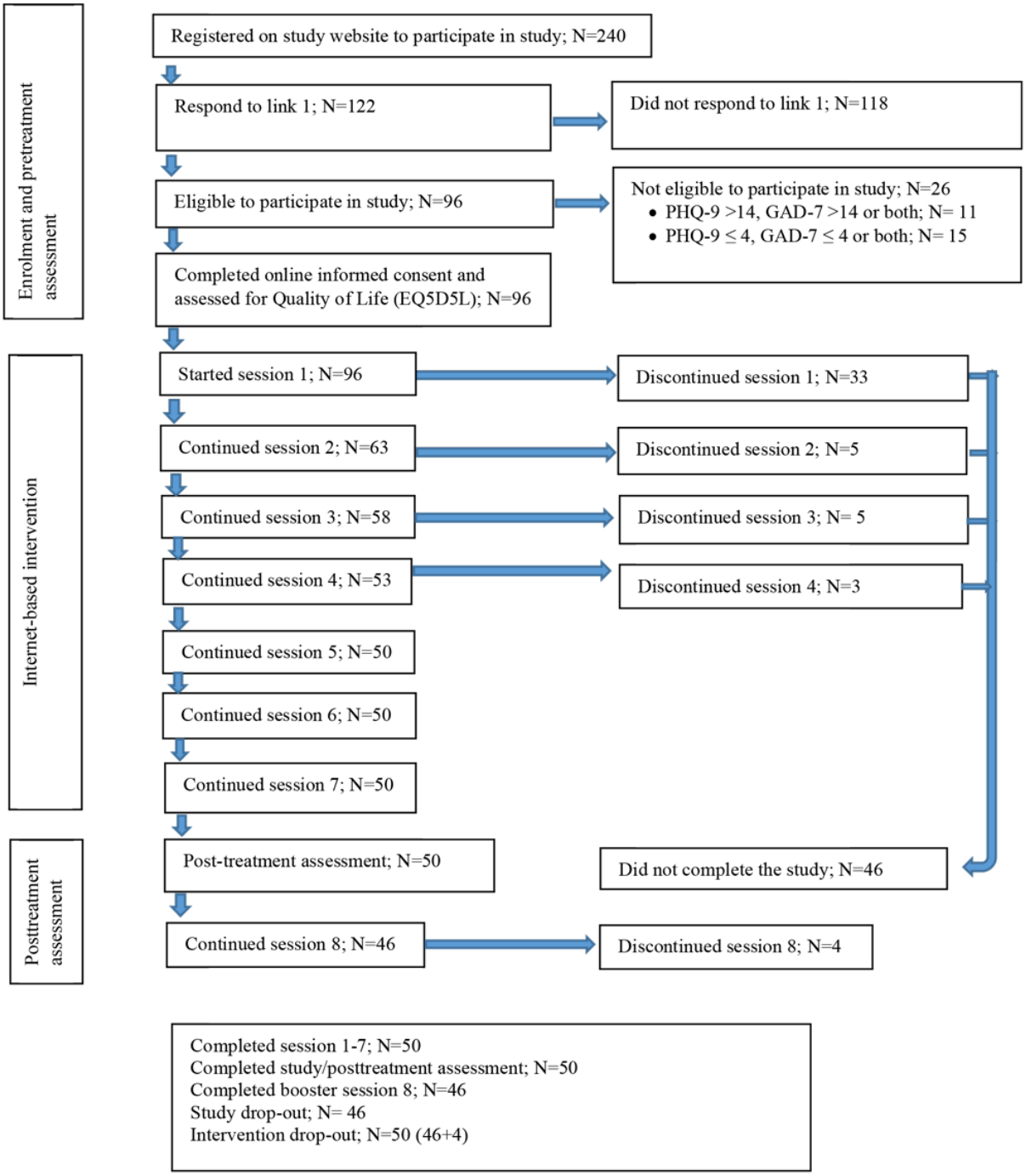
Results

Participants

Of the 240 participants who expressed an interest in participating in the study, 118 did not further respond to the invitation link to participate in the screening (initial uptake=50.8%, 122/240). Of those (n=122) screened for eligibility using the PHQ-9 and GAD-7, 96 were eligible to participate in this study and 26 were excluded after obtaining scores indicating moderately severe to severe or no depression or anxiety. Participants with severe depression or anxiety (n=11) were referred to student counseling services, while those who scored below the mild threshold for depression and anxiety (n=15) were excluded and thanked for their participation and interest in our study. The remaining 96 participants were subsequently invited to provide online informed consent, and they completed the additional quality of life measurement (EQ5D5L) and started the first session (intervention uptake=40.0%, 96/240). Fifty participants completed all 7 sessions and the posttreatment assessment. Almost all participants retained at postassessment also followed the booster session (n=46) 4 weeks after the seventh session.

A total of 46 participants discontinued the intervention during sessions 1-4. On the Minddistrict platform, the ECoaches were able to view their participants' platform, enabling them to notice inactivity such as unread feedback or no further progress on a session. If such inactivity was observed, the ECoach made further attempts to contact the participants through email and text messages (eg, SMS text messages or WhatsApp). If the ECoach received no response from inactive participants, they were considered to have discontinued the intervention. In the end, the participants who discontinued (n=46) were not contacted again for the posttreatment assessment because all previous attempts at communication had failed. Last, 50 participants dropped out from the intervention (sessions 1-7 and booster session 8) and 46 participants dropped out from the study. The flow chart of study participants is presented in Figure 1.

Figure 1. The flowchart of study participants.



The demographic characteristics of the participants and baseline differences between completers and dropouts are presented in Table 3. There were no significant differences in baseline assessment between completers and dropouts (see also Table 3).

Table 3. Participants' characteristics and baseline differences between completers and dropouts.

Characteristics	Completers (N=50)	Dropout (N=46)	*t* (*df*)/ ^{2} (*df*)	*P* value	95% CI
Age (years), mean (SD)	22 (3.74)	22 (5.0)	0.11 (94)[a]	.91	
Gender, n (%)			0.003 (1)[b]	.96	
Female	40 (80)	37 (80)			
Male	10 (20)	9 (20)			
Ethnicity, n (%)			0.85 (1)[b]	.36	
Java	44 (88)	43 (93)			
Other	6 (12)	3 (7)			
Marital status, n (%)			1.62 (2)[b]	.44	
Divorced	1 (2)	0 (0)			
Married	3 (6)	5 (11)			
Single	46 (92)	41 (89)			
Occupational status, n (%)			0.53 (1)[b]	.47	
Employed	7 (14)	9 (20)			
Unemployed	43 (86)	37 (80)			
Level of education, n (%)			0.50 (2)[b]	.78	
Bachelor	40 (80)	35 (76)			
Doctorate	1 (2)	2 (4)			
Master	9 (18)	9 (20)			
Study program, n (%)			2.68 (1)[b]	.10	
Psychology	21 (42)	12 (26)			
Other	29 (58)	34 (74)			
PHQ-9[c], mean (SD)	9.46 (3.59)	9.33 (3.41)	0.00 (94)[a]	.99	–0.06 to 0.06
GAD-7[d], mean (SD)	7.54 (3.8)	7.37 (3.46)	–0.22 (94)[a]	.82	–1.65 to 1.30
EQ5D5L[e], mean (SD)	0.83 (0.10)	0.86 (0.12)	916.5[f]	.08	

[a]Independent sample *t* test.

[b]Chi-square test.

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

[d]GAD-7: 7-item Generalized Anxiety Disorder.

[e]EQ5D5L: Euro Quality of Life 5 Dimension-5 Level Scale.

[f]Mann–Whitney *U* test.

Primary Outcomes

The participants who completed the intervention (N=50) had a mean score of 25.8 (SD 3.40) on CSQ-8, indicating moderate to high level of satisfaction and acceptability regarding the online intervention. They had a mean score of 65.1 (SD 13.37) on SUS, indicating a slightly below average of the desirable usability of 70 or more [58]. Of the 96 participants who started, only 50 completed the intervention sessions, resulting in a 52% adherence rate.

Secondary Outcomes

There was a significant decrease in the PHQ-9 and GAD-7 scores. For depression, the overall mean differences in PHQ-9 between the 2 time points was 3.92 (95% CI 2.75-5.1; Hedges *g* 1.15; *P*<.001). For anxiety, the overall mean differences between the 2 time points in GAD-7 was 3.34 (95% CI 2.06-4.61; Hedges *g* 1.02; *P*<.001), as reported in Table 4. Regarding the EQ5D5L scores, there appeared to be an outlier. However, excluding this outlier did not affect the results, therefore the participant was not excluded from the analysis. At posttreatment assessment, there was a significant increase (*P*=.008) in the EQ5D5L scores, indicating improved quality of life (Table 4).

Table 4. Pretreatment and posttreatment assessment for PHQ-9, GAD-7, and EQ5D5L.

Variable	T0, mean (SD)	T1, mean (SD)	*t* (*df*)/Z	*P* value	Effect size (*g*)	95% CI
PHQ-9[a]	9.46 (3.59)	5.54 (3.21)	6.75 (49)[b]	<.001	1.15	2.75-5.1
GAD-7[c]	7.54 (3.8)	4.2 (2.65)	–4.22[d]	<.001	1.02	2.06-4.61
EQ5D5L[e]	0.83 (0.10)	0.88 (0.10)	–2.66[d]	.008	0.50	

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

[b]Paired sample test.

[c]GAD-7: 7-item Generalized Anxiety Disorder.

[d]Wilcoxon signed-rank test.

[e]EQ5D5L: Euro Quality of Life 5 Dimension-5 Level Scale.

Descriptive Analysis of the Qualitative Data

Overall, participants (n=9) reported to be satisfied when using the online intervention. It was reported to be informative, challenging, and triggered them to further recognize the symptoms of depression and anxiety as a student. The optional module was rated as being the most enjoyable part of the intervention as it provided many personal insights. The recorded relaxation was also in favor as it delivered a calm feeling. Participants further acknowledged the online intervention to be more practical than face-to-face interventions as it overcame geographical and stigma barriers. Only one participant reported being confused for not receiving an immediate response to questions that might arise when working through the sessions.

Good user experience with the intervention was reported, indicating clarity in the instructions and workflow in a session. However, difficulties were also reported as 1 participant felt unfamiliar with reading online content, whereas 2 others had problems with the stability of the internet connection when working on the intervention in a remote area.

Regarding the semistructured interviews, 6 out of 10 participants responded positively on being supported through the internet by an ECoach as they received sufficient support, encouragement, reminders, and had their work progress monitored. Nonetheless, 4 out of 10 participants were less positive about having an ECoach because of the unavailability of synchronous feedback and having difficulty with writing what is on their mind. Moreover, they reported that the likelihood of being misinterpreted was high because of absent nonverbal communication signals. Finally, feedback was written in a generic manner and did not always cover specific tasks, as these participants would have expected the feedback to be more elaborative.

As much as 7 out of 10 participants indicated that the overall content of the intervention was culturally appropriate and relevant to university students in Indonesia. Nonetheless, 3 out of 10 participants indicated that some case examples of the intervention were less relevant to the Indonesian context. For instance, it is uncommon for Indonesian university students to have a part-time job during bachelor studies or to be enrolled in a sport and music academy.

> *Some talk about working. Not all students work, especially bachelor students.*

> *There were some story examples that seem less relevant to the Indonesian culture, such as joining a music or a sport club.*

Discussion

Principal Findings

This study has demonstrated promising outcomes for the feasibility of an internet-based intervention for university students in Indonesia, as indicated by participants' reported acceptability, satisfaction, usability, and uptake regarding the intervention. In addition, a decrease in symptoms of depression and anxiety, and improved quality of life were reported.

Participants reported to have a moderate to a high level of satisfaction and acceptability regarding the online intervention. Results from the interviews also indicated that participants were satisfied with the online intervention as a new approach that acknowledged personal development, and overcame stigma and geographical barriers. The usability/functionality of the internet-based intervention as it applies to the end users was also assessed. One component of usability explained [41] is learnability, which assesses first-time experiences with a new system for end users. A transdiagnostic approach is characterized by a focus on common characteristics that may underpin a number of different psychological disorders such as in case of depression and anxiety disorders. Advantages of such a treatment approach include treating simultaneously these underlying common factors in case of comorbid symptoms [59]. In light of our positive findings regarding the reduction in anxiety and depressive symptoms, the transdiagnostic approach appears promising in the given context. Further research is needed to investigate the effectiveness of such approach in a randomized control trial. However, a transdiagnostic approach delivered online to treat symptoms of depression and anxiety under a single protocol is relatively new. The findings for the mean usability rate for the internet intervention are slightly below average (65.1) for the desired usability ≥70 [58] which is not surprising. Thus, further development and continued improvement are needed to provide individually tailored transdiagnostic intervention, such as by minimizing the use of formal language in the intervention.

With respect to the secondary outcomes of this study, we found a significant decrease (P<.001) in symptoms of depression and anxiety at the posttreatment assessment, and a significant

increase (P=.008) in quality of life. Online interventions may offer a promising treatment solution, given the high prevalence of common mental disorders among university students and the under-resourced counseling services [1,2,10]. Many studies have indicated the effectiveness of an online intervention to treat depression and anxiety among university students [10,19]. Understanding quality of life among university students is also important, as it contributes to their physical, psychological, social, and environmental well-being [60]. As the quality of life encompasses various dimensions closely related to the life of a university student, it is important that symptoms of depression and anxiety are treated properly.

It must be noted, of course, that our study did not have a control group. Therefore, the improvements might be attributed to other factors than the intervention, such as spontaneous recovery or regression toward mean.

All participants of this feasibility study were guided by an ECoach who monitored their progress throughout the intervention. The likelihood of completion rate may be associated with therapeutic guidance [42,58,60]. However, we have not tested this hypothesis, and this remains to be confirmed by future studies in low-resource settings.

The secondary outcome of this intervention was further supported by the interview results, which indicated participants' overall positive response to being treated through the internet by an ECoach, the extent of support received, the average time with regard to receiving feedback, and how comprehensively the feedback was delivered.

A randomized controlled trial will follow this promising feasibility study to further investigate the effectiveness of the existing internet-based intervention to treat depression and anxiety for students within university setting in Indonesia. This is a necessary step before this intervention is made publicly available in Indonesia.

Strengths and Limitations

To the best of our knowledge, this study was one of the first to investigate the feasibility of a guided culturally adapted internet-based intervention to treat symptoms of depression, anxiety, or both among university students in Indonesia. Originally, in the study protocol, we defined appropriate uptake as an adherence rate of 35% due to the novelty of the intervention in Indonesia. However, participants' adherence rates reached 52% (50/96), which is higher than expected and underlines the feasibility of online interventions for Indonesian university students. It should be noted that we provided monetary incentives to participants who completed the sessions. Thus, it is possible that these incentives have enhanced participation rates. Nevertheless, the amount of incentives was very small and thus it is unlikely that participants completed the study only because of this reason. This feasibility study also has several limitations that must be taken into account. First, the majority of the participants were female, bachelor students, Javanese, and were studying psychology. Future research could benefit from investigating more diverse groups from other faculties and universities to improve the generalizability of these preliminary findings. Second, 46 participants could not be invited to undergo the posttreatment assessment, because they could not be contacted by the ECoach by any means. The research team were unable to locate these participants and thus it limits the understanding of reasons for dropout. Third, data regarding participants' uptake (log-on time, time spent on site, and number of sessions attempted) of the online intervention could not be provided in this study as participants had previously been instructed to record the time that they spent online. They did so to avoid confusion because Minddistrict (a Dutch company) displayed the Central European time zone. However, this self-reported approach was considered subjective. Other attempts were made by contacting the platform provider to obtain the participants' recorded time of log-ons but such information was not monitored by the platform. Fourth, the findings regarding the secondary outcome within 2 different time points need to be interpreted with caution as this study was a small pre–post assessment and not a randomized controlled trial. Fifth, another limitation of our study is that our qualitative data were limited in depth, and thus not well suited to thematic analysis. This might have been the result of the way we phrased these questions. In particular, some questions may have been formulated in a too closed manner, thereby preventing the respondents from giving more elaborate answers and convey possible nuances that qualitative research requires. However, the aim of this part of our study was to enrich our quantitative findings. Thus, future qualitative research in this field should aim at more open-ended formulated questions if the aim is to gain in-depth insights into the topic.

Conclusion

Internet-based interventions appear to be acceptable and feasible for reducing symptoms of anxiety and depression and improving quality of life among university students in Indonesia. Future studies should further investigate the (cost-) effectiveness of such interventions as they may be used to supplement existing counseling services in universities, reduce the treatment costs, and maximize treatment accessibility in low-resourced settings.

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Authors' Contributions

HR contributed to the design of the study. MR drafted the manuscript under the supervision of EK and MS. All authors contributed to revising the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

DE has served as a consultant to/on the scientific advisory boards of Sanofi, Novartis, Minddistrict, Lantern, Schoen Kliniken, Ideamed and German health insurance companies (BARMER, Techniker Krankenkasse) and a number of federal chambers for psychotherapy. He is also stakeholder of the Institute for health training online (formerly GET.ON/ now HelloBetter), which aims to implement scientific findings related to digital health interventions into routine care. The remaining authors declare no conflict of interest.

Multimedia Appendix 1
Semi-structured interview questions.
[PDF File (Adobe PDF File), 108 KB - mental_v8i3e20036_app1.pdf]

Multimedia Appendix 2
Screenshot example of intervention session 3 in Bahasa Indonesia.
[PNG File , 323 KB - mental_v8i3e20036_app2.png]

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Abbreviations

CSQ 8: Client Satisfaction Questionnaire-8
EQ5D5L: Euro Quality of Life 5 Dimension-5 Level Scale
GAD 7: Generalized Anxiety Disorder-7
IDR: Indonesian Rupiah
PHQ 9: Patient Health Questionnaire-9
SUS: System Usability Scale

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Original Paper

Characterizing Emotional State Transitions During Prolonged Use of a Mindfulness and Meditation App: Observational Study

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Abstract

Background: The increasing demand for mental health care, a lack of mental health care providers, and unequal access to mental health care services have created a need for innovative approaches to mental health care. Digital device apps, including digital therapeutics, that provide recommendations and feedback for dealing with stress, depression, and other mental health issues can be used to adjust mood and ultimately show promise to help meet this demand. In addition, the recommendations delivered through such apps can also be tailored to an individual's needs (ie, personalized) and thereby potentially provide greater benefits than traditional "one-size-fits-all" recommendations.

Objective: This study aims to characterize individual transitions from one emotional state to another during the prolonged use of a digital app designed to provide a user with guided meditations based on their initial, potentially negative, emotional state. Understanding the factors that mediate such transitions can lead to improved recommendations for specific mindfulness and meditation interventions or activities (MMAs) provided in mental health apps.

Methods: We analyzed data collected during the use of the Stop, Breathe & Think (SBT) mindfulness app. The SBT app prompts users to input their emotional state before and immediately after engaging with MMAs recommended by the app. Data were collected from more than 650,000 SBT users engaging in nearly 5 million MMAs. We limited the scope of our analysis to users with 10 or more MMA sessions that included at least 6 basal emotional state evaluations. Using clustering techniques, we grouped emotions recorded by individual users and then applied longitudinal mixed effect models to assess the associations between individual recommended MMAs and transitions from one group of emotions to another.

Results: We found that basal emotional states have a strong influence on transitions from one emotional state to another after MMA engagement. We also found that different MMAs impact these transitions, and many were effective in eliciting a healthy transition but only under certain conditions. In addition, we observed gender and age effects on these transitions.

Conclusions: We found that the initial emotional state of an SBT app user determines the type of SBT MMAs that will have a favorable effect on their transition from one emotional state to another. Our results have implications for the design and use of guided mental health recommendations for digital device apps.

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KEYWORDS

mental health; mobile apps; smartphone; mobile phone; emotional distress; mindfulness

Introduction

Background

The motivation for managing mental health disorders, precursors of mental health disorders, and emotional problems generally, on a footing equal to how physical health disorders are managed, is growing [1-3]. Mental health disorders, stress, anxiety, depression, and other mood-related conditions are known to affect productivity, comorbid conditions, and physical well-being [4-6]. In fact, when asked, approximately 90% of Americans stated that they value mental health as much as they value physical health [7]. This is not without reason, as the prevalence of anxiety disorders alone in the population at large is estimated to be between 3.8% and 25.0% [8]. Given the high collective prevalence of mental health concerns, behavioral conditions, and mood-related maladies, their impact on quality of life, and the costs associated with the care of individuals affected by such conditions, there is a great need to develop more efficient and reliable ways of not only treating these problems but also preventing them. Unfortunately, developing an appropriate infrastructure to combat mental health problems within the current health system will be daunting and expensive, as many people find available mental health care overly complicated and often inaccessible [9-12]. Fortunately, newer and more accessible approaches to the care of individuals with mental health issues are being developed, including the use of telehealth, an emphasis on risk mitigation as opposed to treatments, and the use of digital therapeutics [13]. Of these, digital therapeutics are receiving significant attention. Digital therapeutics are programs (eg, smartphone apps) that provide guidance on stress or symptom management and alleviation, or to qualitatively change an individual's mood or emotional state in some way (eg, via imagery, mood rating, or tracking), and can be used remotely and at an individual's discretion.

The great potential of digital therapeutics is recognized by public health and government regulatory agencies as well. The Food and Drug Administration has allowed mobile mental health apps to receive approvals and accreditation as bona fide medical health interventions on a similar footing with drugs [14-17]. Care that includes the use of mental health apps can be scaled to help meet the demand for mental health care because the use of these apps may not require as much interaction with trained professionals, and standard clinical exams associated with pharmacotherapy monitoring might also require travel and interaction with a health care provider (eg, for dosing or evaluating potential physical side effects). More importantly, mental health apps have great potential to help provide care in underserved populations where financial, professional scarcity, and societal burdens make other forms of care problematic [18]. Mental health apps have obvious limitations as they are not appropriate for use in all settings. One example of where their use is appropriate is in behavioral and mental health settings involving stress management, where techniques such as encouraging relaxation via, for example, meditations and mindfulness, can be used. In fact, mindfulness and meditation activities (MMAs) have been linked with healthy thought patterns and improved mood and can reduce stress and anxiety that are often precursors or symptoms of certain mental health concerns [19,20].

Unfortunately, although the promise of mental health apps for reducing the risk of and treating some mental health issues and concerns are great, there is a need to vet different strategies for creating mental health apps and understanding the settings in which they might be most effective. This is partly due to difficulties in defining mental health concerns and tracking individuals' symptoms over time in a way that can shed light on when to intervene and in what manner. This is true for very serious mental health disorders, such as treatment-resistant depression, as it is for managing daily stress and anxiety that, if prolonged, could lead to more dramatic mental health issues. For example, determining which personal settings and emotional states are appropriate for different interventions, such as MMAs, are yet to be explored in full [21]. In fact, it is quite likely that there exists a great deal of intra- and interindividual variability in mood and feelings of stress and anxiety that might be necessary to understand and characterize so that guidelines and interventions, such as MMAs, can be tailored or personalized to individual users.

Objectives

We pursued a series of analyses to explore how the moods of the users of the SBT MMA app changed or transitioned as they used the app and its MMA recommendations. As discussed in our previously published paper on data collected via the SBT MMA app [22], the SBT app recommends sets of MMAs to users based on their mood at the time they use the app. In our previous work, we observed a statistically significant trend for improvement in basal mood (eg, a shift toward moods consistent with happiness or less anger) with prolonged use of the app. It was found that most users' moods tended to improve after a single session with an MMA recommended by the app.

In the studies described here, we assessed the specific associations that the recommended MMAs have with the transitions between moods of users at baseline and after they participate in a recommended MMA over the period in which they use the app. In this light, our previous studies motivated the present work, as we did not study the specific transitions from one emotional or mood state to another in the original work; that is, our previous finding that the SBT app did lead to acute and chronic changes in mood, mostly for the better, led to our interest in determining which specific mood states are associated with the use of the app and the specific MMAs. A better understanding of which MMAs are likely to drive changes in emotional states and in which directions could lead to insights into which MMAs might be appropriate for individuals with specific emotional state profiles. Such an understanding could lead to better predictions and MMA recommendations for individual users.

Methods

The App

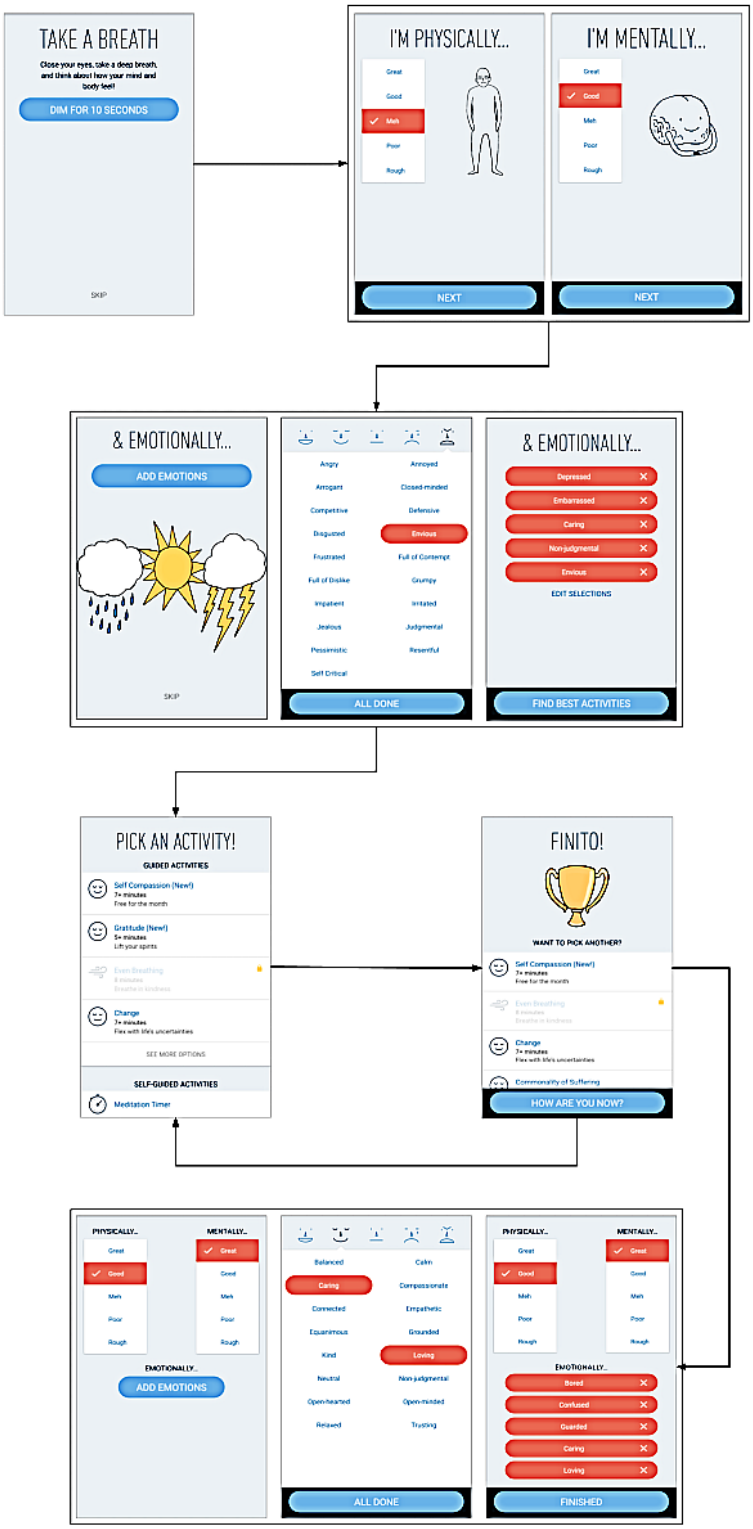
The app developed by SBT is designed to guide users through MMAs, which are created to reduce stress, anxiety, and depression and improve internal focus, mood, mental state, and

sleep. The SBT app is designed for general use and can deliver MMAs through many different platforms (ie, iOS, Android, Alexa). When the app is used, a user is prompted to perform an optional 10-second reflection, which is followed by optional prompts to state how they are feeling mentally, physically, and emotionally. The questions used to assess mental and physical status are based on a 5-point scale with the following categories: great, good, meh, poor, and rough. Following this, users are asked to pursue an emotional check-in involving a selection of 1 to 5 terms from a pool of 115 emotions that describe their current emotional state. After this initial check-in, users are shown some suggested MMAs with labels and context designed, for example, for *Gratitude*, *Silence*, *Breathing*, but they are free to select an MMA of their preference within a defined set. After the completion of an MMA, users can continue to select additional MMAs or end the session. At the end of each session, users are again prompted to do another optional check-in to assess their mental, physical, and emotional state. A flow diagram of the user experience with the SBT app is shown in Figure 1.

We emphasize that all data collected through the SBT app are volunteered by users as stated in the SBT user licensing agreement and privacy policy, and thus, the characterizations of mood and physical well-being are subjective. All reported data were anonymized and aggregated into a data set reflecting user experiences: usernames were replaced with unlinked hash keys, personal information was stripped, and only reporting of the first 3 numbers of zip codes was maintained. This information was ultimately put into a Health Insurance Portability and Accountability Act–compliant format so that users could not be reidentified.

Our data preparation methods were nearly identical to those described in our previous publication on SBT data. However, in the current analysis, the data from several users were removed from all analyses to adhere to privacy policies and best practices in consultation with the legal and compliance team at SBT. Owing to our deidentification process, we could not distinguish which users were removed from previous analyses or which users are now included because they have since met active user filtering criteria. However, based on information about when users started to use the SBT app, it can be inferred that there were 856 new active users who passed our filtering criteria since our last publication, and at least 3219 users were removed for the analyses described here that were considered in our previous analyses because of the adoption of other filtering criteria at SBT. The SBT app has variation in functionality and delivery across platforms, and to avoid confounding effects, we focused our analysis on iOS users only. Users who joined before the last major update of the app (May 1, 2016) were also excluded. Further filtering was pursued to only include active users with ≥10 sessions completed, who had at least six sessions in which they provided both pre- and postemotional check-in information. To avoid cultural differences and language barriers, only users from English-speaking countries (United States, United Kingdom, Canada, and Australia) were included. Finally, for both compliance reasons as well as concerns about the accuracy of the information, we excluded users aged below 13 years or above 100 years from the analysis.

Figure 1. Stop, Breathe & Think (SBT) app user flow diagram. A diagram depicting the users' experience when engaging the SBT app. A natural flow allows the user to reflect, check-in, perform an activity, and then check-in again. Reflections and check-ins are optional but were required data points for our analysis.



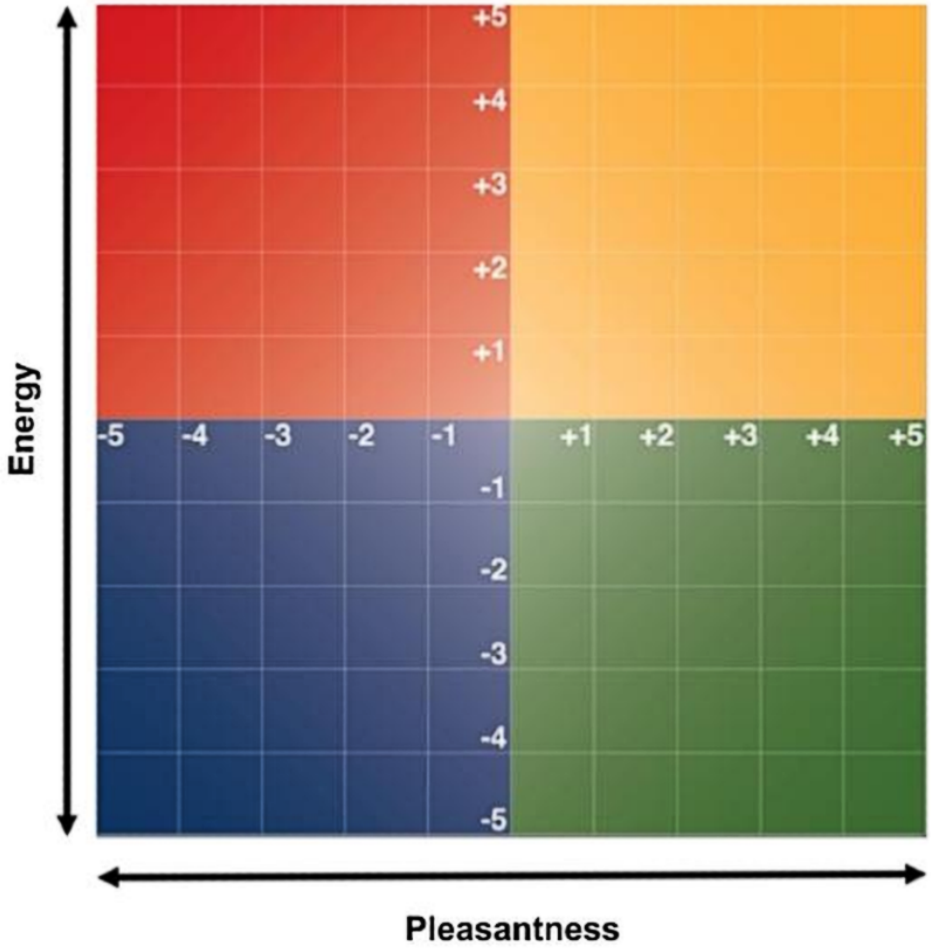
Clustering Emotions

As described in our previous paper, emotions endorsed by users of the app were grouped into clusters based on the user's selection of multiple emotional terms to characterize their complete emotional state at that particular time. Emotions were compared using the Bray-Curtis dissimilarity according to how often they were coselected [23]. We used Principal Coordinate Analysis (PCoA) to translate emotion endorsement dissimilarity into two-dimensional space using the first 2 PCoAs, and then, partitioning around medoids (PAM) was used along with silhouette scores to determine the optimal number of clusters [24]. Each of the 115 emotions was then assigned to a cluster, and the corresponding cluster medoid was recorded. Individual emotional states, both pre- and post-MMA engagement, were

defined by the nearest cluster (in terms of Euclidean distance). These clusters define distinct emotional state categories, and in the current analyses, we focused on the change (or transition) in emotional state categories between pre-MMA and post-MMA.

To better understand and synthesize the results of our emotion clustering, we projected the clusters onto the Yale Mood Meter (YMM; Figure 2) [25]. The YMM groups emotions into 4 quadrants, which are defined by the "energy" of the emotion (y-axis) and the "pleasantness" of the emotion (x-axis). We color-coded these quadrants using the accepted criteria: red=high energy, low pleasantness (denoted as "HELP"); yellow=high energy, high pleasantness (HEHP); blue=low energy, low pleasantness (LELP); and green=low energy, high pleasantness (LEHP). We assigned each of the clusters to one of the 4 quadrants based on the majority of emotions within each cluster that mapped to a YMM quadrant. This mapping allows us to consider transitions from quadrant to quadrant instead of simply a cluster-to-cluster membership, which has several advantages: (1) it reduces our search space from 64 transitions to 16; (2) it increases the sample size for each transition, thus providing better power to detect changes; and (3) it provides an interpretable scale for transitions (ie, an HELP state [red] to HEHP state [yellow]). Although users may have different objectives in engaging the app and an MMA, the assumption is that red (HELP) and blue (LELP) states are undesirable, whereas yellow (HEHP) and green (LEHP) are desirable.

Figure 2. Yale Mood Meter (see the main text for a description and references). A 2 dimensional framework which classifies emotions by their pleasantness (x-axis) and energy (y-axis). Yellow and green quadrants are favorable states whereas red and blue quadrants are unfavorable.



A framework for categorizing emotions developed by Brackett [25] classifies emotions into a two-dimensional space with pleasantness as the x-axis and energy as the y-axis. The negative emotion quadrants red and blue represent low pleasantness, red is higher energy such as anger, and blue is low energy such as sadness. The more favorable quadrants, green and yellow, represent high pleasantness, with energetic emotions such as "excited" fitting in the yellow quadrant, and lower energy emotions such as "calm" fitting in the green quadrant.

Description of the SBT MMAs

The SBT app provides over 100 different MMAs for users to choose from, with varying levels of popularity and usage. Given the number of MMAs and the risk of overfitting in our analysis models, we first considered each MMA individually and then ultimately focused on the top 20 chosen MMAs (representing 86.8% of all completed MMAs) and combined the rest (a total of 21 MMA categories assessed in our analyses) into a single category called "other." The frequency distribution of these MMAs and their descriptions can be found in Multimedia Appendix 1.

Statistical Analysis

To determine the strength of the association between each of the 20 most chosen MMAs and the "other" MMA category and the transition from one emotional state to another, we used generalized linear models (GLMs) as implemented in the R package lme4 [26]. GLMs have many features that make them appropriate for our analyses. For example, GLMs can accommodate and quantify serial correlations among variables in longitudinal analyses, and both fixed and random effects can be considered as important covariates. Random effects are important to consider because they can account for variation in moods chosen by individual SBT users attributable to unmeasured covariates such as individual-specific effects of unknown origin (eg, personal habits, unmeasured stressors, or exposures, etc). GLMs have also been widely used in the statistical analysis of many psychiatric and psychological phenomena [27-29]. For each YMM quadrant, we determined which users' moods were associated with that quadrant when they initially used the app. We then fit a logit-link GLM to the data to test the associations between the basal mood quadrant of a user and the quadrants that the user transitioned to after engaging in the MMA. To enable this, we created dummy variables to indicate whether a user transitioned to a specific YMM quadrant and used this as a dependent variable in the GLM with basal YMM quadrant, count data for the number of MMAs a user completed in a session, age, sex, session index (ie, 1 as the first use of the application, 2 as the second use, etc), as independent variables. We also included other covariates, such as subscription status, user account completion, and time between sessions as additional independent variables. We used the country code in the initial analyses but excluded it in subsequent analyses due to its statistical insignificance. Due to the differences in the number of user engagements (the range was from 10 uses to 1044 uses), we used a $\log_{10}$ transform on session index, which is consistent with our strategy in our previous analysis of the SBT data. All non-MMA independent variables were standardized so that the resulting model beta values (ie, standardized regression coefficients) could be directly compared.

Building a Prototype Learning System for Predicting Emotion Transitions

To evaluate the effectiveness of our analytical models in predicting transitions, we used GLM analysis but restricted the data to a "training set" consisting of 3 sequential observations per user starting with their first completed recorded session. After obtaining models for each of the possible transitions based on data from these 3 initial sessions, we used the models to predict the probability of each transition in subsequent sessions and then selected the transition with the highest probability and matched it with the observed transitions. This allowed us to compare the actual emotional state transition with a predicted transition state and to see if the app could be improved by anticipating MMAs likely to result in positive mood transition in real time. We repeated this analysis several times using both different numbers of initial engagements with the app and the time intervals in our training sets to further evaluate its performance.

Results

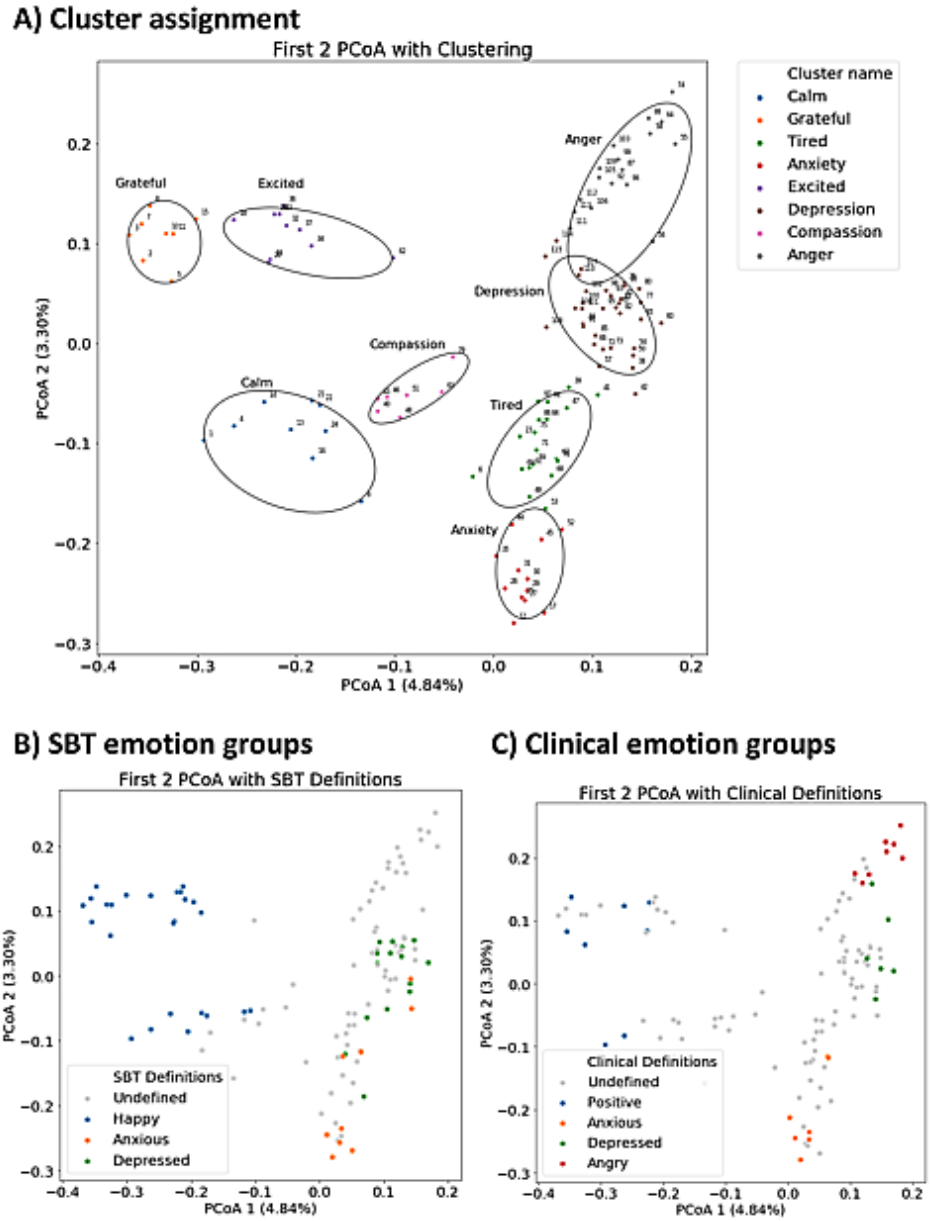
Data Set Summary

Before any filtering, we had observations for nearly 5 million engagements with SBT app MMAs across 677,000 different users. There were 84,000 active users who completed 10 or more sessions, who collectively completed 3.16 million engagements with MMAs. After filtering for the operating system, which users were active, language used in the app, and quality, 11,030 unique users were included in subsequent analyses. These users collectively completed 289,360 MMAs across 253,363 sessions (average of 1.14, SD 0.51 MMAs per session). As shown in Multimedia Appendix 2**,** most users were female (8274/11,030, 75.01%) and were between the ages of 13 and 40. Compared with our previous study, we had fewer users and sessions, due to their removal for legal and compliance reasons, but the users whose data we possessed completed more sessions and emotional check-ins on average.

Clustering Analysis of Emotions

The results of our cluster analysis of emotions were similar to those described in our previously published paper. The optimal number of clusters as defined by the silhouette scores on the PCoA and PAM analyses was 8. Of the 115 emotions, all but 3 emotions (Envious, Fiery, and Self Critical) were assigned to the same clusters as in our previously published analyses. The 8 clusters grouped emotions into categories with very common themes and were validated with prior SBT internal product and clinical groupings (Figure 3). On the basis of these clusters, from each user's emotional state pre- and post-MMA, we could determine which category their emotions were most closely associated with using distances of the emotions to cluster medoids.

Figure 3. Emotional clustering on co-selected terms. Emotional clusters created from coselected terms within the same check-in (see text), are defined using PAM and silhouette scores. Each point represents an emotion that can be endorsed, and can be looked up in corresponding table. (A) The optimal 8 clusters are shown across the first 2 principal coordinate analyses (PCoAs). Clusters are given labels based on a single emotion that is thematic to most emotions within the cluster. (B) In-house, defined emotional labels show consistent grouping within the first 2 PCoAs. (C) Clinically defined emotional labels show consistent grouping within the first 2 PCoAs.



Alignment of clusters to YMM quadrants provided further support for clustering, as most clusters were clearly aligned to a quadrant. As shown in Figure 4, “Calm” and “Compassion” clusters had perfect alignment with the green quadrant, and “Grateful” and “Excited” clusters had perfect alignment with the yellow (HEHP) quadrant. The “Tired” cluster had emotions that crossed between both the blue (LELP; ie, tired, lazy, fatigue) and red (HELP; ie, afraid, panicked, suspicious) quadrants. The “Anger” cluster also had some crossover between red (HELP; ie, angry, impatient, resentful) and blue (LELP; ie, defensive, disgusted, pessimistic) quadrants. Conveniently, the clusters were mapped to quadrants in pairs.

Figure 4. Cluster alignment and pre– to post–mindfulness and meditation activity (MMA) transitions. Clusters were assigned to the Yale Mood Meter (YMM) quadrants based on the majority of emotions within that cluster that corresponded to a YMM quadrant (eg, the "tired" cluster is blue in YMM). (A) Counts of all 115 endorsable emotions in the Stop, Breathe & Think app by each cluster and the YMM quadrant they are associated with. (B) Session counts for transitions from the pre-MMA emotional cluster to the post-MMA emotional state. Calm and grateful clusters were the most frequent post-MMA states. (C) Session counts for transitions from the pre-MMA emotional YMM quadrant to the post-MMA emotional quadrant.

A) Cluster to YMM assignment

Cluster	Blue	Green	Yellow	Red	Total
1 Calm	0	9	0	0	9
2 Grateful	0	0	8	0	8
3 Tired	12	0	0	7	19
4 Anxiety	1	0	0	11	12
5 Excited	0	0	10	0	10
6 Depression	32	0	0	1	33
7 Compassion	0	7	0	0	7
8 Anger	6	0	0	11	17
Total	51	16	18	30	**115**

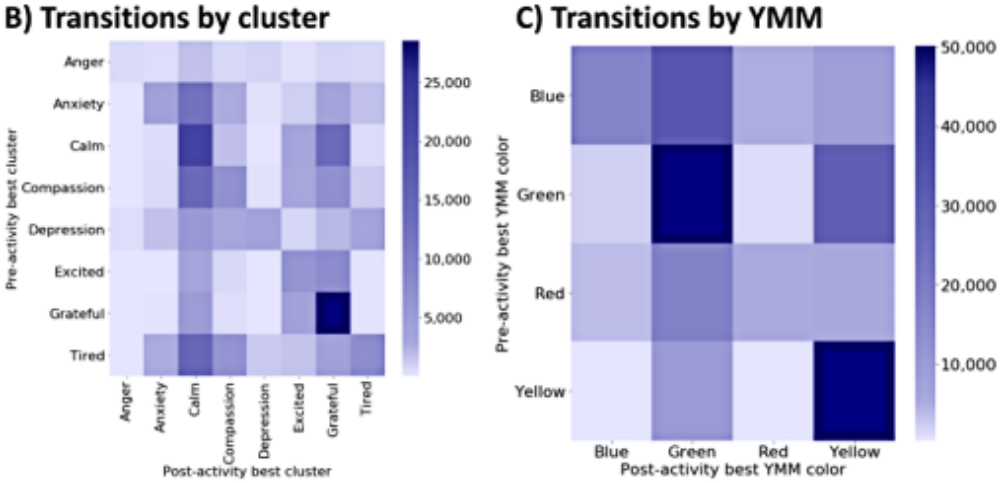


Figure 4 shows the relative frequencies of pre-MMA emotional states and post-MMA emotional states of the users. The most frequent post-MMA cluster was calm, followed by grateful. Users predominately started and ended in positive states (ie, green or yellow clusters), with green (LEHP) being the predominant emotional state that users transitioned to. The most common negative states were tired and anxiety.

Model Features

We did not find any obvious evidence suggesting that a specific MMA is the most effective in transitioning users' emotions to different categories. Each of the 16 GLMs we fit to the data focused on the influence or association of the different MMAs with different transitions and they exhibit varying degrees of association strength between pre- and post-MMA emotions (Figures 5-8). The MMAs *Great Compassion*, *Lion Mind*, and *Gratitude* provided by the app were all associated with transitions from the red (HELP) emotional state quadrant to a pleasant emotional state quadrant (green or yellow), whereas *Falling Asleep*, *Kindness*, and *Commonality of Suffering* were associated with staying in a negative emotional state. For users whose initial emotion was in the blue (LELP) quadrant, the MMAs *Kindness*, *Great Compassion*, and *Counting Breaths* were associated with emotions transitioning out of the green (LEHP) or yellow (HEHP) quadrants. The session index (a proxy for the number of engagements with the app over time) was also associated with users remaining in, or transitioning to, low pleasantness quadrants. Both age and gender were associated with transitions of different types as well. For example, males were more likely than females to transition from negative states to positive states, and older users were more likely to transition to yellow (HEHP) states. There was not enough data to assess the degree to which MMAs could influence users who started in a yellow (HEHP) quadrant and ended in a red (HELP) quadrant.

Figure 5. Transitions starting in Red Yale Mood Meter (YMM) quadrant model odds ratios. Sixteen GLM model fixed effect estimated odd ratios and *P* values (<.001***, <.01**, and <.05*) for mindfulness and meditation activities, gender, session index, and y-intercept split by starting YMM quadrant. Blue bars indicate increased propensity to make a transition, whereas red bars indicate decreased probability of making the transition. Transitions starting in Red YMM quadrant, where users who completed the MMA Lion Mind were 52% less likely to stay in Red, 30% more likely to enter Green, and 28% more likely to enter Yellow than those who did not complete Lion Mind.

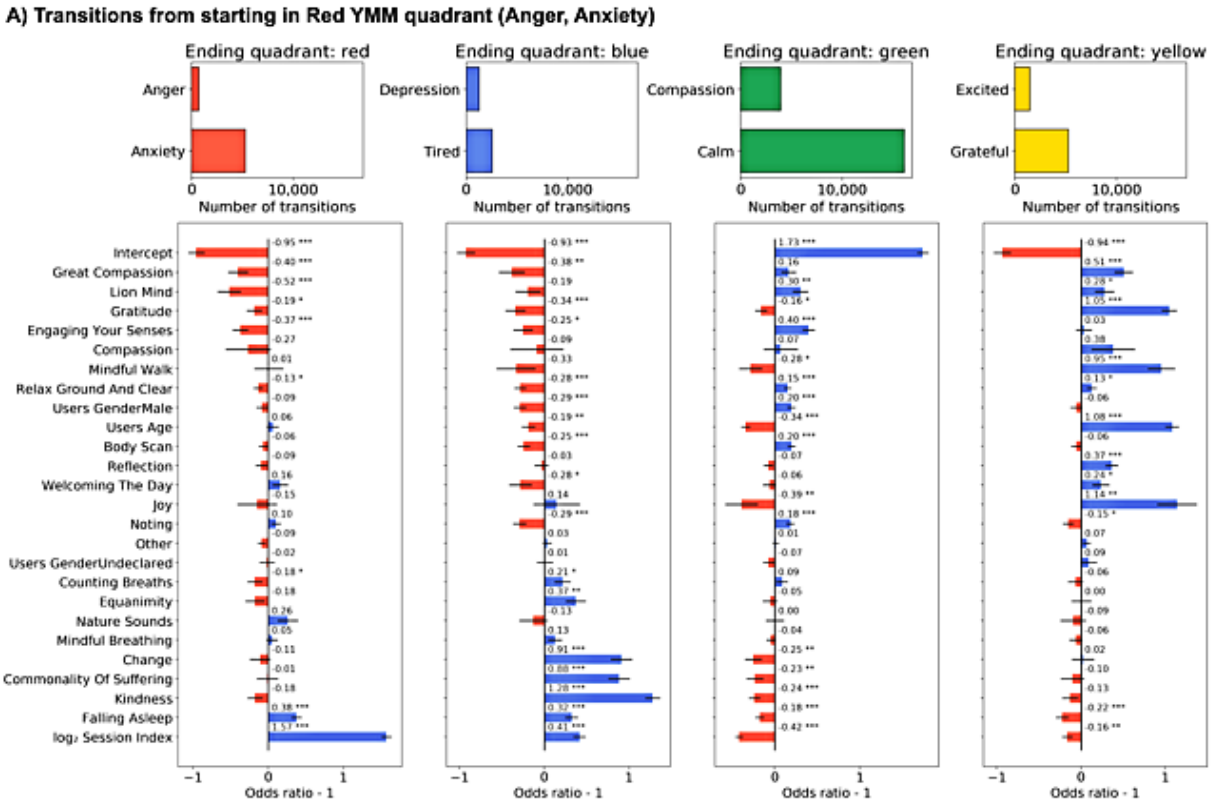


Figure 6. Transitions starting in Blue Yale Mood Meter (YMM) quadrant model odds ratios. Sixteen GLM model fixed effect estimated odd ratios and *P* values (<.001***, <.01**, and <.05*) for mindfulness and meditation activities, gender, session index, and y-intercept split by starting YMM quadrant. Blue bars indicate increased propensity to make a transition, whereas red bars indicate decreased probability of making the transition.

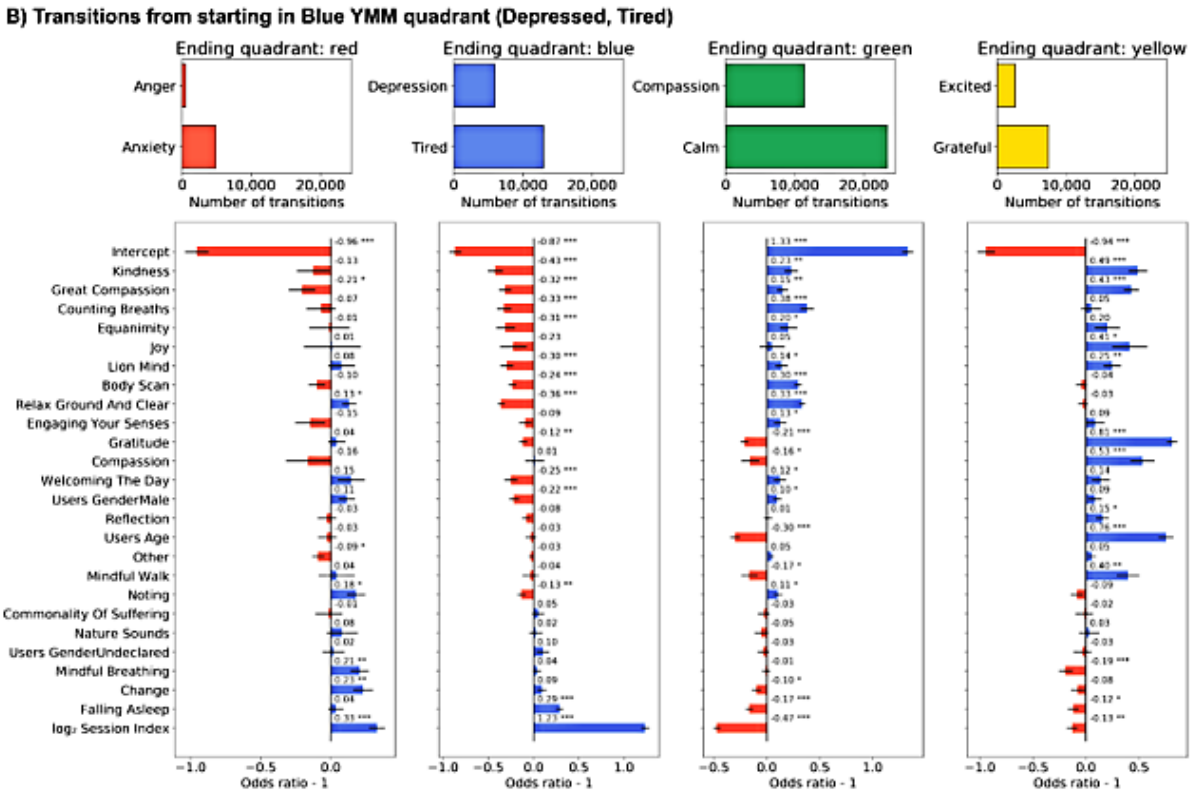


Figure 7. Transitions starting in Green Yale Mood Meter (YMM) quadrant model odds ratios. Sixteen GLM model fixed effect estimated odd ratios and *P* values (<.001***, <.01**, and <.05*) for mindfulness and meditation activities, gender, session index, and y-intercept split by starting YMM quadrant. Blue bars indicate increased propensity to make a transition, whereas red bars indicate decreased probability of making the transition.

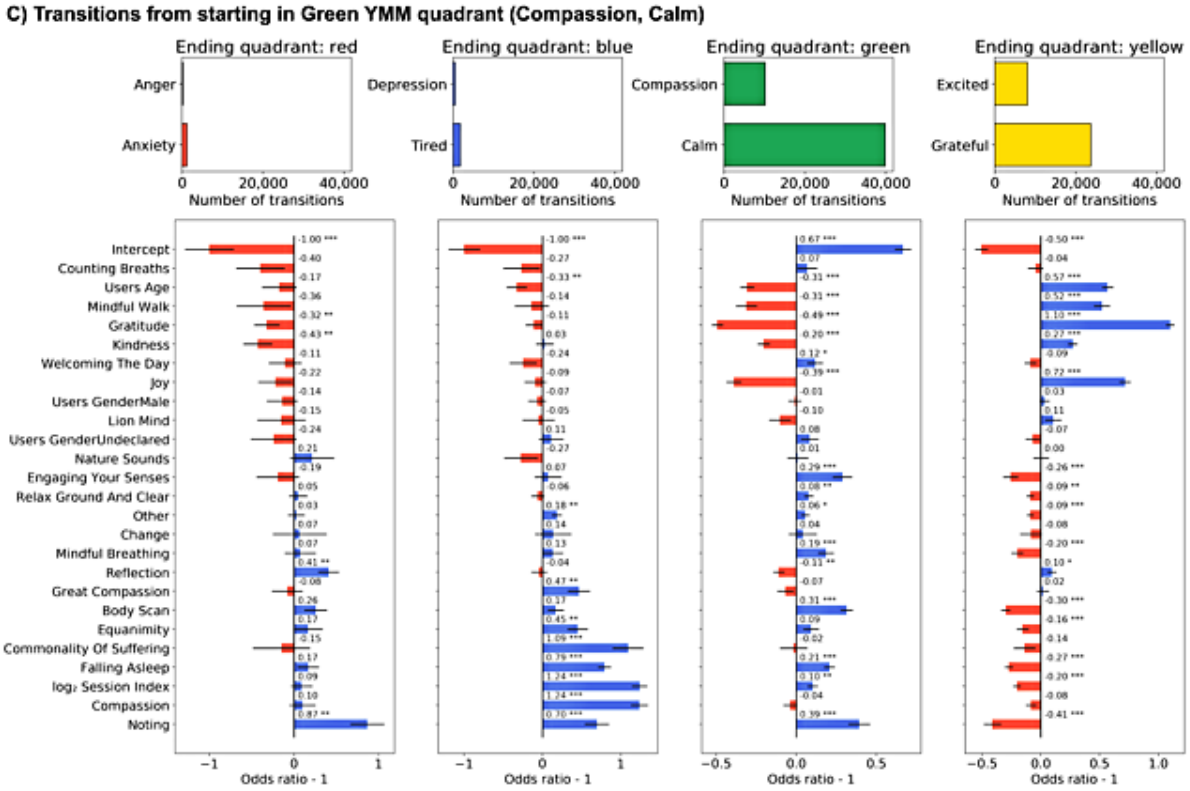
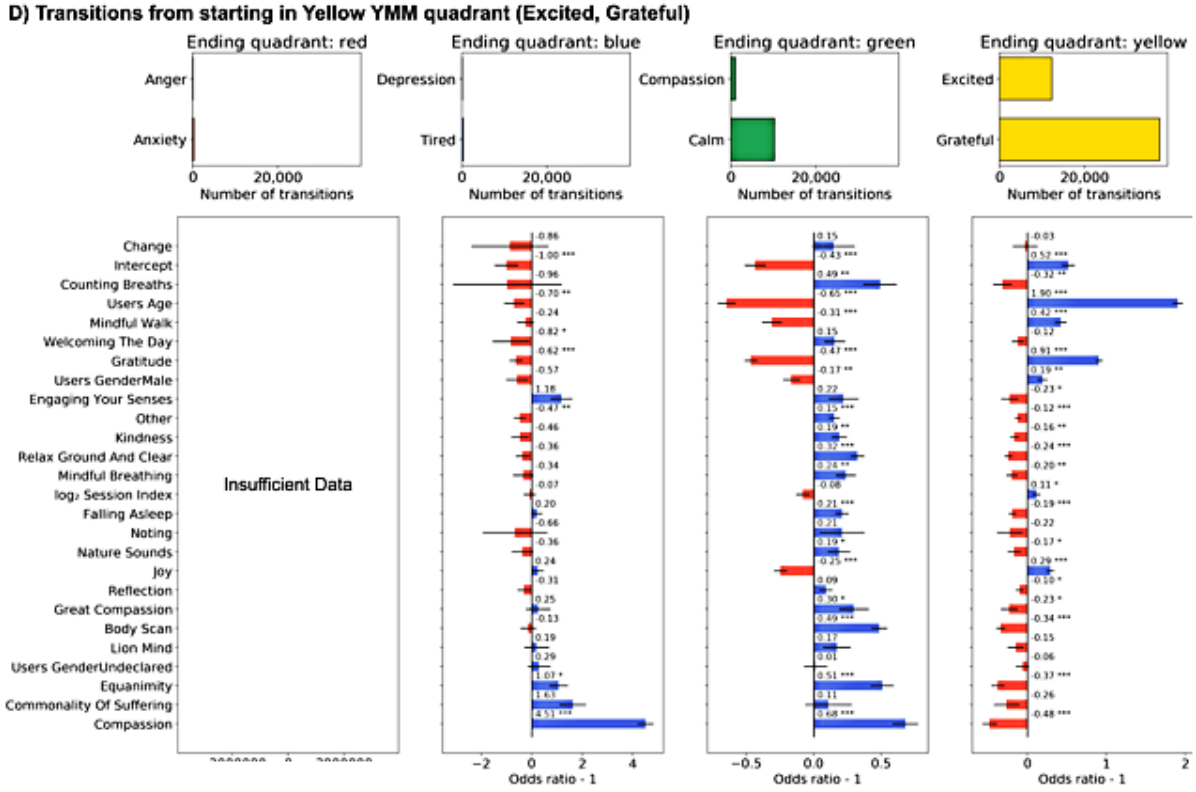


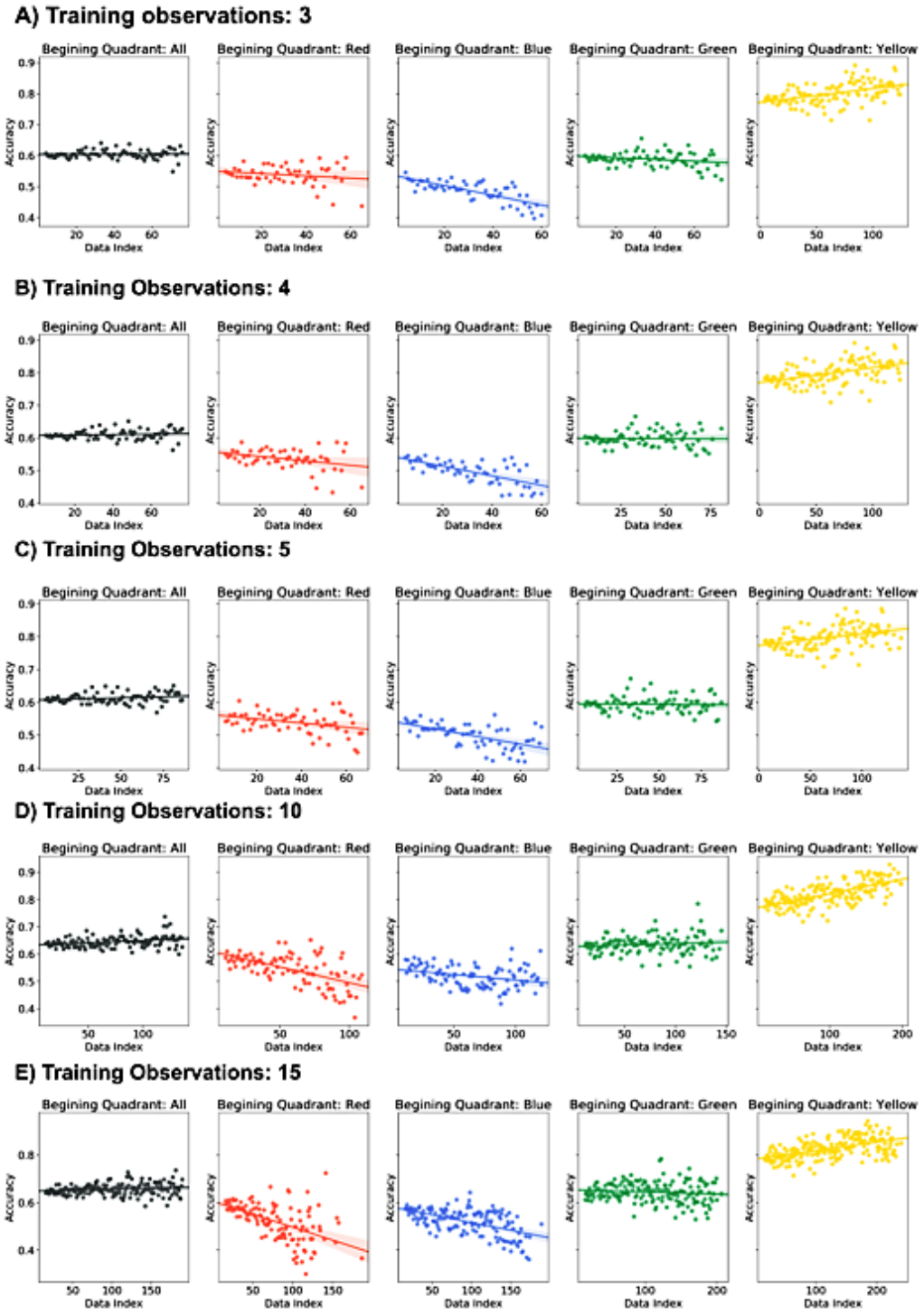
Figure 8. Transitions starting in Yellow Yale Mood Meter (YMM) quadrant model odds ratios. Sixteen generalized linear model fixed effect estimated odd ratios and *P* values (<.001***, <.01**, and <.05*) for mindfulness and meditation activities, gender, session index, and y-intercept split by starting YMM quadrant. Blue bars indicate increased propensity to make a transition, whereas red bars indicate decreased probability of making the transition. There was not enough data to calculate estimates with confidence for transitions from Yellow (HEHP) to Red (HELP).



Simulating a Learning System

The most common YMM quadrant that users transitioned to was green, as expected for an app designed to guide users to a calm and meditative state. The green emotional state quadrant accounted for approximately 45% of all emotional states that users transitioned to. Using data associated with the first 3 engagements with an SBT MMA, we built predictive models to determine which states users are most likely to transition to in subsequent engagements. We then compared the predicted transitions with the actual transitions. We found that the predictions were 61% accurate. Subsequent analyses involving the use of more data from users showed consistency with this level of accuracy (Figure 9 and Multimedia Appendix 4). We found that the accuracy of the predictions differed as a function of the quadrant that the emotions were assigned to before engaging in an MMA, with blue (LELP) being the least accurate and yellow (HEHP) being the most accurate. We also found that the more observations used in training the models, the more accurate the predictions become, as expected. If building models like these was pursued with data collected going forward, then the larger sample size would result in greater power to make predictions and hence generate more accurate predictions, thus potentially continually evolving toward a better recommendation for MMAs given an individual's current mood.

Figure 9. Ending Yale Mood Meter (YMM) quadrant prediction accuracy from distance to training data. Accuracy of models for predicting post-mindfulness and meditation activity (MMA) YMM quadrant emotions with varying number of observations used for training. Accuracy is also shown as a function of the pre-MMA YMM quadrant and suggests differing levels of accuracy and change in accuracy given the pre-MMA quadrant. (A) 3 training observations; (B) 4 training observations; (C) 5 training observations; (D) 5 training observations; (E) 15 training observations.



Discussion

Data Set

With regard to the clustering of emotions, due to the deidentification process of users, it is difficult to directly compare and synthesize aspects of our current analyses with the results of our previously published studies. Despite this, we noted that, in aggregate, the proportions of users in different emotional state categories were more or less the same (age, gender, and emotion endorsement) between the studies. Our clustering analyses produced similar results, which we interpret as consistency in the underlying data as well as in the final results. The key finding of the previous analysis, that users' baseline emotional state improved with the number of engagements with the app, helps put into perspective our findings from our most recent analyses.

Principal Findings

Our analyses suggest that individual MMAs provided by the SBT app have varying degrees of association or potential influence on transitions between emotional states, based on a user's baseline (pre-MMA) emotional state. Furthermore, we found that there is no reason to believe that a "one-size-fits-all" approach to providing a very general MMA recommendation after observing a user's poor mood would be beneficial, as not all MMAs affect individuals in the same way. Rather, we found that depending on what a user's initial mood or mental state was at the time of engagement with the SBT app before pursuing an MMA can influence whether a specific MMA will improve their mental state. Taking this into account, for the app to be more effective, it would be important to "nudge" users away from certain MMAs, which might increase the probability of them remaining in a negative mental state. Gender differences also seem to play a role in how a user's mood will transition after engaging in an MMA, as males appear to have an easier transition from unpleasant emotional states. The user's age also seemed to affect how they transition from poor mental states, as older users seem to heavily favor a more pleasant, energetic state.

Ultimately, some clear themes emerged from our analyses focused on each of our 8 mental state clusters. The first PCoA resulting from our cluster analysis most strongly resembles the pleasantness axis of the YMM (Figure 3), with the left-hand side being more pleasant clusters (grateful, calm, compassion, and excited). The second PCoA somewhat resembles the energy axis of the YMM, with the clusters on the top suggesting higher energy (excited, grateful, and angry). However, we found that the anxiety cluster (mapped to red in the YMM; ie, HELP) was more ambiguous. This could suggest that an additional emotional factor underlying anxiety exists that makes it different from other HELP emotions. Additional projections with the third and fourth PCoAs suggest that the angry and anxiety clusters only share a weak similarity, respectively.

When we examined which MMAs drive emotional transitions, we found some common themes as well as a few surprising results. For example, the *Engaging Your Senses* MMA, which appears to be associated with transitioning users from red (HELP) to green (LEHP), asks a user to tune into each of his or her senses in sequence, observing what they notice without evaluating or judging their experience. The ability to observe one's thoughts, rather than being fully caught up or entangled in them, has been referred to as "metacognitive awareness" and has been shown to be beneficial in dealing with anxiety and stress. This type of MMA may be ideally suited for helping users transition from specific transitions and is consistent with our results. Another well-suited MMA for transitioning away from red (HELP), *Great Compassion*, involves a 3-step process: (1) recognizing that others are just like you and that they want to experience happiness and avoid pain and suffering; (2) broadening one's attention to include people or pets that they love, people they do not know, and even people they have difficulty with, and then imagining that they are breathing in pain and suffering, and breathing out positive energy; and (3) calling to mind people who are of service to others in the world and who can inspire you to do the same. *Great Compassion* may have the effect of moving people out of an angry state because of the process of putting oneself in another's shoes and then cultivating "big picture" thinking, that is, looking at the world a little differently, from a broader perspective. The *Gratitude* MMA has a similar perspective and has the impact of reframing and also helps to cultivate big picture thinking, helping to put things into a larger perspective. These 3 activities all have a focus on separating one's thoughts from the current emotions one is experiencing, and thus are quite likely to lead to similar transitions.

The *Lion Mind* MMA, in contrast, is a quieting activity, using the metaphor of a lion mind versus a dog mind to help take one out of "thought loops" (or ruminating thoughts) that feed anger. It is surprising that the MMA *Kindness* seems ineffective, despite being thought of as the antidote to anger in traditional Tibetan Buddhist philosophy, from which the MMA is derived. It may be that this type of activity works better as a long-term remedy to anger but does not work as an immediate solution that could be used in, for example, anger management strategies. *Commonality of Suffering* and *Change* are similar as they help put things into perspective by tapping into your empathy. With a broader perspective, it is supposed to be easier to feel more relaxed about your own situation or feelings, but users may not be able to reach this perspective given their emotional state. One additional complication may be that *Kindness* and *Change* use a somewhat different and more traditional way of communicating when compared with other MMAs.

For transitions that start from the blue (LELP) quadrant, we obtained surprising results but still notice some common themes. For MMAs that lead to a favorable transition, for example, *Kindness*, *Great Compassion*, Counting *Breaths*, and *Equanimity*, there is a strong focus on interconnectedness and the development of bonds to others. Using this information to anticipate the need for effecting changes in mental state, one could create an app that can better recommend and understand why some MMAs might be more effective given a user's emotional state.

Our previous analysis suggested that a user's baseline emotional state improved with continued use of the application. However, in this study, we noticed that the longer the user engaged with the app, the less likely they are to transition from a negative state, as defined by associations with literature-defined mood quadrants. While counterintuitive, these results do not contradict each other. We do see more users both starting and ending in green (LEHP) or yellow (HEHP) states (as shown in the learning system modeling studies). This might suggest that there are some users who use the app but may not find it effective despite long-term use, or there is a gradual "inoculation" of sorts, whereby users do not find as much benefit from the app as they have benefitted maximally at some point in time. Thus, the effect of the app seems to plateau, which could be alleviated by introducing new and possibly more effective MMAs to a user inured to a current set of MMAs. In addition, there is a unique MMA, *Falling Asleep*, which is meant to help users relax and fall asleep. The "tired" cluster can be considered as both a negative or positive cluster depending on the circumstances, and users who select the *Falling Asleep* meditation could be

moving to this more ambiguous cluster, driving some of the results that we observed.

We find great potential in using the types of models we built to predict the mood a user will transition to based on their MMA selections and initial mood or mental states. Even with a small number of observations, we were able to accurately predict 60.7% of all transitions (15.6% increase over informed guesses and 35.7% increase over random guesses). These models would be more accurate with more data, which suggests that a real-time learning system could be implemented that improves over time to help guide users to MMAs. This would have better chances of a successful mood-elevating transition. As more data are collected, further refinements to the predictive models could be made, as different covariates could be included in the analysis without the worry of overfitting. Other covariates could include, but are not limited to, environmental factors such as time since the last session, last MMA completed, current weather, political events, or other external events in a user's life. This implies that these models could be incorporated into the application and, in real time, help provide improved recommendations for MMA to specific users. Using these models, MMAs could be suggested in a prioritized list, which are ranked by likelihood of a favorable emotional state based on the user's initial state and other features.

Limitations of the Study

Although our study was conducted with data from many users, each with several engagements with the app over varying periods of time, it is entirely observational and does not include the sorts of controls that define, for example, randomized controlled clinical trials. Our analyses were also limited to data reflecting what the users of the app ultimately chose and disclosed within the app. Given that some MMAs have widely differing effects, this would suggest that there are certain MMAs that are likely better suited for inducing different transitions; this phenomenon should be studied in more tightly controlled settings. It should also be noted that the emotional classifications themselves are experimental, and there are many alternative concepts that may differ from our observations in terms of the YMM quadrants [30].

Our filtering criteria for identifying individuals who are appropriate for our analyses could have also created biases in our results. As we examined individuals with 10 or more uses of the app, our attention was naturally confined to individuals who are engaged users and found some personal benefit for its continued use. In contrast, a user who stops after a few uses may not see the same benefits from MMAs in their short experience and hence do not necessarily follow the observed transitions that long-term users exhibit. As noted in our previous publication, long-term use of the app influences basal emotional state. Finally, most users reported being in a YMM green state (LEHP) when engaging with the app initially and did not change their state post-MMA, reducing the number of transitions away from initially poor emotional states that we could study.

Future Directions

As we confined our attention to specific users (eg, iOS users) and MMAs (ie, only those most widely used), we could expand our analyses to all users and MMAs, possibly by clustering the broader set of MMAs in some way. We focused our analysis on the transitions from initial emotional states based on the chosen MMA but ignored other data that were collected (eg, physical state of the person, sex, geolocation, etc). Therefore, we could assess the degree to which these other factors impact our results. For example, we observed that males generally transition to improved mood more frequently than females (ie, starting in a red state [HELP], males are 29% less likely to transition to blue [LELP] and 20% more likely to transition to green [LEHP]), but we did not test which MMAs work better for males (or females) individually. Knowing the effect of these factors and how similar users react to MMAs could help push our efforts toward truly personalizing features of the app and inducing a desired state of mind in a variety of contexts that may help mitigate or avoid associated mental health concerns or symptoms. Ultimately, we believe our findings could motivate more focused studies, through randomized clinical trials, that could lead to further insights into the effectiveness of apps designed to improve mood and help with mental health disorders.

Acknowledgments

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Conflicts of Interest

SS and NJS are advisory consultants and hold equity in Stop, Breathe & Think (now operating under MyLife Inc). JP and JC are cofounders of Stop, Breathe & Think and hold equity in Stop, Breathe & Think. The remaining authors have no conflicts to declare.

Multimedia Appendix 1
Descriptions and frequencies of the top 20 mindfulness and meditation activities (MMAs) completed. The remaining MMAs are aggregated as "other.".
[XLSX File (Microsoft Excel File), 16 KB - mental_v8i3e19832_app1.xlsx]

Multimedia Appendix 2
Detailed study population statistics broken down by gender.
[XLSX File (Microsoft Excel File), 11 KB - mental_v8i3e19832_app2.xlsx]

Multimedia Appendix 3
All 115 endorsable emotions grouped by cluster and associated Yale Mood Meter quadrant.
[XLSX File (Microsoft Excel File), 13 KB - mental_v8i3e19832_app3.xlsx]

Multimedia Appendix 4
Predictive accuracy by amount of training data used. The percentage of users who ended up in a given Yale Mood Meter quadrant compared with the prediction accuracy by increasing the amount of training data used.
[XLSX File (Microsoft Excel File), 10 KB - mental_v8i3e19832_app4.xlsx]

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Abbreviations

GLM: generalized linear model
HEHP: high energy, high pleasantness
HELP: high energy, low pleasantness
LEHP: low energy, high pleasantness
LELP: low energy, low pleasantness
MMA: mindfulness and meditation activity
PAM: partitioning around medoids
PCoA: principal coordinate analysis
SBT: Stop, Breathe & Think
YMM: Yale Mood Meter

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Original Paper

Effects of Web-Based Group Mindfulness Training on Stress and Sleep Quality in Singapore During the COVID-19 Pandemic: Retrospective Equivalence Analysis

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Abstract

Background: The COVID-19 pandemic has negatively impacted psychological health. Mindfulness training, which helps individuals attend to the present moment with a nonjudgmental attitude, improves sleep and reduces stress during regular times. Mindfulness training may also be relevant to the mitigation of harmful health consequences during acute crises. However, certain restrictions may necessitate the web-based delivery of mindfulness training (ie, rather than in-person group training settings).

Objective: The objective of our study was to examine the effects of mindfulness interventions during the COVID-19 pandemic and to evaluate the effectiveness of web-based interventions.

Methods: Data from an ongoing study were used for this retrospective equivalence analysis. Recruited participants were enrollees from mindfulness courses at a local charity organization that promoted mental wellness. This study had no exclusion criteria. We created three groups; two groups received their training during the COVID-19 pandemic (in-person training group: n=36; videoconferencing group: n=38), and a second control group included participants who were trained before the pandemic (n=86). Our primary outcomes were self-reported stress and sleep quality. Baseline levels and changes in these variables due to mindfulness training were compared among the groups via an analysis of covariance test and two one-tailed *t* tests.

Results: Baseline perceived stress (P=.50) and sleep quality (P=.22) did not differ significantly among the three groups. Mindfulness training significantly reduced stress in all three groups (P<.001), and this effect was statistically significant when comparing videoconferencing to in-person training (P=.002). Sleep quality improved significantly in the prepandemic training group (P<.001). However, sleep quality did not improve in the groups that received training during the pandemic. Participants reported that they required shorter times to initiate sleep following prepandemic mindfulness training (P<.001), but this was not true for those who received training during the pandemic. Course attendance was high and equivalent across the videoconferencing and comparison groups (P=.02), and participants in the videoconferencing group engaged in marginally more daily practice than the in-person training group.

Conclusions: Web-based mindfulness training via videoconferencing may be a useful intervention for reducing stress during times when traditional, in-person training is not feasible. However, it may not be useful for improving sleep quality.

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KEYWORDS

mindfulness; COVID-19; videoconference; perceived stress; sleep quality; intervention; telehealth; mental health; psychology

Introduction

During times of crisis, it is important that individuals are equipped with tools for coping with the psychological impacts of change and uncertainty. In this retrospective study, we investigated the effects of mindfulness training in terms of reducing stress and improving sleep quality during the COVID-19 pandemic, which is an event that has resulted in major economic and social disruptions worldwide. More than 7 million confirmed SARS-CoV-2 infections and 400,000 deaths resulting from COVID-19 have been reported as of June 10, 2020.

Studies that have been conducted during the COVID-19 pandemic have reported increases in the incidence of depression, anxiety, and stress across diverse populations [1]. Altered sleep habits and circadian rhythm misalignment resulting from disruptions in routines (ie, those caused by quarantine and lockdowns) may further exacerbate these problems [2,3]. Cross-sectional data have suggested that social support may be a protective factor against the negative consequences of stress [4], and this has promoted the use of psychosocial interventions in stress-affected communities.

Mindfulness practice has been reported as an effective method for coping with stressors, as it provides individuals with flexible strategies for relating to thoughts and emotions. It has also been suggested that mindfulness practice is a potential intervention for stress reduction during the COVID-19 pandemic [5]. In psychiatric research, mindfulness is commonly defined as the awareness that arises from paying purposeful attention to the present moment experience in a nonjudgmental manner [6]. It is commonly taught and cultivated through standardized curricula, such as the Mindfulness-Based Stress Reduction program [7]. Considerable emphasis has been placed on the importance of having a mindful disposition in daily living and engaging in habitual mindfulness practice after the conclusion of formal training.

Meta-analyses have demonstrated that mindfulness has moderate effects in terms of reducing stress in healthy individuals [8] and the incidence of psychopathology [9]. This buffering effect has been observed in laboratory paradigms that acutely induce stress [10,11] and people who experience stress on a chronic basis. This reduction in stress may have beneficial health sequelae, such as decreasing the incidence of harmful behaviors (eg, smoking) [12] and reducing susceptible individuals' likelihood of developing serious depressive or anxiety disorders (per diathesis-stress models) [13].

A related but separate body of research has highlighted the beneficial effects of mindfulness training on sleep quality. High dispositional mindfulness correlates with improved self-reported sleep quality across several populations [14], and a growing number of randomized controlled trials have shown improvements in sleep quality after mindfulness instruction in both nonclinical [15] and clinical populations [16]. Regular poor sleep is associated with the significant deterioration of short- and medium-term quality of life, and as with chronic stress, regular poor sleep may predispose individuals to developing serious psychological problems over time [17].

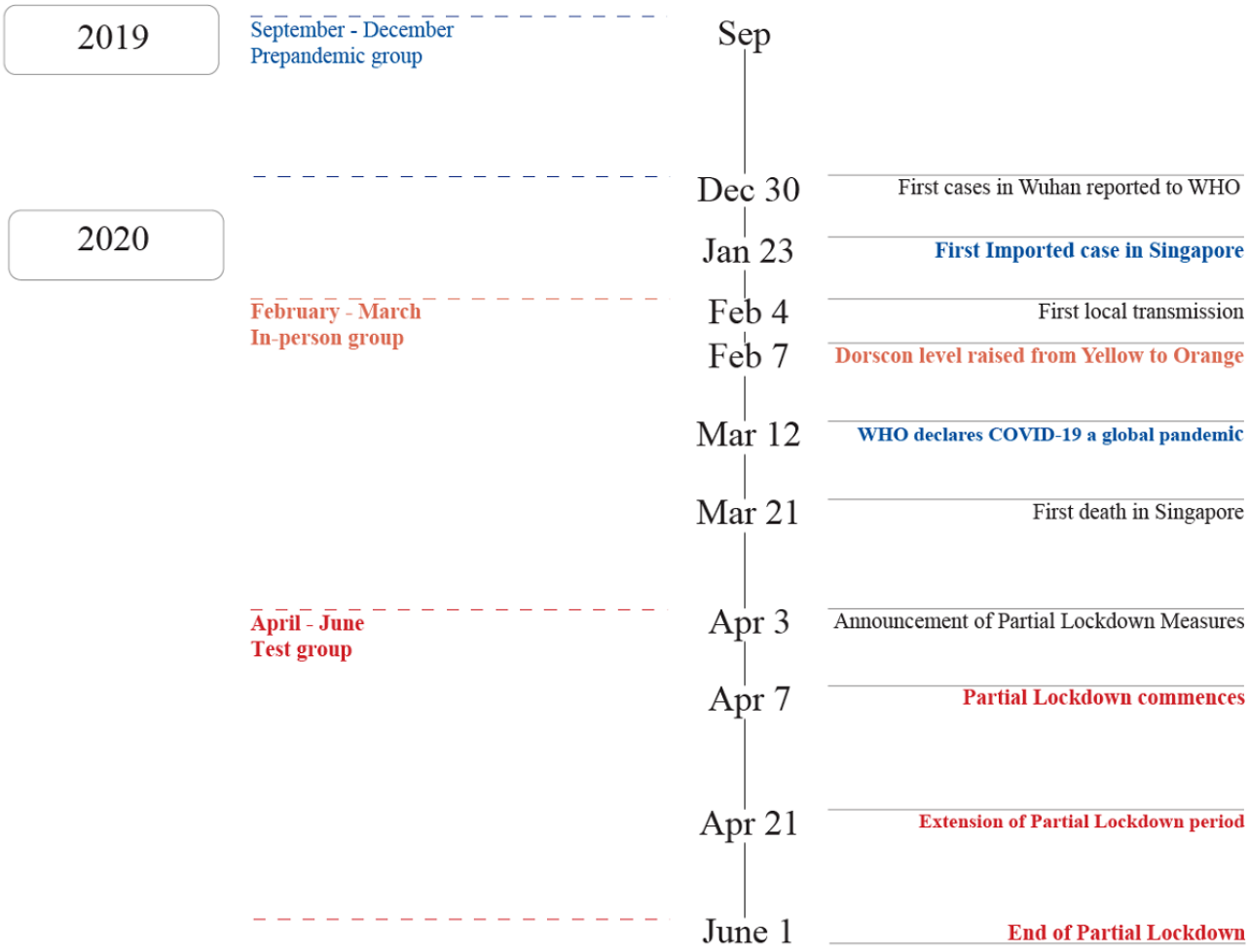
Delivering mindfulness training in traditional group settings may be challenging during a pandemic due to restrictions such as social distancing and lockdowns. Group videoconferencing is an attractive work-around method for providing mindfulness instruction and preserving the high-quality facilitation and social and communal aspects of mindfulness interventions. However, there have been few studies that investigate whether this mode of delivery is as effective as in-person instruction and whether good adherence to a mindfulness program (ie, attendance and daily practice) can be achieved via videoconferencing. There are also very little data on the effects of mindfulness interventions that are conducted during the COVID-19 pandemic. These knowledge gaps motivated us to conduct this study. Specifically, we hypothesized that mindfulness training delivered via videoconferencing would have an effect that is equivalent to that of in-person training in terms of reducing stress and improving sleep quality.

Methods

Aim and Hypotheses

The primary aims of this study were to examine the effects that group mindfulness interventions have on stress and sleep quality during a global crisis (ie, the COVID-19 pandemic) and to determine whether the web-based delivery of mindfulness training was equivalent to traditional, in-person classes. Data from two comparison groups and a control group were analyzed. The first comparison group was composed of participants who underwent training during a period of heightened alert resulting from the community spread of SARS-CoV-2 (ie, February to March 2020), and the second comparison group was composed of participants who underwent mindfulness instruction via group videoconferencing classes that were led by an experienced facilitator during a period of partial lockdown (ie, April to May 2020) (Figure 1). We had 2 hypotheses. For our first hypothesis, we predicted that participants would experience higher levels of perceived stress and poorer sleep quality at baseline during the pandemic than before the pandemic (ie, the control period). For our second hypothesis, we tested whether web-based training (ie, during the lockdown period) was equivalent to in-person training (ie, before and during the COVID-19 pandemic), and we predicted that web-based training would be equivalent to in-person training (ie, before and during the pandemic) in terms of reducing stress and improving sleep quality.

Figure 1. Timeline of key COVID events in Singapore and recruitment periods.



Setting

This study was conducted with people from the general community. During the prelockdown period, participants attended courses at one of the Brahm Centre sites [18], which were located in community hospitals or housing estates around Singapore. During the lockdown period, participants remotely attended mindfulness training from their homes. Questionnaires were completed and submitted via a web-based platform.

Procedure

The data in this analysis were collected from an ongoing study that investigated the effects of baseline variables on mindfulness training. The participants in the ongoing study were enrollees from 1 of 3 different mindfulness courses that are offered by Brahm Centre, which is a charity organization that conducts wellness activities for the general community. The three courses were (1) the Mindfulness Foundation Course [15], (2) the Mindfulness Intermediate Course, and (3) Mindfulness-Based Stress Reduction [7]. Detailed descriptions of the courses that were offered in the ongoing study are reported in the Supplementary Information (Multimedia Appendix 1). The breakdown of the number of participants in each course is shown in Table S1. Although the courses differ in length (ie, 4 weeks for the foundation course and 8 weeks for the intermediate and Mindfulness-Based Stress Reduction courses), we noted that previous studies have generally not found evidence of a dose-response relationship between course length and psychological outcomes in mindfulness training [19,20].

Upon enrolling in one of these courses, participants were invited to take part in this study by completing a set of questionnaires via SurveyMonkey (SurveyMonkey Inc) [21]. These questionnaires included the Perceived Stress Scale (PSS) and the Pittsburgh Sleep Quality Inventory (PSQI). Data from other questionnaires in the survey packet are not discussed further in this paper. Participants were provided with study information and informed that they were providing implicit consent for their participation in this study by completing and submitting the questionnaires. They were required to complete the surveys within 24 hours of the first session of each course. The mindfulness courses consisted of 4 or 8 sessions that were taught by 1 of 2 instructors who were certified by the Centre For Mindfulness at the University of Massachusetts Medical School. These instructors had at least 1000 hours of teaching experience. Web-based classes were delivered via the Zoom videoconferencing platform (Zoom Video Communications Inc) [22]. Participants were strongly encouraged to practice mindfulness exercises (ie, the exercises they were taught) on a daily basis. Following the last session of each course, participants answered the items of the PSS and PSQI again and reported on their average daily mindfulness practice times over the duration of the course.

Participants

We created three different groups based on the periods when participants underwent their mindfulness training. These periods were relative to milestone events that occurred in Singapore during the COVID-19 pandemic. Since group assignment was dependent on the imposition and lifting of restrictions that were not within our control, prospectively randomizing participants into groups was not possible in this study. The test group was comprised of participants who were recruited in April and May 2020 (n=38), which roughly encompassed the period in which Singapore entered a partial lockdown. Participants in this group were provided with web-based group training. The in-person training group included participants (n=36) who signed up for face-to-face group courses that took place during the months of February and March 2020, which approximately corresponded with the period of heightened alert in Singapore. With regard to the prepandemic training group, we used data that were collected from a group of 86 participants who took part in this study from October to December 2019 (ie, the period prior to the first reported case of COVID-19 in Singapore). Participants were community-dwelling individuals who voluntarily signed up for and participated in the mindfulness program, and this study had no exclusion criteria. Figure 1 shows the timeline of landmark events (ie, those related to the pandemic in Singapore) and the periods of participant recruitment. Table 1 shows the baseline demographic and clinical characteristics of the three groups, and Figure 2 shows a diagram of participant flow.

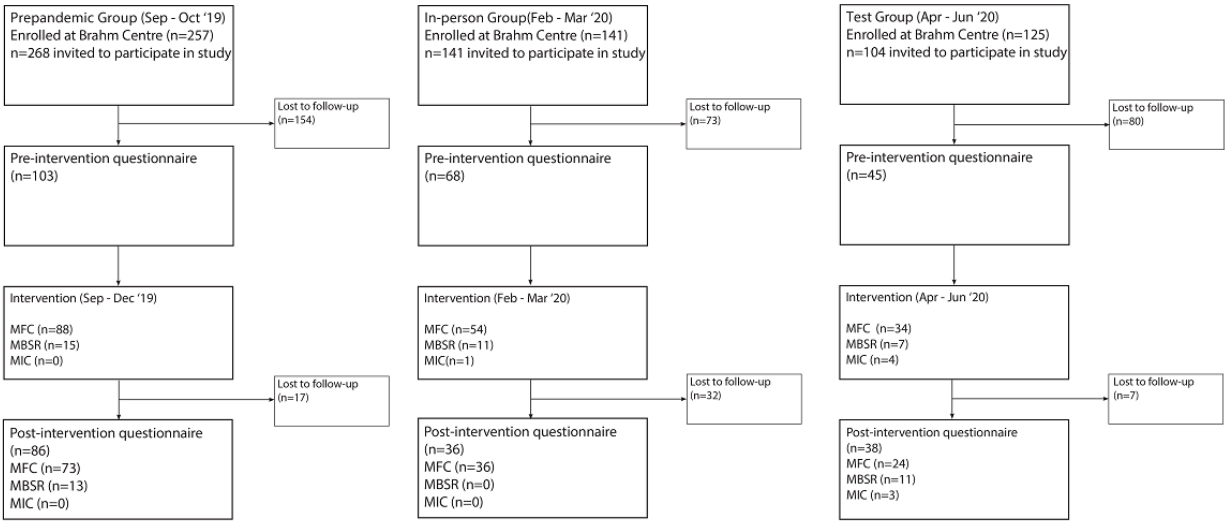
Table 1. Participants' baseline characteristics.

Characteristics	Prepandemic training group	In-person training group	Test group	*P* value[a]
Sample size, n	86	36	38	N/A[b]
Demographic characteristics				
Age (years), mean (SD)	45.46 (11.71)	47.14 (10.98)	49.77 (11.17)	.15
Male, n	26	11	11	.99
Length of education (years), mean (SD)	16.44 (2.63)	15.47 (2.81)	15.61 (2.91)	.19
Previous meditation experience, n	16	3	10	.14
Race, n				
Chinese	79	36	36	N/A
Malay	2	0	1	N/A
Indian	3	0	1	N/A
Other	2	0	0	N/A
Clinical variables, mean (SD)				
Perceived Stress Scale score	20.17 (6.67)	21.19 (8.07)	19.26 (6.84)	.50
Pittsburgh Sleep Quality Inventory score	6.29 (2.96)	5.58 (2.98)	6.82 (3.27)	.22
Total sleep time (minutes)	406.69 (55.57)	402.38 (49.69)	405.23 (68.98)	.93
Sleep onset latency (minutes)	23.64 (25.76)	17.12 (12.66)	27.09 (28.72)	.20

[a]*P* values were derived from the appropriate statistical test (ie, analysis of variance/Chi-square test) for comparing all three groups.

[b]N/A: not applicable.

Figure 2. Diagram of participant flow throughout the protocol. Participants were enrolled in 1 of 3 types of mindfulness courses: 4-week Mindfulness Foundation Course (MFC), 8-week Mindfulness Based Stress Reduction (MBSR), and 4-week Mindfulness Intermediate Course (MIC).



Measures

Our primary outcomes of interest were the global scores of two questionnaires. Both of these questionnaires are considered gold-standard instruments for measuring their respective constructs, as they have excellent psychometric properties.

PSS Instrument

The PSS [23] is a widely used 10-item instrument for measuring subjectively experienced stress.

PSQI Scale

The PSQI [24] is a 19-item scale that is commonly used to self-assess sleep quality and disturbances over a 1-month period. This questionnaire requires participants to report on their average sleep and wake times and the average time they take to fall asleep at night. Global PSQI scores of >5 are indicative of clinical sleep disturbance.

In addition to obtaining global PSQI scores, we conducted an exploratory analysis on the two following self-reported sleep variables: total sleep time and sleep onset latency (ie, the time taken to fall asleep).

Statistical Analysis

We conducted a complete case analysis on participants who provided PSS and PSQI data both before and after the intervention. A one-way analysis of variance (ANOVA) test was conducted to identify differences in baseline PSS scores, baseline PSQI scores, and the amount of practice among the three groups. To compare the effects of the interventions that were delivered before and during the pandemic, we conducted a 2 × 3 repeated measures analysis of covariance (ANCOVA) test in which mindfulness training (ie, pretraining and posttraining) was used as a within-subjects factor and group type (ie, the prepandemic training, in-person training, and test groups) was used as a between-subjects factor. As sphericity assumptions were not violated, no corrections for nonsphericity were applied. Course duration (ie, 4 or 8 weeks) and participants' previous meditation experience were coded as dummy variables and used as covariates. To establish equivalence between web-based and in-person training, we conducted two one-tailed *t* tests to compare the test group to the two control groups. We set the smallest effect size of interest (ie, Cohen *f*) to 0.29 for the comparison between the test group and the prepandemic training group and 0.38 for the comparison between the test group and the in-person training group. Per the recommendation of Lakens [25], the smallest effect size of interest was determined by computing the smallest effect size that our study could detect (thresholds: =.05; =.90). Statistical analysis was conducted with SPSS, version 23 for Mac (IBM Corporation).

Ethical Approval

This study was approved by the National University of Singapore Institutional Review Board and conducted in accordance with the ethical standards of the 1964 Helsinki declaration and its later amendments. Participants were provided with an information sheet about the study. Participants provided implicit consent by completing and submitting the questionnaire. Identifying information was not collected, as per this study's protocol.

Data Sharing Statement

Deidentified participant data from this analysis will be freely available on the Open Science Framework website after publication [26].

Results

Demographics

Participants' baseline, self-reported characteristics are presented in Table 1. The groups did not differ significantly in terms of age, gender, education level, or previous meditation experience.

Perceived Stress

The one-way ANOVA test for the three groups showed that there were no significant differences in baseline levels of perceived stress ($F_{2,159}$=0.69; P=.50). Baseline stress was within the moderate range (ie, a PSS score of 14-26). After comparing the effects of the interventions for each group, we found that training had a significant overall effect ($F_{1,155}$=12.80; P<.001; partial ε^2=.076). However, there were no interactions between the training and group factors ($F_{2,155}$=0.92; P=.40) (Figure 2). Our planned posthoc comparisons showed that perceived stress significantly decreased in all three groups after mindfulness training (prepandemic training group: t_{84}=7.55; P<.001; in-person training group: t_{35}=2.58; P=.01; test group: t_{37}=4.09; P<.001).

The two one-tailed t tests for comparing changes in PSS scores between the test group and the prepandemic training group (the smallest effect size of interest was set to 0.29) revealed that the observed effect size was significantly within the equivalence bounds (t_{124}=2.10; P=.02). This indicated that web-based mindfulness training during the pandemic was equivalent to in-person training before the pandemic in terms of reducing stress. Similarly, the comparison between the test group and the in-person training group (the smallest effect size of interest was set to 0.38) indicated that web-based training during the pandemic was equivalent to in-person training during the pandemic (t_{73}=−2.99; P=.002).

Subjective Sleep Quality

The one-way ANOVA test showed that there were no significant differences in the three groups' baseline, self-reported sleep quality levels ($F_{2,159}$=1.53; P=.22). Participants' PSQI scores were above threshold (ie, a global PSQI score of >5). This suggested that all three groups experienced sleep difficulties. After comparing the effects of the interventions for each group, we found that training had a significant overall effect ($F_{1,155}$=4.45; P=.04; partial ε^2=.028). However, there were no interactions between the training and group factors ($F_{2,155}$=2.00; P=.14) (Figure 3). Our planned posthoc comparisons showed a significant improvement in the prepandemic training group's sleep quality (t_{85}=5.37; P<.001), but there were no significant changes in PSQI scores between the two groups that received training during the pandemic (in-person training group: t_{35}=1.16; P=.25; test group: t_{37}=0.96; P=.34) (Figure 4).

Figure 3. Change in perceived stress. Black lines depict change for individual participants, and red line indicates the mean change and standard errors in the group. Change in perceived stress from pre- to post-intervention is equivalent among the three groups. PSS = perceived stress scale; * P<.05; ** P<.001.

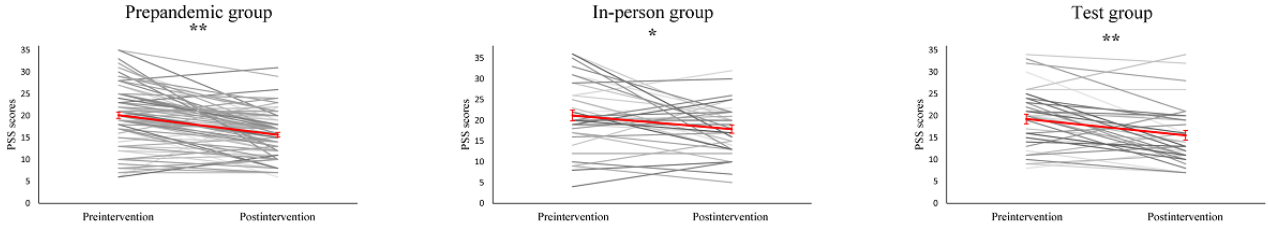
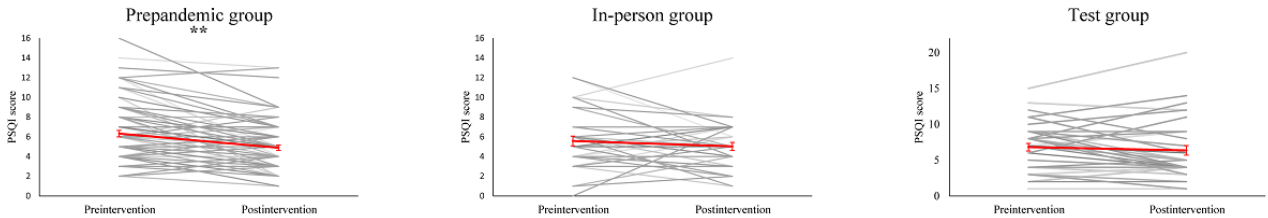


Figure 4. Change in subjective sleep quality. Black lines depict change for individual participants, and red line indicates the mean change and standard errors in the group. Change in self-reported sleep quality was significant in the control group (pre-pandemic) but in neither of the groups trained during the pandemic. PSQI = Pittsburgh Sleep Quality Index; * P<.001.



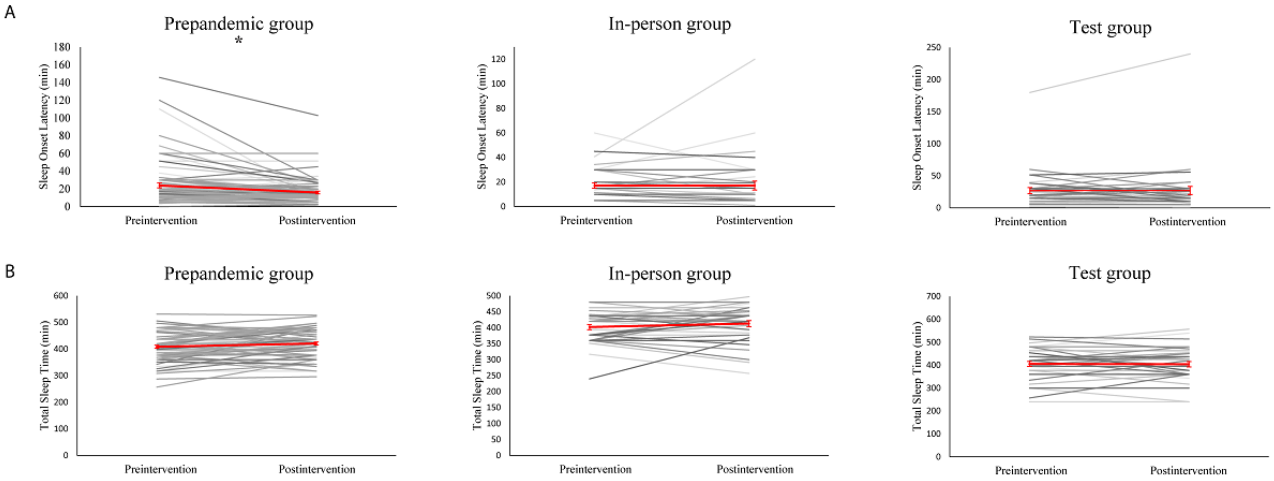
The two one-tailed t tests for comparing changes in PSQI scores between the test group and the prepandemic training group (the smallest effect size of interest was set to 0.29) revealed that the observed effect size was not significantly within the equivalence bounds (t_{123}=0.93; P=.18). This suggested that web-based mindfulness training during the pandemic was not equivalent to in-person training before the pandemic in terms of improving sleep quality. In contrast, the comparison between the test group and the in-person training group (the smallest effect size of interest was set to 0.38) indicated that web-based training during the pandemic was equivalent to in-person training during the pandemic (t_{72}=3.10; P=.001).

Secondary Sleep Variables

We conducted an exploratory analysis on self-reported total sleep times and sleep onset latency. The repeated measures ANCOVA test, which controlled for the effects of course type and previous meditation experience on total sleep time, revealed that there were no significant changes in total sleep time after meditation training ($F_{1,155}$=1.76; P=.19) and no group by training

interactions ($F_{2,157}$=0.88; P=.42). However, participants in the in-person and prepandemic training groups reported that they experienced 10 more minutes of sleep following mindfulness training (Figure 5). The ANCOVA test for assessing sleep onset latency revealed that training did not have a significant effect ($F_{1,155}$=0.44; P=.50) and that there were significant group by training interactions ($F_{2,155}$=3.80; P=.03). Our posthoc comparisons indicated that this interaction was driven by the significant reduction in sleep onset latency in the prepandemic training group (pretraining: mean 23.64 minutes, SD 25.61 minutes; posttraining: mean 15.728 minutes, SD 14.30 minutes; t_{85}=3.92; P<.001) instead of those in the in-person training and test groups (Figure 5).

Figure 5. : Changes in sleep variables. Black lines depict change for individual participants, and red line indicates the mean change and standard errors in the group. (A) Sleep onset latency (SOL) decreases significantly on the control group, but not COVID1 or COVID2. (B) No significant changes were observed in total sleep time (TST). * P<.001.



Our sleep onset latency data contained several outlier values (ie, SDs of >3 from the mean) that were plausible, which may have been the reason for our significant results. Therefore, we reanalyzed the data via nonparametric bootstrap resampling. This involved 5000 reshuffles of the control and test labels [27]. After using this method, we found that training had a significant effect in the prepandemic training group (paired mean difference=−7.92; 95% CI −12.9 to −4.81; P<.001). However, training did not have a significant effect in the in-person training group (paired mean difference=0.028; 95 %CI −3.67 to 8.67; P=.99) and the test group (paired mean difference=0.134; 95% CI −4.48 to 6.34; P=.96). This supported our hypothesis that mindfulness training before the pandemic shortens sleep onset latency and mindfulness training during the pandemic does not (Multimedia Appendix 2).

Course Attendance and Practice Time

We analyzed the percentage of training sessions that participants attended to account for the different course durations. The two one-tailed t tests revealed that the attendance rate of the test group was equivalent to those of the prepandemic training group (t_{124}=1.86; P=.03) and the in-person training group (t_{124}=2.15; P=.02). Course attendance was high in all three groups (prepandemic training group: mean 96.2%, SD 15.9%; in-person training group: 96.5%, SD 8.8%; test group: 96.4%, SD 14.1%).

As the recommended amount of home practice differed between the 4-week and 8-week courses, we only performed a subgroup analysis on the daily practice times of participants in the 4-week courses (prepandemic training group: n=73; in-person training group: n=36; test group: n=27). Participants in the test group had higher daily practice times (mean 15.7 minutes, SD 8.78 minutes) than the prepandemic training group (mean 12.78 minutes, SD 6.19 minutes) and the in-person training group (mean 13.97, SD 8.30 minutes). Our equivalence tests showed that the observed effect size between the test group and the prepandemic training group was not significantly within the equivalence bounds (t_{120}=−0.83; P=.20); however, the effect size between the two groups was not significantly different (t_{97}=−1.21; P=.23). The test group's and in-person training group's practice times were statistically equivalent (t_{61}=−2.19; P=.01).

Discussion

Principal Findings

Unlike other studies [28,29], we found no evidence of heightened stress and poorer sleep quality (ie, compared to baseline levels) during the COVID-19 pandemic compared to those before the pandemic. These findings may be specific to our participants, who were generally well educated and of relatively high socioeconomic status. Our results are in line with data from a study that had a large sample of working professionals in Singapore. These working professionals exhibited increases in weekend sleep duration and comparable levels of sleep efficiency during the lockdown period compared to those before the lockdown period [30]. Regardless, our participants still reported moderate levels of stress and sleep disturbance on average, suggesting that interventions for improving these outcomes are valuable.

The key finding from this study was that the effects of mindfulness training during the COVID-19 pandemic were equivalent to those of in-person mindfulness training during and before the pandemic in terms of reducing stress. However, we did not find evidence that this training improved sleep

quality. These findings remained consistent regardless of whether the training was conducted in person or via a web-based platform. Videoconferencing has emerged as a very useful tool for mental health providers, as it can be used when restrictions have necessitated measures such as social distancing and quarantine. Furthermore, our data support the effectiveness of mindfulness training that is delivered in this format.

To date, there have been little data on the effects of mindfulness training during the COVID-19 pandemic. Although a randomized study that was conducted in Wuhan during the pandemic has reported on the sleep-related benefits of brief mindfulness practices (ie, compared to a mind-wandering control condition) [31], the measures it used were not validated, and the intervention (ie, self-guided practice for 10 minutes per day) was unfacilitated and of relatively low intensity.

A possible reason for the discrepancy between the two outcome variables in this study is that the effect size of training for improving sleep was smaller than that for improving stress, and our sample size was not sufficiently powered to detect this difference. However, the reduction in sleep onset latency in the prepandemic control group was large, and almost no changes in this variable were observed after mindfulness training during the pandemic (Multimedia Appendix 1). This is evidence against our explanation. We thus posit that there are undiscovered factors that relate to coping with a global crisis and specifically weaken the effects of mindfulness training on sleep quality. For example, irregular schedules, less light exposure, and reduced physical activity during a pandemic may play a large role in influencing sleep, and these factors are not targeted by mindfulness training [32]. If this is the case, our data have implications for prescribing mindfulness interventions during a crisis. Our data suggest that mindfulness training participants' primary desired goal should be stress reduction instead of sleep improvement.

When mindfulness was first introduced in Western medicine, mindfulness instruction was typically delivered in groups, as inquiry and discussion were integral parts of training sessions. With the increasing penetration of technology in society, there has been growing interest in the digital delivery of this training due to its potential for reaching a large number of people at a relatively low cost. Studies on digital mindfulness training have used a variety of dissemination methods; web-based and email-based delivery are the most common [33]. In contrast, relatively few trials have used group videoconferencing, which confers the advantage of allowing both teachers and participants to interact remotely for group sharing and inquiry activities. These are key components that are present in face-to-face training. The need for such high-quality facilitation [34] is an often-ignored aspect in the field of mindfulness research. Digital platforms that do not provide live instruction and allow participants to have real-time discussions with an experienced teacher (ie, a person who embodies the qualities of mindfulness) may result in misunderstandings (ie, with regard to how mindfulness should be practiced) or adverse impacts on participants. Foundational attitudes that are fundamental in mindfulness practice (eg, nonstriving and letting go) may not be intuitive to people who are accustomed to the teleological foundations of treatment in Western medicine. Therefore, in-person guidance and inquiry are particularly important for inexperienced practitioners. Furthermore, videoconferencing preserves the other social elements (eg, peer-to-peer sharing of experiences through the use of Zoom breakout rooms) of the intervention that may be critical to behavioral change.

Videoconferencing as a means of delivering mindfulness training has been tested in a small number of studies, and it generally results in superior outcomes compared to those of untreated controls. However, none of these studies have formally tested the equivalence between videoconferencing-based mindfulness training and in-person mindfulness training, as established by our analysis. For example, Zernicke et al [35] reported moderate reductions in stress and mood disturbance in a randomized, wait-list controlled trial of cancer survivors who participated in a videoconferencing-based, mindfulness-based cancer recovery program. Furthermore, Gardner-Nix et al [36] reported that the positive effects that in-person and remote mindfulness-based pain management have on mental health and pain catastrophizing were superior to those of a wait-list control. However, they did not establish the equivalence of the mindfulness conditions. Beyond fully facilitated treatments, other studies that report on the positive results of web-based training have used individualized mentoring and coaching as an adjunct to self-administered content [37]. Therefore, recent evidence indicates that remotely delivered mindfulness training has beneficial effects on a wide spectrum of different health outcomes.

With regard to treatment acceptance, we found that adherence to the intervention was good; participants attended 96.3% (709/736) of the classes and practiced for an average of 15 minutes per day, as prescribed. This differs from app-based mindfulness training, in which app use tends to decrease over time [38]. This is partially due to difficulties in incorporating app use into a routine [39]. A particular strength of our study protocol was that the mindfulness interventions involved standardized curricula, which were delivered by highly experienced instructors. These interventions have also been tested and reported on in prior studies [15].

Limitations

This study has a number of limitations that are worth noting. As this was a retrospective analysis, participants in this study were not randomized by condition, thereby introducing the risk of bias (eg, selection bias whereby participants with COVID-19 were more motivated to engage in mindfulness training than those without COVID-19), However, due to the nature of our study, randomization for investigating the effects of training during a crisis period was not possible. Furthermore, we were not able to conduct a priori power analysis, and our sample size was determined by the maximum recruitment of participants within the two target periods. As such, we had to use relatively wide equivalence bounds to test our hypotheses.

We also noted that the postintervention rates of attrition were substantial and imbalanced between groups, and we were unable to rule out the possibility that these dropouts were not random. Regardless, this level of attrition is typical for web-based survey studies with limited experimenter-participant contact [40,41].

Of note, our sample was predominantly Han Chinese and well educated. Further research is needed to determine the generalizability of our reported effects to other populations.

Future Directions

The findings in this analysis are encouraging. They suggest that prospective randomized controlled trials should be conducted to provide stronger evidence for the effectiveness of videoconferencing. Future studies should also focus on understanding why mindfulness interventions are not effective in terms of improving sleep quality during times of crisis and determining how standard treatments might be adapted to target sleep difficulties.

Conclusions

Our data suggest that group mindfulness training that is delivered via videoconferencing is as effective as traditional, in-person training in terms of reducing stress. However, in-person and web-based mindfulness training during the pandemic were not comparable to prepandemic mindfulness training in terms of improving sleep quality. Videoconferencing may be an attractive, alternative method of delivering mindfulness training for reducing stress when restrictions make in-person training less viable.

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Authors' Contributions

JL conceived and designed the study. ZL, LSP, and EL collected the data. JL and ZL analyzed the data. All authors contributed to manuscript preparation.

Conflicts of Interest

LSP and EL are employed by the Brahm Centre.

Multimedia Appendix 1
Detailed information of mindfulness training courses.
[DOCX File , 17 KB - mental_v8i3e21757_app1.docx]

Multimedia Appendix 2
Estimation plots showing the mean difference and 95% confidence interval between sleep onset latency before and after the mindfulness interventions. 5,000 bootstrap resamples were used to create each distribution. Sleep onset latency decreased significantly in the control group (paired mean difference = -7.92 [95.0% CI -12.9, -4.81], P<.001), but not in COVID1 (paired mean difference = 0.028 [95.0% CI -3.67, 8.67], P=.99) or COVID2 (paired mean difference = 0.134 [95.0% CI -4.48, 6.34], P=.96).
[PNG File , 164 KB - mental_v8i3e21757_app2.png]

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Abbreviations

ANCOVA: analysis of covariance
ANOVA: analysis of variance
PSQI: Pittsburgh Sleep Quality Inventory
PSS: Perceived Stress Scale

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Original Paper

Feasibility and Initial Outcomes of a Group-Based Teletherapy Psychiatric Day Program for Adults With Serious Mental Illness: Open, Nonrandomized Trial in the Context of COVID-19

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Abstract

Background: In the context of the COVID-19 pandemic, many behavioral health services have transitioned to teletherapy to continue delivering care for patients with mental illness. Studies that evaluate the outcome of this rapid teletherapy adoption and implementation are pertinent.

Objective: This single-arm, nonrandomized pilot study aimed to assess the feasibility and initial patient-level outcomes of a psychiatric transitional day program that switched from an in-person group to a video teletherapy group during the COVID-19 pandemic.

Methods: Patients with transdiagnostic conditions who were at risk of psychiatric hospitalization were referred to the Adult Transitions Program (ATP) at a large academic medical center in the United States. ATP was a 3-week intensive outpatient program that implemented group teletherapy guided by cognitive and behavioral principles delivered daily for 3 hours per day. Feasibility was assessed via retention, attendance rate, and rate of securing aftercare appointments prior to ATP discharge. Patients completed standardized patient-reported outcome measures at admission and discharge to assess the effectiveness of the program for improving quality of mental health, depression, anxiety, and suicide risk.

Results: Patients (N=76) started the program between March and August of 2020. Feasibility was established, with 70 of the 76 patients (92%) completing the program and a mean attendance of 14.43 days (SD 1.22); also, 71 patients (95%) scheduled at least one behavioral health aftercare service prior to ATP discharge. All patient-level reported outcomes demonstrated significant improvements in depression (95% CI –3.6 to –6.2; Cohen *d*=0.77; *P*<.001), anxiety (95% CI –3.0 to –4.9; Cohen *d*=0.74; *P*<.001), overall suicide risk (95% CI –0.5 to –0.1; Cohen *d*=0.41; *P*=.02), wish to live (95% CI 0.3 to 1.0; Cohen *d*=0.39; *P*<.001), wish to die (95% CI –0.2 to –1.4; Cohen *d*=0.52; *P*=.01), and overall mental health (95% CI 1.5 to 4.5; Cohen *d*=0.39; *P*<.001) from admission to discharge.

Conclusions: Rapid adoption and implementation of a group-based teletherapy day program for adults at risk of psychiatric hospitalization appeared to be feasible and effective. Patients demonstrated high completion and attendance rates and reported significant improvements in psychosocial outcomes. Larger trials should be conducted to further evaluate the efficacy and effectiveness of the program through randomized controlled trials.

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KEYWORDS

COVID-19; teletherapy; intensive outpatient; serious mental illness; mental health; therapy; telemedicine; telehealth; feasibility; outcome; behavioral science; pilot; implementation; effective

Introduction

Background

Despite 50 years of research examining the utility of telehealth technologies, video teleconferencing has a poor record of implementation, with slow, uneven, and fragmented uptake into routine health care operations [1]. The COVID-19 pandemic prompted behavioral health providers to abruptly shift to video teleconferencing to deliver critical mental health services while supporting statewide stay-at-home orders and physical distancing measures. The quick adoption of telehealth was of particular relevance for transitional behavioral health programs, given that during times of crisis, intensive outpatient programs (IOPs) and partial hospitalization programs (PHPs) play a critical role in preventing psychiatric hospitalization and relapse among patients with serious mental illness (SMI) [2]. Although the impact of the COVID-19 pandemic on people with SMI is still being studied, early evidence indicates that these individuals are experiencing worsening psychiatric symptoms in response to the pandemic [3-5]. Transitioning existing group interventions to video teleconferencing in a systematic manner is one way to adapt clinical practice to meet the needs of vulnerable patients during the pandemic.

Video teleconferencing group psychotherapy and support have been shown to be feasible and have produced similar outcomes to in-person care while maintaining high levels of patient satisfaction [6]. Video teleconferencing groups have used a variety of therapeutic interventions, including cognitive behavioral therapy, acceptance and commitment therapy, and mindfulness. Video teleconferencing groups have also been shown to replicate therapeutic group processes such as a sense of cohesion [7]. To date, few studies have examined the feasibility and efficacy of delivering transitional video teleconferencing group programs to adults with SMI who were recently discharged from or are at high risk of psychiatric hospitalization. One randomized controlled trial (RCT) found that patients with schizophrenia who received intensive case management via video teleconferencing had significantly fewer hospitalizations compared to those who received face-to-face case management and telephone calls from nurses [8]. Furthermore, a descriptive study found a 50% decline in the number of readmissions and fewer days spent in the hospital after implementing a video teleconferencing follow-up program for discharged older adults [9].

SMI is defined as “a mental, behavioral, or emotional disorder resulting in serious functional impairment, which substantially interferes with or limits one or more major life activities” [10]. Adults living with an SMI, such as bipolar disorder or recurrent major depression, are at increased risk for substance abuse, homelessness, and death by suicide [10]. SMI with psychiatric instability accounts for disproportionately high numbers of emergency department (ED) visits and hospital admissions [11]. With regard to psychiatric hospitalization, suicide rates have been shown to be approximately 100 times the global rate during the first 3 months after discharge, and patients admitted with suicidal thoughts or behaviors have been reported to have suicide rates near 200 times the global rate [12]. The provision of step-down, transitional treatment may reduce suicide risk, psychiatric readmission, and the financial burden associated with acute psychiatric care [13-15]. Likewise, offsetting hospital admissions during pandemic times reduces potential exposure risk for SMI patients while simultaneously freeing up inpatient resources to manage census volumes. As such, there is a pressing need to rapidly restructure face-to-face transitional behavioral health programs for digital delivery to ensure safe and socially distant access to evidence-based care during the COVID-19 public health emergency.

Best-practice recommendations for post–psychiatric hospital discharge and prevention of psychiatric hospital admission includes IOP and PHP interventions that implement evidence-based psychotherapeutic treatments such as cognitive behavioral therapy (CBT) [16] or dialectical behavioral therapy (DBT) [17]. Existing studies have demonstrated that patients with transdiagnostic psychiatric conditions who received short-term, intensive outpatient treatment showed clinical improvements and used fewer inpatient psychiatric and emergency medical services [2]. These findings, however, are based on in-person programs, and few studies have examined the feasibility and effectiveness of video teleconferencing delivery of transitional programs for adults with acute psychiatric needs.

Objectives

The present study evaluated the feasibility and initial effectiveness of the Adult Transitions Program (ATP), a group-based teletherapy IOP for adults with transdiagnostic conditions who are at risk for psychiatric hospitalization. After the COVID-19 pandemic started, ATP rapidly switched from an in-person to a teletherapy format to assure patient and staff safety and to maintain continuity of care. Feasibility was defined in terms of the number of patients who completed the program, average days of attendance, and securing of behavioral health aftercare services prior to ATP discharge. Effectiveness was assessed using standardized patient-reported outcome (PRO) measures of quality of mental health and symptoms of depression, anxiety, and suicidality completed at admission and discharge. It was hypothesized that patients would demonstrate high feasibility of ATP and report significant clinical improvement in psychosocial outcome measures. If supported, the findings could further justify the delivery of ATP through the teletherapy format for patients with acute psychiatric needs.

Methods

Procedures

The study protocol was approved by the Mayo Clinic’s institutional review board. This open trial used an observational, retrospective cohort study design. Patients were referred to the program from the ED, inpatient psychiatric hospital units, and outpatient behavioral health services. ATP implemented a rolling admission process, with this study including patients who were admitted into the program between March and August 2020. Eligibility to enter the program was determined by either an in-person or video teleconferencing preprogram evaluation delivered by either licensed professional clinical counselors (LPCCs) or registered nurses (RNs).

If patients were deemed eligible for the program, they were assigned to one of the three tracks (see the Program Description section) by an LPCC who managed the triage and admission process. Prior to the start of the program, patients received a therapy binder delivered via mail or picked up by the patients at the hospital. As part of routine clinical practice, patients completed PRO measures electronically at admission and discharge. Program staff sent these measures via the electronic health record (EHR, ie, EPIC), and the results were automatically incorporated to the patients' EHRs. An LPCC reviewed the patients' PRO measure scores at admission and discharge with the patients, and the results were used to guide treatment planning and progress monitoring as part of the program's effort to implement measurement-based care [18]. A chart review was conducted to obtain the demographics, feasibility, and effectiveness data from the patients' EHRs.

Inclusion and Exclusion Criteria

Inclusion criteria were adults (aged 16-65 years) who had transdiagnostic psychiatric conditions (eg, mood disorders, anxiety disorders, psychosis, personality disorders, and substance use); were at risk for psychiatric hospitalization or rehospitalization; and reported having access to a mobile or computer device to connect to the video teleconferencing software (ie, Zoom). Exclusion criteria from the program were cognitive impairment that prevented participation in the group format and higher symptom severity that was more appropriately addressed in a higher level psychiatric inpatient or residential setting. Data from patients who did not provide authorization for their clinical data to be used for research purposes were also excluded from the final analysis.

Program Description

ATP was developed as a short-term IOP to bridge patients who were recently discharged from, or at risk for, psychiatric hospitalization. The original program started in 2013 and was delivered in-person. Due to the COVID-19 pandemic, the program underwent a rapid transition to video teleconferencing in March 2020. We referred to available guidelines on teletherapy [19-21] as well as to a model to select and use strategies to facilitate successful teletherapy adoption and implementation [22]. The multidisciplinary team consisted of a clinical director/clinical psychologist, medical director/psychiatrist, nurse practitioners/physician assistants (NPs/PAs), LPCCs, occupational therapists, and RNs. Psychotherapy groups were led by LPCCs who attended a weekly consultation meeting facilitated by a doctoral-level clinical psychologist to ensure treatment adherence and fidelity. All disciplines attended daily huddles to discuss safety management and patient progress.

The ATP video teleconferencing format was delivered 5 days per week, 3 hours per day, and it consisted of primarily group-based interventions with rolling admission. The two primary goals of the program were to provide immediate practical skills to manage symptoms and support recovery and to transition patients to the appropriate level of care (eg, outpatient therapy, substance use treatment, an intensive DBT program). As such, we adapted our group psychotherapy content based on several evidence-based CBT principles, which included strategies drawn from behavioral activation (BA) [23], a DBT skills group [24], and process-based therapy [25].

Because the duration of the program was relatively short, we selected strategies from these different modalities and delivered them to patients modularly. We did not make any changes in the curriculum when we transitioned to the video teleconferencing group format. The program consisted of three tracks, with 8 patients in each track at any given time. Track 1 was designed for patients with comorbid psychiatric disorders and addiction who might also struggle with suicidality. Group interventions included a BA group that focused on selecting daily goals and scheduling activities (eg, self-care, pleasurable activities, social activities, and activities to increase mastery and productivity); a recovery group for addiction guided by the DBT model [26]; and a DBT skills group [24]. Of note, because a typical DBT skills group is delivered in 6 months to 1 year, we did not cover the full DBT skills group manual. Instead, we selected several strategies from each of the four DBT skills core modules: mindfulness, emotion regulation, interpersonal effectiveness, and distress tolerance. Specifically, our clinical workgroup selected skills that are most relevant for our patient population (ie, those who are at risk of psychiatric hospitalization) and could be readily used in the short time they were in the program (ie, 3 weeks). For example, instead of going through all interpersonal effectiveness skills, our program focused on DBT assertiveness skills such as DEAR MAN (Describe, Express, Assert, Reinforce, Stay Mindful, Appear Confident, Negotiate) because asking for help and being assertive are commonly occurring barriers for our patients.

Track 2 was designed for patients with transdiagnostic psychiatric conditions who struggled with high suicidality and self-injurious behaviors. Similar to Track 1, this track consisted of a BA group and a DBT skills group; however, instead of a recovery group, an occupational therapy (OT) group was included in programming. Track 3 was primarily designed for patients with anxiety and depression with less acuity than those in Tracks 1 and 2. The treatment modality for this group was mainly guided by a process-based therapy model [25] that included evidence-based CBT principles to target common psychological challenges (eg, cognitive fusion, low motivation to create behavioral change, and avoidance). Strategies from acceptance and commitment therapy [27] and CBT are incorporated into modular topics in this track.

In addition to receiving three group teletherapy sessions per day, patients also received individual sessions throughout their enrollment in the program. Each patient was assigned a primary LPCC who was responsible for developing the treatment plan, providing individual interventions when needed, monitoring progress, and preparing for aftercare. On average, patients met with an LPCC at three time points: admission, midpoint check-in, and discharge. Patients also met with an NP/PA at least once during admission to discuss medications. Those who were assigned to Track 2 received OT evaluation at admission. If needed, additional individual sessions could be arranged while patients were in the program. Almost all individual sessions were delivered via video teleconference, unless an in-person session was deemed to be more appropriate.

As many patients struggled with suicidal behaviors, strategies from the Collaborative Assessment to Manage Suicidality [28] were implemented in individual sessions, as needed. All patients who were accepted to the program completed the Suicide Status Form (SSF) during the preprogram evaluation. If elevated suicide ideation and intent were observed, patients met with an LPCC to develop a safety and stabilization plan and determine strategies to use to cope with suicidal behaviors (eg, distress tolerance skills, asking for social support, distraction). We provided information to a crisis line or recommended patients to go to the nearest ED if their suicide ideation and intent could not be managed independently.

Video Teleconference Support

Patients who were accepted into the program received assistance from ATP staff and information technology support staff to prepare for the first group video teleconferencing. Patients were asked to set up the required Health Insurance Portability and Accountability Act (HIPAA)–approved encrypted software, Zoom, on their device. Patients were able to use their smartphone, laptop, or computer. Assistance included a test call to teach patients how to use the video teleconferencing platform and to ensure adequate connectivity.

Prior to the start of the program, patients received the link to the group video conference room. When patients logged into Zoom, they were automatically placed in the waiting room to assure that only those who were enrolled in the program were accepted to the chat room by the facilitators. Each psychotherapy group was led by two LPCCs; one functioned as the primary facilitator who led the presentation and group discussion, while the other assisted patients with any technological issues. The program consisted of open group admission, and when a new patient started the program, the facilitator went through the group norms, which included but were not limited to the importance of attending group video teleconferences in a private area and turning on their camera to assure confidentiality.

Several features that were routinely used over Zoom were the chat feature, whiteboard, shared screen for slide presentations and videos, and the waiting room in which we placed patients during breaks between group psychotherapy sessions. It was also feasible to conduct psychotherapy experiential exercises via video teleconferencing, such as performing guided group mindfulness exercises, completing psychotherapy forms, and watching psychotherapy skills videos.

Measures

All measures were completed via the EHR through the patient portal. Sociodemographic data included biological sex, age, ethnicity, gender identity, sexual orientation, marital status, employment status, and financial resource strain. Program feasibility was defined as the rate of patients who completed the program. Our benchmark for feasibility was that 75% of patients would complete the three-week program and attend at least 8 out of 15 days. Because ATP was developed to assure that patients had an appropriate continuum of care, another benchmark for feasibility was to assure that patients had at least one behavioral health service appointment after ATP discharge.

Patients completed four primary outcome measures at admission and discharge to assess program effectiveness. Overall quality of mental health was measured using the Patient-Reported Outcomes Measurement Information System (PROMIS) Global-10 [29] to assess overall physical and mental health. This 10-item scale has been shown to be reliable, precise, and comparable to legacy instruments. In this study, we report only the overall mental health *t* scores ranging from 0 to 100 with the following cut points of poor, fair, good, very good, and excellent [30]. Depressive symptoms were measured using the Patient Health Questionnaire-9 (PHQ-9) [31], a 9-item scale with a total score range from 0-27 wherein higher scores are suggestive of greater depressive symptoms; scores of 5, 10, 15, and 20 represent mild, moderate, moderately severe, and severe depression, respectively. Anxiety symptoms were measured using the Generalized Anxiety Scale-7 (GAD-7) [32], a 7-item scale with a total score range from 0 to 21 wherein higher scores are suggestive of greater anxiety symptoms; scores of 5, 10, and 15 represent mild, moderate, and severe anxiety, respectively. Finally, suicide risk, wish to live, and wish to die were measured using the SSF [33]. Suicide risk was reported on a scale of 1 (low) to 5 (high). Wish to live and wish to die were reported on a scale of 0 (low) to 8 (high).

Statistical Analyses

Feasibility was measured by calculating the percentage of patients who completed the program. Average days attended was also calculated as another metric for feasibility. Finally, as a benchmark for feasibility, we calculated the percentage of patients who secured at least one behavioral health service appointment prior to ATP discharge. Paired *t* tests were used to examine changes from admission to discharge in the psychosocial outcomes of quality mental health, depression, anxiety, and suicidality. These analyses included only patients who completed both the admission and discharge measures (n=60). *P* values <.05 were considered significant. A linear model was used to assess differences in symptom improvement for patients in the three different tracks by regressing the group indicator onto the change in symptom score from baseline to discharge and adjusting for baseline score. Data were analyzed using SAS, version 9.4 (SAS Software).

Results

Baseline Characteristics

Patients had a mean age of 36.6 years (SD 13.4), ranging from 18 to 73 years in age. The majority of the 76 patients were female (n=65, 86%) and White (n=69, 91%), married (n=22, 29%) or single (n=44, 57.9%), cisgender (n=73; 96%), heterosexual (n=52; 68%), and employed (n=46, 61%). The 76 patients had the following psychiatric diagnoses as a primary presenting problem: major depressive disorder (n=52, 68%), bipolar disorder (n=6, 8%), anxiety disorder (n=22, 29%), personality disorder (n=13, 17%), substance use disorder (n=6, 8%), and schizophrenia (n=2, 3%). The majority of patients had comorbid psychiatric diagnoses (n=41, 54%). The full baseline characteristics of the sample are reported in Table 1.

Table 1. Baseline characteristics of the study sample (N=76).

Characteristic	Value
Age (years), mean (SD)	36.55 (13.43)
Sex, n (%)	
Female	65 (86)
Male	11 (15)
Gender, n (%)	
Female	63 (83)
Male	10 (13)
Transgender female	2 (3)
Transgender male	1 (1)
Race, n (%)	
White	68 (90)
Other	5 (7)
African American	2 (3)
Chose not to disclose	1 (1)
Ethnicity, n (%)	
Hispanic or Latino	4 (5)
Non-Hispanic or Latino	69 (91)
Puerto Rican	1 (1)
Chose not to disclose	1 (1)
Unknown	1 (1)
Marital status, n (%)	
Single	44 (58)
Married	22 (29)
Separated	4 (5)
Widowed	1 (1)
Divorced	5 (7)
Employment, n (%)	
Currently employed	46 (61)
Not employed	27 (36)
Disabled	3 (4)
Financial resource strain, n (%)	
Not hard at all	23 (30)
Not very hard	14 (18)
Somewhat hard	21 (28)
Hard	5 (7)
Very hard	9 (12)
Patient refused to answer	1 (1)
Not on file	3 (4)
Sexual orientation, n (%)	
Lesbian or gay	3 (4)
Heterosexual	52 (68)
Bisexual	4 (5)

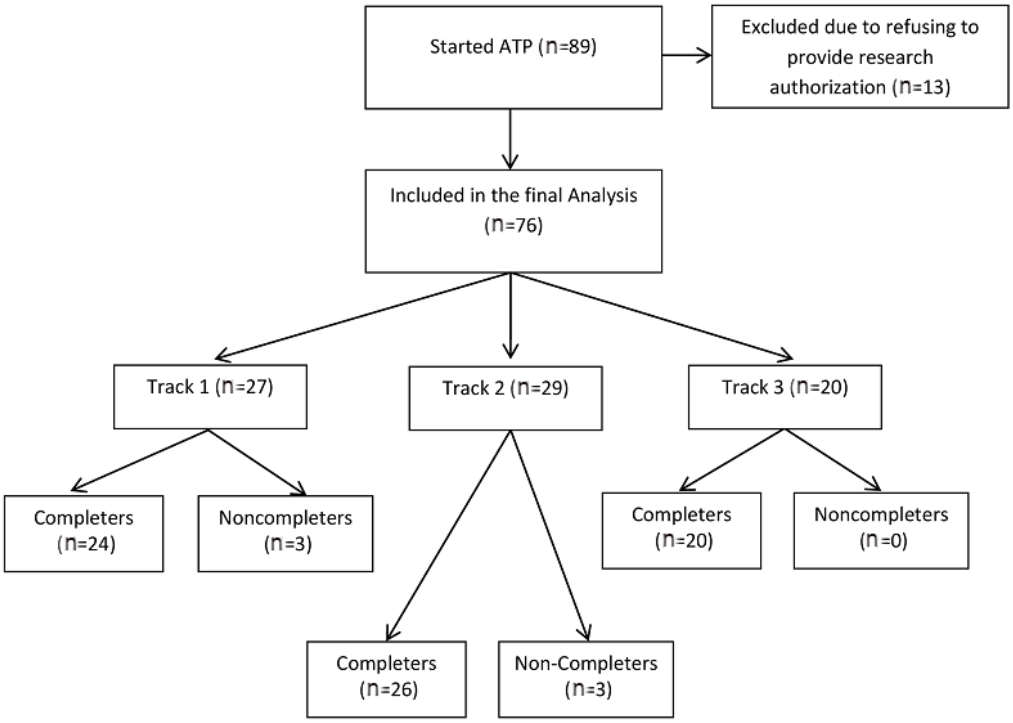
Characteristic	Value
Other	1 (1)
Don't know	14 (18)
Chose not to disclose	2 (3)
Presenting problems, n (%)	
Major depressive disorder	52 (68)
Bipolar disorder	6 (8)
Anxiety disorder	22 (29)
Personality disorder	13 (17)
Substance use disorder	6 (8)
Schizophrenia	2 (3)
Comorbidity, n (%)	
With one diagnosis	35 (46)
With comorbid diagnoses	41 (54)
Track, n (%)	
Dialectical behavioral therapy AM	26 (34)
Dialectical behavioral therapy PM	29 (38)
Cognitive behavioral therapy AM	20 (26)
Source of referral, n (%)	
Inpatient	26 (34)
Emergency department	3 (4)
Primary care	23 (30)
Other outpatient	19 (25)
Other programs	5 (7)
Days completed, mean (SD)	14.43 (1.22)
Medication management appointment scheduled, n (%)	67 (88)
Group psychotherapy appointment scheduled, n (%)	10 (13)
Case management scheduled, n (%)	6 (8)
Residential treatment scheduled, n (%)	1 (1)
Substance use disorder treatment scheduled, n (%)	1 (1)
Referred for therapy, n (%)	3 (4)
Referred for group therapy, n (%)	13 (17)
Referred for substance use disorder treatment, n (%)	1 (1)
Individual psychotherapy or outpatient therapy, n (%)	59 (78)
Program absences (days), n (%)	
None	49 (65)
1-3	18 (24)
4-7	3 (4)
Noncompleters	6 (8)

Program Feasibility

Figure 1 delineates the flow of patients in this study. From the initial 89 patients who started the program, 13 were excluded because they declined to have their clinical data used as part of research. Thus, the completion rate of the program was 70/76 (92%). Completion was defined as patients who attended at least 50% of the sessions [34]. The number of attended sessions ranged from 8 to 15, and patients completed an average of 14.38 days (SD 1.42). In terms of aftercare post–ATP discharge, 93%

(71/76) of patients scheduled at least one behavioral health service appointment. Specifically, 74% (56/76) received outpatient psychotherapy and medication management, 13% (10/76) received at least outpatient psychotherapy or medication management and group psychotherapy, 8% (6/76) only had medication management, and 3% (2/76) only received outpatient psychotherapy.

Figure 1. Participant enrollment and completion of the video teleconferencing ATP. ATP: Adult Transitions Program.



Program Effectiveness

Improvement was observed for all PRO measures (Table 2). Depression scores improved from a mean of 14.4 (SD 6.5) at admission to 9.6 (SD 6.0) at discharge (PHQ-9 change, 95% CI –3.6 to –6.2; Cohen *d*=0.77; *P*<.001). Likewise, patients reported improvements in self-reported anxiety, from 11.8 to 7.7 (GAD-7 change, 95% CI –3.0 to –4.9; Cohen *d*=0.74; *P*<.001). In terms of suicidality, patients reported significant improvements in overall suicide risk (SSF change, 95% CI –0.5 to 0.1; Cohen *d*=0.41; *P*=.02), wish to live (SSF change, 95% CI 0.3 to 1.0; Cohen *d*=0.39; *P*<.001), and wish to die (SSF change 95% CI –0.2 to –1.4; Cohen *d*=0.52; *P*=.01). Finally, patients also reported significant improvement in their overall mental health, from 40.2 at admission to 42.0 at discharge risk (PROMIS Global 10 change, 95% CI 1.5 to 4.5; Cohen *d*=0.39; *P*<.001). Additionally, we conducted a stratified analysis to compare changes in PRO measure outcomes between patients in the three different tracks. There were no statistically significant differences in the outcome measure changes across the tracks.

Table 2. Changes in standardized patient reported outcome measures from admission to discharge (N=76).

Measure	Responses (n)	Mean score (SD)		*P* value
		Admission	Discharge	
Patient Health Questionnaire-9	60	14.40 (6.47)	9.58 (6.04)	<.001
Generalized Anxiety Disorder-7	60	11.80 (5.57)	7.67 (5.52)	<.001
Alcohol Use Disorder Identification Test (AUDIT)	55	2.80 (3.84)	2.47 (3.60)	.18
Wish to live	58	6.26 (1.81)	6.95 (1.69)	<.001
Wish to die	58	1.67 (2.15)	0.74 (1.29)	.01
Risk of suicide	58	1.53 (0.82)	1.24 (0.58)	.02
PROMIS[a] Global 10	37	40.19 (4.43)	42.04 (5.02)	<.001

[a]PROMIS: Patient-Reported Outcomes Measurement Information System.

Discussion

Key Findings

The aim of this open, nonrandomized, retrospective trial was to assess the feasibility and initial effectiveness of ATP, an IOP delivered via video teleconferencing for adults with SMI who were at risk for psychiatric hospitalization. The rapid switch of the program from in-person to video teleconferencing was a response to the start of the COVID-19 pandemic during the initial months of 2020. Below, we discuss our key findings along with limitations and future directions.

The feasibility of offering ATP via video teleconferencing was evaluated primarily in terms of completion rate (ie, attending at least 8 out of 15 program days), average days attended, and securing at least one behavioral health service appointment prior to ATP discharge. Based on the 76 patients who were included in the final analysis, 70 patients (92%) completed the program. This completion rate was higher than typical completion rates for psychiatric IOP or PHP programs, which are <60% [35,36]. Furthermore, the average number of days completed by patients was 14.43 (SD 1.22), which indicated that the majority of patients only missed approximately 1 day in the three-week program. Because continuation of care has been shown to be an important predictor of future relapse and functional recovery [37], we selected securing aftercare appointments prior to ATP discharge as the last benchmark of program feasibility. Our chart review indicated that the vast majority of patients scheduled at least one behavioral health service appointment before discharge. The most frequently scheduled aftercare appointments included either medication management or psychotherapy. Thus, these three metrics indicated that it was feasible to deliver ATP via video teleconferencing, as demonstrated by the high completion rate, good attendance, and successful aftercare transition. However, we could not conclude how these feasibility outcomes compared to in-person iterations of ATP.

With regard to effectiveness, overall quality of mental health, symptoms of depression, anxiety, wish to live, wish to die, and reported suicide risk improved from admission to discharge. The effect sizes for the outcome measures ranged from small to moderate effect sizes. Because patients were assigned to one of the three tracks, we conducted a stratified analysis to assess potential differences in symptom changes by track. The results indicated no significant differences in the changes of the standardized PRO measure scores between the three different tracks, suggesting that both the shared and differing content across the tracks were similarly effective in reducing distress and improving quality of life.

Limitations and Future Directions

This study has several limitations that should be discussed. First, the lack of a control condition limits our ability to firmly conclude that the positive feasibility outcomes and changes in PRO measures were solely due to the program interventions and/or delivery mode. To assess the efficacy of ATP delivered via video teleconferencing format, an RCT is warranted. A larger RCT should include comparison groups, such as ATP delivered via an in-person format, or a wait-list control condition. Second, a lack of follow-up data limited our understanding of the long-term impact of ATP delivered via video teleconferencing to sustain improvements in overall mental health, depression, anxiety, and suicidal behaviors. Long-term follow-up would also be important to assess whether patients who completed ATP adhered to the aftercare recommendations and reduced the rate of psychiatric hospitalization post–ATP discharge. Third, although the effectiveness analysis showed encouraging results, this was based on a completer analysis. Furthermore, although it is not possible to determine if the missing data affected the results positively or negatively, missing data appeared to occur at random, and individuals with missing data were no different as a group than those without missing data in terms of demographic variables such as age, gender, and other baseline variables. Future studies should include a more rigorous protocol to treat missing data, such as follow-up with patients who prematurely dropped out or did not complete the PRO measures at different time points.

Conclusion

This pilot investigation demonstrated the feasibility and initial effectiveness of ATP, a program that was rapidly switched to a video teleconferencing format during the COVID-19 pandemic. The majority of patients completed the program and demonstrated high attendance rates. It was feasible to secure aftercare behavioral health appointments prior to program discharge to ensure continuation of care. Patients also reported improvements in self-reported measures of mental health, psychiatric symptoms, and quality of life. This finding is encouraging because a rapid transition to video teleconferencing during a world pandemic may reduce the mental health crisis that has been predicted to soon follow. The delivery of group-based IOP via video teleconferencing that implemented evidence-based cognitive and behavioral principles for patients with transdiagnostic psychiatric conditions is a promising strategy to improve access to behavioral health services during and after the COVID-19 pandemic. Because this is a pilot trial, the results and conclusion should be taken carefully. Larger trials should be conducted to further test the significance of this program model, its cost-effectiveness, and its efficacy to reduce the public health burden of mental illness, particularly in the context of a world pandemic such as COVID-19.

Conflicts of Interest

None declared.

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Abbreviations

ACT: acceptance and commitment therapy
ATP: Adult Transitions Program
BA: behavioral activation
CBT: cognitive behavioral therapy
DBT: dialectical behavior therapy
DEAR MAN: Describe, Express, Assert, Reinforce, Stay Mindful, Appear Confident, Negotiate
ED: emergency department
EHR: electronic health record
GAD-7: Generalized Anxiety Disorder Scale-7
HIPAA: Health Insurance Portability and Accountability Act
IOP: intensive outpatient program
LPCC: licensed professional clinical counselor
NP: nurse practitioner
OT: occupational therapy
PA: physician assistant
PHP: partial hospitalization program
PHQ-9: Patient Health Questionnaire-9
PRO: patient-reported outcome
PROMIS: Patient-Reported Outcomes Measurement Information System

RN: registered nurse
RTC: randomized controlled trial
SMI: serious mental illness
SSF: Suicide Status Form
SUD: substance use disorder

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